Collaboration

Sr. No.	Title of the Collaborative activity	Name of the collaborating agency with contact details	Name of the participants	Source of financial support	Year of collaboration	Duration	Nature of the activity	Link to the relevant documents
	2014-15							
1	For Treatment & Management Of TB Patients	Revised National Tuberculosis Control Programmed	MGM Medical College and Hospital Aurangabad	Revised National Tuberculosis Control Programmed (RNTCP)	2010	Till Date	Training of staff Establishment of TB centre Treatment	https://www.mgmuhs.com/NAAC/c3/3.7.1/1%202013%20RNTCP.pdf
2	Employee Health Check-Up	Hercules Hoists Ltd , Khalapur, Raigad	MGM Hospital NM	Hercules Hoists Ltd , Khalapur, Raigad	2011	Till Date	Medical Examination and Investigation	https://www.mgmuhs.com/NAAC/c3/3.7.1/2014%20Hercules.PDF
3	Integrated Counseling And Testing Centers (ICTCS) For	National AIDS control organization (NACO)	MGM Medical College And Hospital NM	National AIDS control organization (NACO)	2013	Till Date	Training for staff Counseling	https://www.mgmuhs.com/NAAC/c3/3.7.1/2%202013%20Naco.pdf
4	Supporting International Initiatives That Will Promote Research, Education And Provision Of Health Care In	International Society Of Biomechanics	Dr Rajani Mullerpatan	International Society Of Biomechanics	2013	Till Date	Academic Training of staff and Diagnosis and Treatment Research Counsultancy	https://www.mgmuhs.com/NAAC/c3/3.7.1/3%202013%20ISB%20physiotherapy..pdf
5	Practical Training And Experience To Acquire Skills Under Expert Supervision	Saint Annes Hospital, Aurangabad	MGM Medical College and Hospital Aurangabad	NA	2013	Till Date	Training for student of MGM Medical college and MGM Nursing College	https://www.mgmuhs.com/NAAC/c3/3.7.1/4%202013%20%20St.%20Annes%20hospital.pdf
6	Training Of MD Students For Autopsy	Govt. Medical College, Aurangabad	MGM Medical College and Hospital Aurangabad	NA	2013	Till Date	Exposer of various autopsy Investigation & Procedure	https://www.mgmuhs.com/NAAC/c3/3.7.1/5%202013%20%20GMC%20aurangabad..pdf
7	Sharing A Desire Develop Mutually Strengthening And Enriching International Clinical , Educational And Research Experience For Both Faculty And Students	World Spine Care Clinic	Dr Rajani Mullerpatan	World Spine Care Clinic	2013	Till Date	Research related lectures for students by expertise of WSCC Exchange of students Consideration of scholarship for students who wish to study Joint Research activities and publication Exchange of academic and clinical information and materials	https://www.mgmuhs.com/NAAC/c3/3.7.1/6%202014%20World%20Spine%20Care%20&%20physio.pdf
8	Research,clinical training,	The University of Pennsylvania, USA	MGM Institute of Health Sciences	NA	2013	Till Date	Project Work Research Academic exposure for students and faculty	https://www.mgmuhs.com/NAAC/c3/3.7.2/2013%20Pennsylvania-1-Copy.pdf
9	Indian Patent Fill	Birla Institute Of Technology And Science (BITS), Goa, BARC	Dr Mansee Thakur, Dr Girish Pai, Dr DS Joshi,	MGMIHS, BITS , BARC	2014	2016	Research Faculty Exchange Paper and Patent Publications	https://www.mgmuhs.com/NAAC/c3/3.7.1/2014%20BITS%20Goa.PDF

10	Training Of Medical UG ,PG , Students, Interns, Nurses And Other Paramedical Staff In Community Health	MGM Medical College And Yusuf Meherally Centre, TARA	MGM Medical College And Hospital NM	NA	2014	Till Date	Primary health care to the benificeries of RHTC , Academic Training of Students Conducting General OPD every day Conduct Speciality OPD - (Opthalmology) Conduct Free surgical camp every Sunday Celebtrating of Helath day activities like TB day , World AIDS day Health Education activities Work with Anganwadi worker inthe community. Mobile health camps in the tribal communities Immunization to all ANC mother and children Health survey School Helath checkp IEC activity for community people Involvement in extension and outreach activity Multy dignostics camp	https://www.mgmuhs.com/NAAC/c3/3.7.1/8%202014%20MOU,TARA...pdf
11	Employee Health Check-Up	Shandra Green Energy	MGM Hospital NM	Shandra Green Energy	2014	Till Date	Annual Health checkup	https://www.mgmuhs.com/NAAC/c3/3.7.1/2014%20Shandra%20green%20ltd.PDF
12	Research , Phd Work And Publications	National Institute For Research In Reproductive Health (NIRRH), Mumbai	Dr Mansee Thakur , Himanshu Gupta, Smital Kulkarni, Navmi Dayal,	NA	2014	Till Date	Research Faculty utilized from NIRRH Publications	https://www.mgmuhs.com/NAAC/c3/3.7.1/2015%20NIRRH%20DEEPAK%20MODI%20CO-GUIDE.PDF
13	Two Machine ie Intense Light and Narrow Band UVB should be kept in skin OPD of MGM hospital	Marathwada Association Of Dermatologist, Venereologist & Leprologists	MGM Medical College and Hospital Aurangabad (Dr. Pravine Suryavanshi, Dr.AG Shroff, Dr. MY Khedkar)	Marathwada Association Of Dermatologist, Venereologist & Leprologists	2014	Till Date	Counsultancy , Training Utilization of Instrument for student and Patient	https://www.mgmuhs.com/NAAC/c3/3.7.1/9%202014%20MADVL..pdf
14	Eye Donation Centre Of MGM Is Affiliated To Eye Bank Of Kamalnayan Bajaj Hospital	Kamalnayan Bajaj Hospital	MGM Medical College and Hospital Aurangabad	NA	2014	Till Date	Eye Donation Centre	https://www.mgmuhs.com/NAAC/c3/3.7.1/10%202014%20Kamal%20Nayan%20Bajaj%20Eye%20Donation%20Center.pdf

15	Eye Donation Centre Of MGM Is Affiliated To Eye Bank Of Drushti Eye Institute	Drushti Eye Institute	MGM Medical College and Hospital Aurangabad	NA	2014	Till Date	Eye Donation Centre	https://www.mgmuhs.com/NAAC/c3/3.7.1/11%202014%20Drushti%20Eye%20Bank..pdf
16	Employee Health Check-Up	Colgate Palmolive	MGM Medical College and Hospital Aurangabad	Colgate Palmolive	2014	Till Date	Medical Examination and Investigation	https://www.mgmuhs.com/NAAC/c3/3.7.1/2014%20Colgate.PDF
17	Placement of student for field work at MGM Hospital	Tata Institute Of Social Sciences	MGM Medical College And Hospital NM (Dr	Tata Institute Of Social Sciences	2014	2015	Provide Field work exposure	https://www.mgmuhs.com/NAAC/c3/3.7.1/2014%20TISS.PDF
18	Research , Phd Work And Publications, Academic Training	MGM College of Enginering and Technology	Dr Mansee Thakur, Dr VK Suri, Dr Girish Pai, Yogesh Patil , Dr GD Jindal	NA	2014	Till Date	Research Faculty utilized from MGMCET for teaching Publications	https://www.mgmuhs.com/NAAC/c3/3.7.2/2014%20MOU%20MGM%20Eng%20Clg.PDF
19	Research Purpose	Shraddha Analytical	Dr Himanshu Gupta and Dr Mansee Thalur	NA	2015	2015	Out Sourcing	https://www.mgmuhs.com/NAAC/c3/3.7.1/2015%20Shraddha%20Analytical%20services.PDF
20	Training UG/PG	Health Services Zilla Parishad Aurangabad	MGM Medical College and Hospital Aurangabad	NA	2015	Till Date	Training UG/PG	https://www.mgmuhs.com/NAAC/c3/3.7.1/12%202015%20Health%20Zilla%20Parishad%20Aug..pdf
21	Research Purpose	University Of Sydney	Dr Rajani Mullerpatan and Dr Shibhan K Kaul	NA	2015	Till Date	Develop and ursue collaborative research project, Faculty Exchange for the purpose of participating in Encouage the exchange of scientific materials, Publication and other Information between the Institution	https://www.mgmuhs.com/NAAC/c3/3.7.1/13%202015%20SYDNEY%20MOU%20&%20physio..pdf
22	Provide the Educational Material/Bookto the Institute	Johnson & Johnson Pvt Ltd.	MGM Medical College and Hospital Aurangabad (Dr Pravin Suryavanshi)	Johnson & Johnson Pvt Ltd.	2015	2016	Skill lab material providing for Training Enhancement of student learning activities by providing Books	https://www.mgmuhs.com/NAAC/c3/3.7.1/2015%20ETHICON%20Johnson.PDF
23	Employee Health Check-Up	CIPET	MGM Medical College and Hospital Aurangabad	CIPET	2015	Till Date	Medical Examination and Investigation	https://www.mgmuhs.com/NAAC/c3/3.7.1/2015%20Cipet.PDF
24	Employee Health Check-Up	M/S Jainex Aamcol LTD	MGM Medical Center & Research Institute	M/S Jainex Aamcol Ltd	2015	Till Date	Hospitalization For various diseases including superspecialty Investigation , Procedure Treatment Employees	https://www.mgmuhs.com/NAAC/c3/3.7.1/14%202015%20Jainex%20MOU%20Scan%20aurangabad.PDF
25	Academic Training	Philadelphia Hospital, Ambala City.	Mr. Pankaj Malik (MBBS Students)	NA	2014	2015	Internship Training	https://www.mgmuhs.com/NAAC/c3/3.7.1/2014-19%20Internship%20letters.pdf
	Academic Training	General Hospital, Gurgaon.	Ms. Shivali Gulati (MBBS Students)	NA	2014	2015	Internship Training	

	Academic Training	Bhatia Hospital, Mumbai.	Ms. Shrea Kapoor (MBBS Students)	NA	2015	2016	Internship Training	
	Academic Training	Patna Medical College, Patna.	Ms. Kavita Kumari (MBBS Students)	NA	2015	2016	Internship Training	
	Academic Training	Dr. Ram Manohar Lohia Hospital, New Delhi.	Ms. Ela Sharma (MBBS Students)	NA	2015	2016	Internship Training	
	Academic Training	Government of Maharashtra, District Hospital, Osmanabad.	Mr. Shahapurkar Abhishek Abhay (MBBS Students)	NA	2015	2016	Internship Training	
	Academic Training	Northern Railway, Central Hospital, New Delhi.	Ms. Garima Gupta (MBBS Students)	NA	2015	2016	Internship Training	
	Academic Training	Lokmanya Tilak Muncipal Medical College, Mumbai.	Ms. Rainuka Rana (MBBS Students)	NA	2015	2016	Internship Training	
	Academic Training	K. J. Somaiya Medical College & Research Centre, Mumbai.	Ms. Deshmukh Minal Sanjay ,Ms. Dalwani Vrinda Mahesh, Ms. Camy Alkesh Shah (MBBS Students)	NA	2015	2016	Internship Training	
	Academic Training	Topiwala National Medical College, Mumbai.	Ms. Anvekar Priyanka Vinesh (MBBS Students)	NA	2015	2016	Internship Training	
	Academic Training	Seth G. S. Medical College & King Edward VII Memorial Hospital, Mumbai.	Ms. Lavina Vijay Desai (MBBS Students)	NA	2015	2016	Internship Training	
	Academic Training	Terna Medical College & Hospital, Nerul, Navi Mumbai	Mr. Shah Vivek Surendra (MBBS Students)	NA	2015	2016	Internship Training	
2015-16								
26	Preventive, Promotive, And Curative	Shahid Baba Deep Singh Dispensary Managed By Punjabi Cultural And Welfare Association	MGM Medical College And Hospital NM	Shahid Baba Deep Singh Dispensary Managed By Punjabi Cultural And Welfare	2015	Till Date	Preventive, Promotive, And Curative Inveatigation of Blood and urine sample	https://www.mgmuhs.com/NAAC/c3/3.7.1/16%202015%20Sahid%20baba%20deep%20singh.pdf
27	Laboratory Services	Unipath Specialty Laboratory Ltd	MGM Medical College and Hospital Aurangabad	NA	2015	Till Date	Provide Laboratory services	https://www.mgmuhs.com/NAAC/c3/3.7.1/17%202015%20Unipath..pdf
28	Eye Donation	Director Health Services	MGM Medical College and Hospital Aurangabad	NA	2015	Till Date	Eye Donation Awareness programm about Preventive, Promotive, And Curative	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20%20Jt%20Director%20of%20health%20ser%20(Leprosy%20&%20TB)%20Dr%20Prashant.pdf
29	Employee Health Check-Up	Harman Finochem Ltd.	MGM Medical Center & Research Institute	Harman Finochem Ltd.	2015	Till Date	Hospitalization For various diseases including superspecialty Procedure Treatment Employees	https://www.mgmuhs.com/NAAC/c3/3.7.1/19%202015%20MOU%20Harman%20Finochem%20aurangabad.pdf

30	Placement of student for field work at MGM Hospital	Tata Institute Of Social Sciences	MGM Medical College And Hospital NM (Dr	Tata Institute Of Social Sciences	2015	2016	Provide Field work exposure	https://www.mgmuhs.com/NAAC/c3/3.7.1/2014%20TISS.PDF
31	Collaboration In The Field Education, Research And Medical Training	Kyungpook National University Medical Center, Korea	MGM Medical College and Hospital Aurangabad	NA	2015	2017	Exchange of Faculty & Students for education and training Joint organization of lectures, seminars, workshop and symposia Networking for international healthcare Joint academic and research collabration	https://www.mgmuhs.com/NAAC/c3/3.7.1/20%202015%20Kyungpuk%20University%20of%20Korea..pdf
32	Health Care Activity / Projects	IIT Mumbai	Dr Rajani Mullerpatan	NA	2015	Till Date	Research, Training for Student and Faculty	https://www.mgmuhs.com/NAAC/c3/3.7.1/2016%20IIT%20Mumbai%201.PDF
33	To care of Children with Craniofacial Deformities and	Maya Foundation NGO	MGMIHS	Maya Foundation NGO	2015	Till Date	Diagnostics Treatment	https://www.mgmuhs.com/NAAC/c3/3.7.1/24%202016%20maya%20foundation..pdf
34	Blood Collection Centre , Processing Blood Investigations At Subsidized Rates	Dr. Babasaheb Ambedkar Muncipal Corporation Hospital, Khopoli	MGM Medical College And Hospital NM	Dr. Babasaheb Ambedkar Muncipal Corporation Hospital, Khopoli	2015	Till Date	Health Checkup Provide Laboratory services Provide outreach services Provide Medicines and Medical Instruments	https://www.mgmuhs.com/NAAC/c3/3.7.1/22%202015%20MOU,KHOPOLI..PDF
35	Clinical Evaluation of Breath-Based Point of Care Test For Diagnosis of Pulmonary	IKP Knowledge Park	MGMIHS (Dr Sameer Pachpute)	NA	2015	2016	Research Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/23%202015%20IKP.pdf
36	A Randomized, multi center, open label, two-treatment, two-period, two-sequence, multiple dose,crossover, steady state bioequivalence study of Everolimus tablets,	Veeda Clinical Research Pvt. Ltd,	Dr Chandrashekhar Tamane	Veeda Clinical Research Pvt. Ltd,	2016	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/26%202016%20Veeda%20%20Dr%20Tamane%20Veeda%20CR.pdf
37	Officer's Health Check-Up	Govt of Maharahtra	MGM Medical College and Hospital Aurangabad	Govt of Maharahtra	2016	Till Date	Officer's Health Check-Up	https://www.mgmuhs.com/NAAC/c3/3.7.1/27%202016%20%20Maharashtra%20State%20Govt%20Employee%20Health%20check%20up..PDF
38	For Treatment & Management Of TB Patients	University Of UTAH	MGMIHS (Dr Sameer Pachpute)	University Of UTAH	2016	2017	Non Invasive TB Triage & Patient Mapping Platform Using Breath Via Low Cost Titanium Dioxide Nano Tube Sensor	https://www.mgmuhs.com/NAAC/c3/3.7.1/28%202016%20Uthah..pdf
39	A Randomized, Double-blind, Parallel Group Study to Evaluate the Effect and Safety of Test Biscuits as Compared to Placebo Biscuits in Regulating Blood Glucose	Karmik Life Sciences	Dr. Deepak Bhosle	Karmik Life Sciences	2016	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/29%202016%20Dr%20Deepak%20Bhosale%20karmic.pdf
40	Development of Product	Raja Ramanna Centre Foradvanced, Technology	Dr Mansee Thakur, Dr VK Suri, Dr Girish Pai, Yogesh	RRCAT	2016	Till Date	Training Research	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20RRCAT.pdf

41	Health Check Up	Forest Deptt. Aurangabad	MGM Medical College and Hospital Aurangabad	Forest Deptt. Aurangabad	2016	Till Date	Medical Examination and Investigation	https://www.mgmuhs.com/NAAC/c3/3.7.1/2016%20Forest%20Dept%20Mukhya%20van%20savrakshak.PDF
42	Research Purpose	IIT Mumbai	Dr VK Suri, Yogesh Patil Dr Himanshu Gupta, Smital Kulkarni	NA	2016	Till Date	Central Research Faculty Explorated & Utilized for Research Purpose	https://www.mgmuhs.com/NAAC/c3/3.7.1/2016%20IIT%20Mumbai%201.PDF
43	Executive Health Check-Up	Powergrid	MGM Medical College and Hospital Aurangabad	Powergrid	2016	Till Date	Medical Examination and Investigation	https://www.mgmuhs.com/NAAC/c3/3.7.1/2016%20Power%20Grid.PDF
44	Academic Training	Government Medical College, Patiala.	Ms. Shivneet Kaur Brar (MBBS Students)	NA	2016	2017	Internship Training	https://www.mgmuhs.com/NAAC/c3/3.7.1/2014-19%20Internship%20letters.pdf
45	Academic Training	Lokmanya Tilak Municipal Medical College, Sion, Mumbai.	Mr. Yadav Shivakumar Veludas (MBBS Students)	NA	2016	2017	Internship Training	
	Academic Training	Pt. Jawaharlal Nehru Memorial Medical College, Raipur, Chhattisgarh	Ms. Akanksha Vishwakarma (MBBS Students)	NA	2016	2017	Internship Training	
	Academic Training	Gauhati Medical College, Guwahati.	Ms. Krishnakhi Goswami (MBBS Students)	NA	2016	2017	Internship Training	
	Academic Training	Seth G. S. Medical College & K.E M. Hospital, Parel, Mumbai.	Ms. Goiporia Mahafrin Homiar, Ms. Mehta Shikha Paresh, Ms. Gandhi Lorie Mahendra , Ms. Lodha Ayushi Mahavir , Mr. Jain Akash Jeevan , Ms. Beri Riddhima Rajiv (MBBS Students)	NA	2016	2017	Internship Training	
	Academic Training	Sir Ganga Ram Hospital, New Delhi.	Ms. Anushruti Gupta (MBBS Students)	NA	2016	2017	Internship Training	
	Academic Training	Terna Medical College & Hospital, Nerul, Navi Mumbai.	Ms. Thomas Joyce Jobkutti (MBBS Students)	NA	2016	2017	Internship Training	
	Academic Training	Grant Government Medical College, Mumbai.	Ms. Achawal Shruti Sanjay, Mr. Raje Rohit Shrikant (MBBS Students)	NA	2016	2017	Internship Training	
	Academic Training	Bombay Hospital Trust, Mumbai.	Mr. Chouhan Siddharth Champalal (MBBS Students)	NA	2016	2017	Internship Training	
	Academic Training	Smt. Kashibai Navale Medical College & General Hospital, Pune.	Mr. Patkar Chinmay Rajendra (MBBS Students)	NA	2016	2017	Internship Training	

2016-17								
46	Teaching Learning Programme	UNESCO Chair in Bioethics	MGM Institute of Health Sciences	NA	2016	Till Date	Academic training for staff, Lecture series for students and staff	https://www.mgmuhs.com/NAAC/c3/3.7.1/30%202016%20Unisco%20Bioethics.pdf
47	Research , Phd Work And Publications, Academic Training	MGM Dental College	Dr Sabita Ram, Dr Mansee Thakur, Dr VK Suri, ,Dr Niharika , etc	NA	2016	Till Date	Research Faculty utilized from MGM dental college for teaching Publications	https://www.mgmuhs.com/NAAC/c3/3.7.1/31%202016%20MOU%20MGM%20Dental%20clg.PDF
48	Academic training	MGM College of Nursing Vashi Navi mumbai	Dr Merry Mathew	NA	2016	Till Date	Research Exchange of academic staff Exchange of students	https://www.mgmuhs.com/NAAC/c3/3.7.1/32%202016%20MGM%20Nursing%20vashi.pdf
49	Academic training	MGM College of Physiotherapy	Dr Rajani Mullerpathani, Dr Bela Agarwal	NA	2016	Till Date	Research Exchange of academic staff Exchange of students	https://www.mgmuhs.com/NAAC/c3/3.7.1/33%202016%20Mou%20MGM%20Physiotherapy.pdf
50	To start Eye camp activity	Samta Memorial Foundation	MGM Medical College and Hospital Aurangabad	Samta Memorial Foundation	2016	Till Date	Free Cataract Surgery Center Organised diagnostic eye camp	https://www.mgmuhs.com/NAAC/c3/3.7.1/34%202016%20Samata%20memorial%20Foundation .PDF
51	A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study Of Paclitaxel Injection Concentrate For Nano-Dispersion (PICN) And	Sun Pharma Advanced Research Company Ltd (SPARC)	Dr Chandrashekhar Tamane	Sun Pharma Advanced Research Company Ltd (SPARC)	2016	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/35%202016%20Tamane%20Sun%20pharma.pdf
52	A Randomized, Double-Blind, Placebo-Controlled, Three-Arm, Parallel Group, Multi-Centric, Clinical Study To Evaluate The Therapeutic Bio-Equivalence Of Two	Lambda Therapeutic Research Limited	Dr Ashish Deshmukh	Lambda Therapeutic Research Limited	2016	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/36%202016%20Dr%20Ashish%20Deshmukh%20Lambda.pdf
53	Medical Health Check-Up	Wockhardt	MGM Medical College and Hospital Aurangabad	Wockhardt	2016	Till Date	Medical Examination and Investigation	https://www.mgmuhs.com/NAAC/c3/3.7.1/37%202016%20%20Wockhardt .PDF
54	Rotary External Posting Of Physiotherapy Students	Hegdewar Hospital Aurangabad	MGM Medical College and Hospital Aurangabad	Hegdewar Hospital Aurangabad	2016	Till Date	For Internship	https://www.mgmuhs.com/NAAC/c3/3.7.1/38%202016%20Hedagewar.PDF
55	Research & Efficiency Of Test	J Mitra & Co. Pvt Ltd	MGM Medical College and Hospital Aurangabad	J Mitra & Co. Pvt Ltd	2016	20.09.2016	Research collabration among the parties herein Set the ground for efficacy testing of dengue NSI antigen FIA test kit Research Development for exchenging knowledge . Training for students	https://www.mgmuhs.com/NAAC/c3/3.7.1/39%202016%20J%20Mitra.pdf

56	Mutually Beneficial Program Which Serve To Enhance The Intellectual Life And Skill Development On Both Campus	Pillai College Of Education And Research	MGM Nursing college NM	NA	2016	Till Date	Exchange of Faculty & Students for education and training	https://www.mgmuhs.com/NAAC/c3/3.7.1/40%202016%20MOU%20with%20Pillai%20college%20nursing.pdf
							Conduct short certificate course Provide nesessary help to community service Provide awareness and interation through conducting talk and workshop	
57	A Phase IV, Open-Label, Multi-center Study to Evaluate the Safety of Apixaban in Indian Subjects Undergoing Elective Total Knee Replacement or Total	PPD Pharmaceutical Development India Pvt Ltd	Dr Girish Gadekar	PPD Pharmaceutical Development India Pvt Ltd	2016	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/41%202016%20Dr%20Girish%20Gadekar%20PPD.pdf
58	Clinical Trial	Ardent Clinical Research Services	MGM Medical College and Hospital Aurangabad	Ardent Clinical Research Services	2016	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2016%20Ardent%20Clinical%20Research%20MOU.pdf
59	Clinical Trial	Grapecity Research solutions LLP	MGM Medical College and Hospital Aurangabad	Grapecity Research solutions LLP	2016	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2016%20Grapecity%20Research%20Solutions%20MOU.pdf
60	Health Care IT Solutions To Hospital	21 St Century Informatics India	MGM Medical College and Hospital Aurangabad	NA	2017	Till Date	Health Care IT Solutions To Hospital	https://www.mgmuhs.com/NAAC/c3/3.7.1/42%202017%20Century%20Informatics.pdf
61	Management of tuberculosis patients according to RNTCP by private practitioners in Aurangabad City - A cross sectional study.	Jt Director Of Health Services (Leprosy & TB)	Dr. Prashant D. Warkari,	NA	2017	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20%20Jt%20Director%20of%20health%20ser%20(Leprosy%20&%20TB)%20Dr%20Prashant.pdf
62	Free Diagnostics and teatment for women in ruler sector	Gebbs Foundation India	MGM Medical College and Hospital Aurangabad	Gebbs Foundation India	2017	Till Date	Diagnostic Treatment	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Gebbs.%20Foundation.pdf
63	A rarulomized, open label, patallel-group, actjle-comparator controlled, muhi-center study to eraludte tfu efrcacy lnd safety ofLllipristal acetate (5 ng tablets), as comparcdwith	Cliantha Research Limited	Dr Lakshmi Rachkonda	Cliantha Research Limited	2017	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Cliantha..PDF

64	Title An open label, Two Arms, Comparaiive, Phase'lV Clinical Study evaluatLng safely and efficacy of Oratil LZ (combination of Cefuroxime 250m9 + Linezo id 600m9) versus L nezolid 600m9 in patiefts with	Macleods	Dr Anuradha Patil	Macleods	2017	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Dr.Anuradha%20Patil%20MACLEODS%20CTA.pdf
65	A ProsPective, I\rulticentric, Phase lV Clinical Study evaluating safety and efficacy of Leuprorelin 3.5mg lnjectlon plus Enzomac Tablet (Trypsin 96 mg +	Macleods	Dr Swati Shiradkar	Macleods	2017	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Dr.Swati%20Shiradkar%20MACLEODS%20CTA.pdf
66	Real world, non-interventional, observational study of Venusia Max Cream as Moisturizer in Psoriasis	Bioquest Solution Pvt Ltd	Dr H R Jerajani	Bioquest Solution Pvt Ltd	2017	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Dr%20Jjirajani%20Bio%20Quest%20pvt%20ltd.pdf
67	A Multicenter, Randomized, Double-Blind, Vehicle-Controlled Phase II Study to Evaluate the Efficacy, Tolerability, and Safety of Topical Povidone-Iodine	JSS Clinical Research Ltd	Dr Ashish Deshmukh	JSS Clinical Research Ltd	2017	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Dr%20Ashish%20Deshmukh%20JSS..pdf
68	Provide Pre Employment And Periodic Health Checkup Of The Employees.	Hospira Health Care India Pvt .Ltd	MGM Medical College and Hospital Aurangabad	Hospira Health Care India Pvt .Ltd	2017	Till Date	Hospitalization For various diseases including superspecialty Investigation , Procedure Treatment Employees	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20HOSPIRA-RENEWAL-2017.pdf
69	HIV Viral Load Test For HIV +Ve Patients.	AIDS Health Care Foundation (AHF)	MGM Medical College and Hospital NM	AIDS Health Care Foundation (AHF)	2017	Till Date	Reaching out of large no of people on HIV/AIDS prevention , testing, treatment, diagnostics Provide training and fellowship programs Create awareness staff and students Provide stigma free prevention , testing ,diagnostic and treatment all HIV affected people including TB and Hepatatis pateints	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20AIDS%20health%20care%20foundation%20AHF..pdf
70	Cataract Case Detection & Surgery	District Blindness Control Society	MGM Medical College and Hospital Aurangabad	District Blindness Control Society	2017	Till Date	Screening of population in all village Indentification of cases fit for cataract surgery	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20District%20Blind%20Society.pdf

							Pre opration examination and Investigation Post surgery treatment	
71	To evaluate efficacy and safety of Bacillus clausii (2 billion spores/5 ml) suspension as an add on therapy to standard of care in acute viral diarrhoea in children	Wockhardt Ltd	Dr Nimain Mohanty	Wockhardt Ltd	2017	Till Date	Research Clinical Trail Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017-MOU,Wockhardt.PDF
72	An Open Label Prospective, comparative, randomized, clinical study evaluating efficacy and safety of treatment A (Tamsulocin 0.4 mg Modified release capsule) versus treatment B (FDC	Macleods	Dr Prashant Darakh	Macleods	2017	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Dr.Prashant%20Darakh%20MACLEODS%20CTA.pdf
73	A Two arm, Comparative, Parallel, Randomized, double-blind, double-dummy Clinical study to evaluate and compare the efficacy and safety of Cefrine (combination of	Macleods	Dr Rajendra Bohra	Macleods	2017	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Dr.Rajendra%20Bohra%20MACLEODS%20CTA.pdf
74	An open label, Two arm, Comparative,Randomized Phase IV Clinical Study evaluating efficacy and safety of Alrista Forte (Epalrestat 150 Mg + Methylcobalmin	Macleods	Dr. Deepak Bhosle	Macleods	2017	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Dr.Deepak%20%20Bhosle%20MACLEODS%20CTA.pdf
75	Research	IIT Madras	Dr Rajani Mullerpatan	NA	2017	Till Date	Research Teaching for PG	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20IIT%20MADRAS..pdf
76	Health Card To Widows Of Farmers Committed Suicide	Yashswini Samajik Abhiyan	MGM Medical College and Hospital Aurangabad	Yashswini Samajik Abhiyan	2017	Till Date	Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Yashaswini%20samajik%20Abhiyan.PDF
77	Research / Training	ETHICON Johnson & Johnson Pvt Ltd.	MGM Medical College and Hospital Aurangabad	ETHICON Johnson & Johnson Pvt Ltd.	2017	02.07.2017	Research Development for Efficacy testing of Triclosan coated suture material Research collabtration Training for students	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Ethicon%20Jhonson%20&%20Jhonson.PDF
78	Pre Employment health checkup	CANPACK India Pvt Ltd	MGM Medical College and Hospital Aurangabad	CANPACK India Pvt Ltd	2017	Till Date	Medical Examination and Investigation	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Canpack%20India%20MOU%20aurangabad.pdf

79	Academic Training	Bombay Hospital Trust, Mumbai.	Mr. Chouhan Siddharth Champalal (MBBS Students)	NA	17.02.20	2017	Internship Training	https://www.mgmuhs.com/NAAC/c3/3.7.1/2014-19%20Internship%20letters.pdf
	Academic Training	Gauhati Medical College, Guwahati.	Ms. Krishnakhi Goswami (MBBS Students)	NA	11.05.20	2017	Internship Training	
	Academic Training	Government Medical College, Patiala.	Ms. Shivneet Kaur Brar (MBBS Students)	NA	04.05.20	2017	Internship Training	
	Academic Training	Grant Government Medical College, Mumbai.	Ms. Achawal Shruti Sanjay, Mr. Raje Rohit Shrikant (MBBS Students)	NA	15.02.20	2017	Internship Training	
	Academic Training	Lokmanya Tilak Municipal Medical College, Sion, Mumbai.	Mr. Yadav Shivakumar Veludas (MBBS Students)	NA	06.05.20	2017	Internship Training	
	Academic Training	Pt. Jawaharlal Nehru Memorial Medical College, Raipur, Chhattisgarh	Ms. Akanksha Vishwakarma (MBBS Students)	NA	11.05.20	2017	Internship Training	
	Academic Training	Seth G. S. Medical College & K.E M. Hospital, Parel, Mumbai.	Ms. Goiporia Mahafrin Homiar ,Mr., Ms. Beri Riddhima Rajiv , Jain Akash Jeevan ,Ms. Mehta Shikha Paresh , Ms. Gandhi Lorie Mahendra,Ms. Lodha Ayushi Mahavir (MBBS Students)	NA	11.02.20	2017	Internship Training	
	Academic Training	Sir Ganga Ram Hospital, New Delhi.	Ms. Anushruti Gupta (MBBS Students)	NA	20.05.20	2017	Internship Training	
	Academic Training	Smt. Kashibai Navale Medical College & General Hospital, Pune.	Mr. Patkar Chinmay Rajendra (MBBS Students)	NA	18.02.20	2017	Internship Training	
	Academic Training	Terna Medical College & Hospital, Nerul, Navi Mumbai.	Ms. Thomas Joyce Jobkutti (MBBS Students)	NA	18.02.20	2017	Internship Training	
2017-18								
80	"A 24'week, randomised, doublЄ'blind, double-dummv parallel group, multi cenire, active'controlled study to evaluatc cfficacy and safety ofremogliflozin etabonate in subjccts with type'2 diabetes mcllitus.	Glenmark Pharmaceutical Ltd	Dr Deepak Bhosale	Glenmark Pharmaceutical Ltd	2017	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Dr%20Deepak%20Bhosale%20Glenmark.pdf
81	Executive Health Check-Up	Skoda Ltd	MGM Medical College and Hospital Aurangabad	Skoda Ltd	2017	Till Date	Medical Examination and Investigation	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Skoda.PDF

82	A Study to Evaluate the Effect of Dapagliflozin on Incidence of Worsening Hearl Failure or Cardiovascular Death in in Patients lvith phronic Heart Failure with	Astrazeneka Pharma India Ltd	Dr Prashant Udgire	Astrazeneka Pharma India Ltd	2017	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Dr%20Deepak%20Bhosale%20Astrazeneka.pdf
83	Employee Health Check-Up	SPS Intermodal Services (India) Pvt Ltd	MGM Medical College and Hospital NM	SPS Intermodal Services (India) Pvt Ltd	2017	Till Date	Medical Examination and Investigation	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017.SPS%20Intermodal%20Services-signed.pdf
84	26 Week, Multicenter,randomized	Astrazeneka Pharma India Ltd	Dr Deepak Bhosale	Pharmaceutical Research Associates	2017	Till Date	Research Teaching for PG	https://www.mgmuhs.com/NAAC/c3/3.7.1/
							Clinical training. Counsaltancy Industry -academia interaction	
85	A Randomized, Double-Blind, Placebo-Controlled, Phase 2 Study to Assess the Efficacy, Pharmacokinetics, Pharmacodynamics and Safety of LNP1892	LUPIN	Dr Sudhir Kulkarni	LUPIN	2017	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Dr%20Sudhir%20Kulkarni%20Lupin.pdf
86	Research	Sinergy Nanosystem	MGMSBS ,MGMIHS (Dr Mansee Thakur)	NA	2017	Till Date	Research Project Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Sinergy%20Nano%20system.PDF
87	Tie Up Of Sport Authority Of India	Sports Authority Of India	MGM School of Physiotherapy Aurangabad	Sports Authority Of India	2017	Till Date	Provide sport medicine Faculty to UG/PG Physiotherapy Students	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Sports%20Authority%20India..pdf
88	Work of Micro Nano engineering development and deplomentof India specific low cost biomedical devices	Allied Scientific Products	MGMSBS ,MGMIHS (Dr Mansee Thakur)	NA	2017	Till Date	Research Project Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20allied%20scientific%20&%20SBS-Copy.pdf
89	Project - MGM TBDS	Chennai Interventional Pulmonology And Critical Care Assosiates Pvt Ltd	MGMSBS ,MGMIHS (Dr Mansee Thakur)	NA	2017	Till Date	Research Project Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Chennai%20International%20Pulmonology.PDF
90	For Laboratory Services	Ratnanidhi Charitable Trust	MGM School of Physiotherapy NM (Dr Rajani Mullerpatani)	Ratnanidhi Charitable Trust	2017	Till Date	Patient care Training for students Research Faculty Exchange Exchange scientific material , publication, and information	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Ratnanidhi%20Charitable%20Trust..pdf
91	Employee Health Check-Up	Mylan Laboratory Ltd , Taloja , Panvel	MGM Hospital NM	Mylan Laboratory Ltd , Taloja , Panvel	2017	Till Date	Pre Employment Health checkup	https://www.mgmuhs.com/NAAC/c3/3.7.1/2016.Mylan%20Laboratory%20Ltd.-1
92	International Training Center	American Heart Association (AHA)	MGM Medical College and Hospital NM (Dr Sameer Kadam)	NA	2017	Till Date	Training for student and faculty	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20MOU%20American%20Heart%20association%20(AHA)%20nm%20(2).PDF

93	Provide affordable 24 hr world class medical health care service including laboratory service to its pateints	Siddhi Metropolis Healthcare	MGM Medical College and Hospital Aurangabad	Siddhi Metropolis Healthcare	2017	Till Date	Provide Laboratory services	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20Sidhi%20Metropolis%20Lab..pdf
94	Training And Clinical Trial	Zila Parishad Raigad DRTB Center Raigad	MGM Medical College and Hospital NM (Dr Potdar)	NA	2017	14.11.2020	Provide financial and material support Provide technical guidelines , updateds , manual & circular Provide RNTCP drugs	https://www.mgmuhs.com/NAAC/c3/3.7.1/12%202015%20Health%20Zilla%20Parishad%20Aug..pdf
95	Annual Preventive Health Checkup	Alliz Health	MGM Medical Center & Research Institute	NA	2018	Till Date	Medical Examination and Investigation	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018-AllizHealth.pdf
96	Fish waste management through biotechnological interventions	Pavan Green Technologies Ltd	MGMIHS (Dr Raman Yadav)	NA	2018	Till Date	Research Student exchange faculty exchange	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20Pavan%20Green%20Biotechnologies%20ltd%20& %20Omics.pdf
97	Internship training program	Glaxosmithkline Pharmaceutical Ltd	MGM Medical College and Hospital NM (Dr Rohit Sane MD Pharmacology	NA	2018	08.06.2018	Student training Project work Collaborative resaerch	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20Galaxosmithkline..pdf
98	Eye Banking & Cornea Storage	Sahiyara Eye Bank	MGM Medical College and Hospital NM	NA	2018	Till Date	Utilization corneal tissue for transplantation, Research, Medical education Performspecular microscopy testing for tissue Necessary training to eye bank	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20MOU%20Sahiyara%20Eye%20Bank.pdf
99	Academic Training	Tata Memorial Hospital	Berin Dixon Dsa,Swapnil Jadhav , Shraddha Keny (Dr Archana Mishra)	NA	2018	25.06.2018	Training Patient care management Inventory control	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017-%2019%20Internship.pdf
	Academic Training	Fortis Hospital Vashi	Jayesh Tawade,Swati Mane ,Vishambar Chauhan (Dr Archana Mishra)	NA	2018	20.07.2018	Training Quality management and Accreditation	
	Academic Training	PD Hinduja National Hospital & Medical Research Centre	Heena Malekar (Dr Archana Mishra)	NA	2018	11.07.2018	Training Inventory control Quality control	
	Academic Training	Nanavati Super Speciality Hospital	Krutika Halwai (Dr Archana Mishra)	NA	2018	14.07.2018	Training Orientation of patient management	
	Academic Training	Unique Hospital , Surat	Foram Patel (Dr Archana Mishra)	NA	2018	25.07.2018	Training Biomedical waste management Quality management	
	Academic Training	Shree Mahavir Health & Medical Relief Society Surat	Foram Patel (Dr Archana Mishra)	NA	2018	15.05.2018	Training Quality management and Accreditation	

100	Phase 3 Multicenter Double blind study to evaluate the long term safety and efficacy of barciunib in adult patients with atopic dermatitis	Elli Lilly Company (India) Pvt Ltd Gurgaon Haryana	Dr H R Jerajani	Elli Lilly Company (India) Pvt Ltd Gurgaon Haryana	2018	Till Date	Clinical Trial Research and Publication High quality training for faculty as wel as students Networking and support to the clinical research community	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20Eli%20Lilly%20And%20Company%20..pdf
101	A Multicenter Randomized double blind placebo controlled study to evaluate the efficacy and safety of baricitinib in adult patients with moderate to severe	Elli Lilly Company (India) Pvt Ltd Gurgaon Haryana	Dr H R Jerajani	Elli Lilly Company (India) Pvt Ltd Gurgaon Haryana	2018	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20Eli%20Lilly%20And%20Company.pdf
102	Optimizing health care delivery and the overall health and well being of special children as well as education and learning of clinical skills for physiotherapy students	Aarambh Autistic Centre	MGM School of Physiotherapy Aurangabad	Aarambh Autistic Centre	2018	Till Date	Provide optimal health care for special children Improve collaboration , communication cordination of service Trainig for students Provide physical function and fitness screening of special children	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20Aarambh%20Autistic%20Centre%20MOU..pdf
103	Optimizing health care delivery and the overall health and well being of special children as well as education and learning of clinical skills for physiotherapy students	Primary Health Centre Adul	MGM School of Physiotherapy Aurangabad	Primary Health Centre Adul	2018	Till Date	Provide optimal health care for special children Improve collaboration , communication cordination of service Trainig for students provide physical function and fitness screening of special children	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20PHC,%20Adul..pdf
104	Promoting teaching ,educational, research & other collaborative activity for mutual benefit of sport person	Sports Authority Of India	MGM School of Physiotherapy	NA	2018	Till Date	Training Clinical Trial Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20Sports%20Authrity%20of%20India%20MOU..pdf
105	MGM , Kamothe Acts As A Mother Blood Bank	MGM Vashi, Storage Center	MGM Medical College and Hospital NM	NA	2018	Till Date	Supply Blood units and Blood product	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20MOU%20with%20MGM%20VASHI%20BLOOD%20STORAGE%20CENTER.pdf
106	Academic, Clinical training , Internship , Project work, student/ faculty exchange , Research	SVERI college of Engineering Pandharpur	MGM School of Biomedical Sciences (Dr Mansee Thakur)	NA	2018	Till Date	Project Work Internship Research Students/ Faculty exchange	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20mou%20sveri%20and%20sbs.pdf

107	Academic Training	Ashwini Rural Medical College, Hospital and Research Centre, Solapur	Ms. Maindarkar Apurva Ajay (MBBS Students)	NA	2018	2019	Internship Training	https://www.mgmuhs.com/NAAC/c3/3.7.1/2014-19%20Internship%20letters.pdf
	Academic Training	B.J. Medical College, Ahmedabad.	Mr. Shalin Jain (MBBS Students)	NA	2018	2019	Internship Training	
	Academic Training	Balabhai Nanavati Hospital Mumbai	Ms Gupta Prachi, Mr Shetty Shruthi, Ms Nayak Nisha, Mr Patel Kairav, Ms	NA	2018	2019	Internship Training	
	Academic Training	Bhatia Hospital, Mumbai	Mr. Allahbadia Sidharth Vivek, Ms. Eram Azeem Mahaldar, Ms. Kabra Minal Satyanarayan , Mr. Dodeja Ajay Dayal , Ms.	NA	2018	2019	Internship Training	
	Academic Training	Bombay Hospital & Medical Research Centre, Mumbai.	Mr. Satia Raunak Naresh, Ms. Changle Shreeya Shailesh, Mr. Mayur Vijay Bhalghat (MBBS	NA	2018	2019	Internship Training	
	Academic Training	Calcutta National Medical College, Kolkata.	Ms. Dyuti Sit (MBBS Students)	NA	2018	2019	Internship Training	
	Academic Training	Chhattisgarh Institute of medical sciences Bilaspur	Ms Srishti Jaiswal (MBBS Students)	NA	2018	2019	Internship Training	
	Academic Training	Civil Hospital Bathinda Punjab	Mr Sankalp Markan (MBBS Students)	NA	2018	2019	Internship Training	
	Academic Training	Civil Hospital Sonipat	Ms Srishty Vij (MBBS Students)	NA	2018	2019	Internship Training	
	Academic Training	Civil Hospital, Gurgaon.	Ms. Pragya Yadav (MBBS Students)	NA	2018	2019	Internship Training	
	Academic Training	Civil Hospital, Gurugram.	Mr. Dheeraj Chhabra (MBBS Students)	NA	2018	2019	Internship Training	
	Academic Training	Civil Hospital, Sirsa, Haryana.	Mr. Anirudh Pahwa (MBBS Students)	NA	2018	2019	Internship Training	
	Academic Training	Civil Hospital, Sonepat, Haryana.	Ms. Srishty Vij (MBBS Students)	NA	2018	2019	Internship Training	

	Academic Training	District Civil Surgeon, District Hospital, Barshi Road, Beed	Ms. Jethliya Madhushri Nandkishorji ,Mr. Kale Aditya Madhusudan (MBBS Students)	NA	2018	2019	Internship Training	
	Academic Training	District General Hospital Buldana	Ms Sawale Aishwarya Vinayak (MBBS Students)	NA	2018	2019	Internship Training	
	Academic Training	District Hospital Mathura UP	Ms Barot Astha Dinesh, Mr Ankit Jain, Ms. Barot Astha Dinesh ,Mr. Ankit Jain (MBBS Students)	NA	2018	2019	Internship Training	
	Academic Training	Dr. Balabhai Nanavati Hospital, Mumbai	Ms. Aastha Jain , Mr. Gautam Tanmay Navin, Ms. Shetty Shruthi Santosh, Ms. Rao Shraddha Ganesh, Mr. Shah Raj Harshad, Ms. Parlikar Malvika Rajiv, Ms. Mehta Drishti Hiten, Mr. Tripathi Ashutosh Chandraprakash , Mr. Binyala Siddhant Rajesh, Mr. Chitalia Dhairya Shailesh, Ms. Ladwal Ritika Rakesh (MBBS Students)	NA	2018	2019	Internship Training	
	Academic Training	Dr. Shankarrao Chavan Govt. Medical College, Vishnupuri, Nanded.	Mr. Ghei Prem Sanjay (MBBS Students)	NA	2018	2019	Internship Training	
	Academic Training	Dr. Ulhas Patil Medical College & Hospital, Jalgaon.	Ms. Saoji Pinaki Sachin (MBBS Students)	NA	2018	2019	Internship Training	
	Academic Training	Government Medical College, Aurangabad.	Ms. Bagban Tahseen Javed (MBBS Students)	NA	2018	2019	Internship Training	
	Academic Training	Grant Government Medical College, Mumbai	Ms. Gilani Uzma Sayed Khushnud,Ms. Patil Jidnyasa Dilip (MBBS	NA	2018	2019	Internship Training	
	Academic Training	Masina Hospital, Mumbai	Ms. Rochlani Sonika Sureshlal , Mr. Patel Asjad Afzal (MBBS Students)	NA	2018	2019	Internship Training	
	Academic Training	Post Graduate Institute of Medical Education and Research, Dr. Ram Manohar Lohia Hospital, New Delhi.	Ms. Anubhuti Shandilya (MBBS Students)	NA	2018	2019	Internship Training	

	Academic Training	SMS Medical College and Controller of Attached Hospitals, Jaipur	Ms. Urvi Gaur (MBBS Students)	NA	2018	2019	Internship Training	
	Academic Training	Smt. Kashibai Navale Medical College & General Hospital, Pune.	Ms. Dhage Sneha Vyankatrao (MBBS Students)	NA	2018	2019	Internship Training	
	Academic Training	Terna Medical College & Hospital, Navi Mumbai.	Mr. Patel Gaurav Jayantilal (MBBS Students)	NA	2018	2019	Internship Training	
	Academic Training	Topiwala National Medical College, Mumbai.	Ms. Shah Bansari Bhadrakant (MBBS Students)	NA	2018	2019	Internship Training	
2018-19								
108	Innovation & Inncubation manegemet plateform to establishment of technology	Jugaadfunda Innovations LLP Pune	MGM Institute of Health Sciences	NA	2018	Till date	Research Startup Enterprinership	https://www.mgmuhs.com/NAAC/c3/3.7.1/MOM%20JF%20MGM%201.pdf
109	Academic Training	MGM Law College Nerul	Dr Karuna	NA	2018	Till date	Internship to Students , Obeservership , Faculty Exchange	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20MGM%20law%20clg.pdf
110	Academic Training	MGM College of Commerece	Principle	NA	2018	Till date	Internship to Students , Obeservership , Information lecture and practical relating to IT and Account	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20MGM%20Clg%20Commerece.PDF
111	Academic Training	MGM College of Computer Science and Information Technology	Dr Chaitali and Dr Piyush	NA	2018	Till date	Internship to Students , Obeservership , Information lecture and practical relating to IT	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20MOU%20MGM%20Clg%20of%20Comp%20&%20IT.PDF
112	Academic Training	MGM Institute of Manegement Studies and Research	Dr Saloni	NA	2018	Till date	Internship to Students , Obeservership , Information lecture and practical relating to Quality management and accreditation	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20MGM%20Inst%20of%20Management.PDF
	Academic Training	Mission Spine Foundation	MGM Institute of Health Sciences	NA	2018	Till Date	Academic training to PG Students	
113	Academic Training	Fortis Hospital mulund	Swapnil Jadhav , Berin Dixon Dsa (Dr Archana Mishra)	NA	2018	31.07.2018	Academic Training Quality management and accreditation	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017-%2019%20Internship.pdf
	Academic Training	HBT Medical College & Dr RN Cooper MUN Gen Hospital Mumbai	Krutika Halwai,Heena Malekar, Kiswa Ansari (Dr Archana Mishra)	NA	2018	23.08.2018	Training Orientation of patient management	
	Academic Training	KEM Hospital Parel	Swati Mane,Vishambar Chauhan (Dr Archana Mishra)	NA	2018	24.08.2018	Training Inventory control Quality control	
	Academic Training	Sanjivani Hospital & ICCU centre Surat	Foram Patel (Dr Archana Mishra)	NA	2018	26.08.2018	Training Qualtiy control	
	Academic Training	Brihanmumbai Mahanagar Palika , Public Health dept Mumbai	Swapnil Jadhav ,Berin Dixon Dsa (Dr Archana Mishra)	NA	2018	15.08.2018	Training Inventory control Quality control	

114	Academic, Clinical training , Internship , Project work, student/ faculty exchange , Research	Pillai College of Arts , Commerce & scienc	MGM SBS (Dr Mansee Thakur)	NA	2018	2019	Academic Training Project Work Clinical training Internship Research Students/ Faculty exchange	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20mou%20pillai%20and%20biotech.pdf
115	For Laboratory Services	Oncquest Laboratories Ltd	MGM Medical College and Hospital Aurangabad	NA	2018	Till Date	For Laboratory Services	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20OncquestLab..pdf
116	For Blood & Blood Components Supply	Dattaji Bhale Blood Bank	MGM Medical College and Hospital Aurangabad	NA	2018	Till Date	Processing & distribution of blood to those in need	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20Dattaji%20Bhale%20Lab..pdf
117	Free Health Service for mentaly retairded child	Swayamsiddha NGO	MGM School of Physiotherapy Aurangabad	Swayamsiddha NGO	2018	Till Date	Provide Free health checkup Training of students	https://www.mgmuhs.com/NAAC/c3/3.7.1/2017%20%20Swyamsiddha%20MOU..pdf
118	Data collection and Data analysis	Sancheti College of Physiotherapy	Dr Rajani Mullerpatan	NA	2018	Till Date	Research Purpose	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20MOU%20Sancheti%20college%20P
119	Research Study on Spectrum of CYP21A2 Mutation in congenital adrenal	Bai Jerabai Wadia Hospital for children ,Acharya Dhonde Marg	Anjali Patil and Dr Anjali Sabnis	NA	2018	Till Date	Student training Project work Collaborative resaerch	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20Wadia%20Hospita%20+%20.Anjali%20Patil.pdf
120	Study of variability of mutation in CYP21A2 gene in congenital adrenal	Bai Jerabai Wadia Hospital for children ,Acharya Dhonde Marg	Tejaswini and Dr Anjali Sabnis	NA	2018	Till Date	Student training Project work Collaborative resaerch	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20Wadia%20hospital%20.+Tejashwini.pdf
121	Study of HLA B 1502 Genotype in children with epilepsy	Bai Jerabai Wadia Hospital for children ,Acharya Dhonde Marg	Akshay and Dr Anjali Sabnis	NA	2018	Till Date	Student training Project work Collaborative resaerch	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20Wadia%20hospital%20+.%20Akshay.pdf
122	Mutational Spectrum of patients with DMD	Bai Jerabai Wadia Hospital for children ,Acharya Dhonde Marg	Swati and Dr Anjali Sabnis	NA	2018	Till Date	Student training Project work Collaborative resaerch	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20Wadia%20hospital%20+%20.Swati.pdf
123	Study of prevalance of single nucleotide polymorphism in autistic children	Bai Jerabai Wadia Hospital for children ,Acharya Dhonde Marg	Aditi and Dr Anjali Sabnis	NA	2018	Till Date	Student training Project work Collaborative resaerch	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20%20Wadia%20hospital%20%20Aditi.pdf
124	Screening of antimicrobial activity and physicochemical analysis of shawas kas chitamani rasa	Shree Dhootapapeshwar Ltd , Veer Savarkar Chowk,, Panvel, Navi Mumbai, Maharashtra 410206	Kshipra and Dr Mansee Thakur	NA	2018	Till Date	Student training Project work Collaborative resaerch	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20Shree%20Dhootpapeshwar%20+%20kshipra1.pdf
125	A Randomized, Double-Blind, Placebo-Controlled, three-arm, Parallel Design, Multiple site, Study to Evaluate the Therapeutic equivalence and Safety of Tacrolimus Ointment,0.1% (Encube Ethicals Private Limited) with Protopic® - (Tacrolimus Ointment 0.1% (Astellas Pharma US, Inc) in the treatment of Moderate to Severe Atopic Dermatitis	Accutest Research Lab	Dr. Ashish Deshmukh	Accutest Research Lab	2018	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20%20Accutest%20CTA%20dR.%20Ashish%20Deshmukh.pdf

126	A Multicentric, Open lable, Randomized, Comparative, clinical study evaluating safety and Efficacy of Fixed Dose combination of Trypsin 48 mg + Bromelain 90 mg + Rutoside Trihydrate 100 mg enteric coated tablet versus Serratiopeptide 10 mg enteric coated tablet in patient for heling potential in surgical wound after minor surgery.	Macleods	Dr. Mahendra Surywanshi	Macleods	2018	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20%20Macleods%20CTA%20Dr%20Mahendra%20Surywanshi.pdf
127	Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization,	SIRO Clinpharm Pvt. Ltd	Dr.Shivaji Pole	SIRO Clinpharm Pvt. Ltd	2018	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2018%20SIRO%20Clinpharm%20pvt%20ltd%20CTA_Lipiodol.pdf
128	A Phase III Randomized, Double Blind, Parallel Group, Placebo Controlled, Multi-Centre, Multinational Study to Evaluate Efficacy and Safety of TRC150094 as an	IQVIA HDS (lndia) Private Limited	Dr. Deepak Bhosle	IQVIA HDS (lndia) Private Limited	2019	Till Date	Research Teaching for PG Clinical training. Counsaltancy Industry -academia interaction	https://www.mgmuhs.com/NAAC/c3/3.7.1/2019%20CTA%20IQVIA%20Dr.deepak%20bhosle..pdf
129	Comparison between growing Muskmelon (cucumis melo) in different hydrophonic	Himedia , Vadhni Industrial estate Ghatkopar	Surabha and Dr Mansee Thakur	NA	2019	Till Date	Student training Project work Collaborative resaerch	https://www.mgmuhs.com/NAAC/c3/3.7.1/2019%20MOU%20%20Hi%20Media%20+Saurabh%20Pawar.pdf
130	Comparison between growing Cucumber (cucumis sativus) in different hydrophonic	Himedia , Vadhni Industrial estate Ghatkopar	Kalaivani and Dr Mansee Thakur	NA	2019	Till Date	Student training Project work Collaborative resaerch	https://www.mgmuhs.com/NAAC/c3/3.7.1/2019%20MOU%20Hi%20Media%20+%20S%20Kalaivani.pdf
131	Academic, Clinical training , Internship , Project work, student/ faculty exchange , Research	Pillai College of Arts , Commerce & scienc	MGM SBS (Dr Mansee Thakur)	NA	2019	Till Date	Project Work Internship Research Students/ Faculty exchange	https://www.mgmuhs.com/NAAC/c3/3.7.1/2019%20mou%20pillai%20and%20biotech.pdf
132	Academic, Clinical training , Internship , Project work, student/ faculty exchange , Research	Nirmala Niketan college of Home Sciences , New Marine Lines mumbai	MGM SBS (Dr Mansee Thakur)	NA	2019	Till Date	Project Work Internship Academic Clinical training Research Students/ Faculty exchange	https://www.mgmuhs.com/NAAC/c3/3.7.1/2019%20Nirmala%20Niketan%20College..pdf
133	Project Work	ChromoXpert	Dr Anjali Sabnis	NA	2019	Till Date	Student training Project work Collaborative resaerch	https://www.mgmuhs.com/NAAC/c3/3.7.1/2019%20MOU%20Chromo%20Xpert.pdf

134	Academic Training	Balabhai Nanavati Hospital Mumbai	Mr Qureshi Mohammed Umar Ayub, Ms Pereira Jessica Jude, Ms Subhedar Narendra, Mr Asrani Devesh Hitesh, Mr Agarwal Laksh Abhay , Mr Bandodkar Nishant (MBBS Students)	NA	2019	2020	Internship Training	https://www.mgmuhs.com/NAAC/c3/3.7.1/2014-19%20Internship%20letters.pdf
	Academic Training	Civil Surgeon Buldana	Ms Tayde Yashashree (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Civil Hospital Sonipat	Ms vaishali Singh (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Civil Hospital Beed	Ms Upadhye Neha (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	BJ Govt Medical College Pune	Ms Dube Sheetal Arun (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Govt. Medical College, Amritsar	Mr. Harmanpreet Singh (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Indira Gandhi Institute of Medical Sciences, Medical College, Patna	Mr. Siddharth Manu (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Swami Ramanand Teerth Rural Government Medical College, Ambajogai, Beed	Mr. Munde Anand Rajaram (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Masina Hospital, Mumbai.	Mr. Vasan Prakash Singh Swaran Singh (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Belagavi Institute of Medical Sciences, Belagavi.	Ms. Kodamnalli Shweta Shantreddy (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Civil Hospital, Nashik	Mr. Bhide Shivraj Mahadeo (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Govt. Multi-Specialty Hospital, Sector -16, Chandigarh.	Ms. Bhatti Akanxa (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Bombay Hospital & Medical Research Centre, Mumbai.	Ms. Kanchwala Aashna Vajiulla (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Bhatia Hospital, Mumbai.	Mr. Bafna Varun Vipul (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Chhatrapati Shivaji Maharaj Hospital, Kalwa, Thane.	Ms. Chavan Mansi Sunil (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Geetanjali Medical College & Hospital, Udaipur.	Mr. Mohit Atray (MBBS Students)	NA	2019	2020	Internship Training	

	Academic Training	L.T.M. Medical College, Mumbai.	Ms. Agateertha Tejashree Keerteppa (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Calcutta National Medical College, Kolkata.	Mr. Shayan Datta (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	S.B.L.S. Civil Hospital, Jalandhar	Mr. Gupta Archit Sanjeev (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Indira Gandhi Institute of Medical Sciences, Medical College, Patna	Mr. Siddharth Manu (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Government Medical College, Patiala	Mr. Girdher Shubham Sudershan (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Government Multi-Specialty Hospital, Chandigarh.	Ms. Kaura Arshiya Rajiv (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	SMS Medical College and Controller of Attached Hospitals, Jaipur.	Mr. Choudhary Nishant Tarachand (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Rajiv Gandhi Medical College & Chhatrapati Shivaji Maharaj Hospital, Thane.	Ms. Virkar Girija Vikas (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Government Medical College, Amritsar.	Mr. Sehgal Tarun Ashwani (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Dr. Balabhai Nanawati Hosital, Mumbai.	Mr. Bandodkar Nishant Deepak (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Government of Maharashtra Health Department, District Hospital, Beed.	Ms. Bembde Vaidehi Ramakant (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Government Medical College, Majuragate, Surat.	Ms. Sanghani Ishita Jayeshbhai (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Government Medical College & Hospital, Chandigarh	Ms. Bindra Jatin Pardeep Kumar (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Surat Municipal Institute of Medical Education and Research, Surat, Gujarat.	Ms. Patel Parinda Dixitkumar (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Topiwala National Medical College, Mumbai.	Ms. Munshi Fatima Munir Ahmed (MBBS Students)	NA	2019	2020	Internship Training	

	Academic Training	Civil Hospital, Gurugram	Ms. Kachru Pratiksha Ranjan (MBBS Students)	NA	2019	2020	Internship Training	
	Academic Training	Government Medical College, Majuragate, Surat.	Ms. Gandhi Aneri Setu (MBBS Students)	NA	2019	2020	Internship Training	
135	Knowladge patner Inccubation and Establishing policy	Samruddhi TBI Foundation Sangli	MGM Institute of Health Sciences	NA	2019	Till Date	Research	https://www.mgmuhs.com/NAAC/c3/3.7.1/MOM%20STBI%20MGM.pdf
				NA			Startup	
				NA			Enterprinership	

2019 - 2020						
	Link: https://www.mgmuhs.com/pdfs/AQAR_2019-20/F-3.7.1.pdf					
Sr. No.	**Title of the Collaborative activity**	**Name of the collaborating agency with contact details**	**Name of the Participant**	**Source of financial support**	**Year of the Collaboration**	**Duration in day**
1	To provide a formal basis for the interaction between MGMIHS and GSK for the internship for student	Glaxosmithkline Pharmaceuticals Ltd	MGM Medical College , Navi Mumbai	Glaxosmithkline Pharmaceuticals Ltd	2019-2020	**60**
2	Supply Blood Components	MGM VASHI	MGM Medical College , Navi Mumbai	MGM VASHI	2019-2020	**732**
3	Integration of Extended Immune Monitoring (ExImM) and clinical parameters for early prediction of disease trajectory/progression, treatment planning and prophylaxis to improve COVID-19 prognosis	ICMR + ACTREC (TATA Hospital, Kharghar)	MGM Medical College , Navi Mumbai	ICMR + ACTREC (TATA Hospital, Kharghar)	2019-2020	**730**
4	For testing of H1N1 Influenza and SARS Cov-2 (COVID - 19)	Terna Diagnostics, Molecular Lab, Nerul	MGM Medical College , Navi Mumbai	Terna Diagnostics, Molecular Lab, Nerul	2019-2020	**363**
5	Validate the AI Tool developed by MYB in reliably diagnosing COVID 19 cases by use of Xray images	More-Ya Biosciences Limited Liability Company (LLP), Pune	MGM Medical College , Navi Mumbai	More-Ya Biosciences Limited Liability Company (LLP), Pune	2019-2020	**1831**
6	Counseling and testing center for HIV	National AIDS control org. (NACO), Govt of India	MGM Medical College , Navi Mumbai	National AIDS control org. (NACO), Govt of India	2019-2020	**365**
7	COVID 19 Hospital	Panvel Municipal Corporation	MGM Medical College ,	Panvel Municipal Corporation	2019-2020	**61**
8	DR TB center	CEO, ZP Raigad, & District National Tuberculosis, Elimination Programme Society, Raigad	MGM Medical College , Navi Mumbai	CEO, ZP Raigad, & District National Tuberculosis Elimination Programme society, Raigad	2019-2020	**1091**
9	For testing of H1N1 Influenza testing on RT PCR	Smt Kashibai Navale Medical College and General Hospital, Molecular Lab, Narhe Pune	MGM Medical College , Navi Mumbai	Smt Kashibai Navale Medical College and General Hospital, Molecular Lab,	2019-2020	**342**
10	Interdisciplinary Clinical Research with AIIMS, Nagpur and M/S Ambosia Food Farm Co. Uttrakhand	M/S Ambosia Food Farm Co. Uttrakhand	MGM Medical College , Navi Mumbai	M/S Ambosia Food Farm Co. Uttrakhand	2019-2020	**365**

11	Clinical Research	Novartis /Ardent	MGM Medical College , Aurangabad	Novartis /Ardent	2019-2020	383
12	Clinical Research	JSS / CIPLA	MGM Medical College , Aurangabad	JSS / CIPLA	2019-2020	357
13	Clinical Research	Quest / Sonde	MGM Medical College , Aurangabad	Quest / Sonde	2019-2020	450
14	Clinical Research	Torrent/SIRO/Grapecity	MGM Medical College , Aurangabad	Torrent/SIRO/Grapecity	2019-2020	424
15	Clinical Research Project	JSS/Glasshouse	MGM Medical College , Aurangabad	JSS/Glasshouse	2019-2020	296
16	Clinical Research Project	Novalead Pharma /JSS	MGM Medical College, Aurangabad	Novalead Pharma / JSS	2019-2020	297
17	Clinical Research Project	Mediclin Clinical Research	MGM Medical College, Aurangabad	Mediclin Clinical Research	2019-2020	267
18	Clinical Research Project	Neon	MGM Medical College, Aurangabad	Neon	2019-2020	400
19	Clinical Research Project	Serum Institute of India Pvt. Ltd	MGM Medical College, Aurangabad	Serum Institute of India Pvt. Ltd	2019-2020	173
20	Clinical Research Project	Glenmark	MGM Medical College, Aurangabad	Glenmark	2019-2020	192
21	Clinical Research Project	Ardent Clinical Research Services,	MGM Medical College, Aurangabad	Ardent Clinical Research Services,	2019-2020	365
22	Clinical Research Project	Ardent Clinical Research Services,	MGM Medical College, Aurangabad	Ardent Clinical Research Services,	2019-2020	365

23	Clinical Research Project	Christian Medical College, Vellore	MGM Medical College, Aurangabad	Christian Medical College, Vellore	2019-2020	267
24	Clinical Research	Biosphere Clinical Research Pvt Ltd	MGM Medical College, Aurangabad	Biosphere Clinical Research Pvt Ltd	2019-2020	3652
25	Clinical Research	Grapecity Research Services	MGM Medical College, Aurangabad	Grapecity Research Services	2019-2020	1827
26	Clinical Research	Ardent Clinical Research Services	MGM Medical College, Aurangabad	Ardent Clinical Research Services	2019-2020	3653
27	Clinical Research	DOCLIN Clinical Research Services	MGM Medical College, Aurangabad	DOCLIN Clinical Research Services	2019-2020	3651
28	Clinical Research	NMC Services	MGM Medical College, Aurangabad	NMC Services	2019-2020	3652
29	Clinical Research	Q-RED Clinical Research Services	MGM Medical College, Aurangabad	Q-RED Clinical Research Services	2019-2020	3683
30	Sponsored Travel to St. Mary's University Canada for conference as guest speaker	Indo-Canadian Shastri Institute Travel grant	MGM School of Physiotherapy	Indo-Canadian Shastri Institute Travel grant	2019-2020	8
31	waiver for conferences, seminars and other event, student interaction, faculty participation as a resourse person	Nirmala nikentan	MGM School of Biomedical,NM	Nirmala nikentan	2019-2020	1825
32	Innovation & Inncubation manegemet plateform to establishment of technology commercialization	Juggadfunda Innovation LLP	MGM School of Biomedical,NM	Juggadfunda Innovation LLP	2019-2020	1825
33	Academic, Clinical training , Internship , Project work, student exchange, Research	Apollo fertility centre	MGM School of Biomedical,NM	Apollo fertility centre	2019-2020	1825
34	Academic, Clinical training , Internship , Project work, student/ faculty exchange , Research	Institute for future education entrepreneurship and leadership(iFeel), Lonavala	MGM School of Biomedical,NM	Institute for future educationentrepreneurship and leadership(iFeel), Lonavala	2019-2020	1825

35	Student training , Project work, Collaborative resaerch	Himedia , Vadhni Industrial estate Ghatkopar	MGM School of Biomedical,NM	Himedia , Vadhni Industrial estate Ghatkopar	2019-2020	365
36	Student training , Project work, Collaborative resaerch	Himedia , Vadhni Industrial estate Ghatkopar	MGM School of Biomedical,NM	Himedia , Vadhni Industrial estate Ghatkopar	2019-2020	365
37	Academic, Clinical training , Internship , Project work, student/ faculty exchange , Research	Pillai College of Arts , Commerce & scienc	MGM School of Biomedical,NM	Pillai College of Arts , Commerce & scienc	2019-2020	1825
38	Student training , Project work, Collaborative resaerch	ChromoXpert	MGM School of Biomedical,NM	ChromoXpert	2019-2020	365
39	Academic, Project work, student/ faculty exchange , Research and publication, development of products	SVERI college of Engineering Pandharpur	MGM School of Biomedical,NM	SVERI college of Engineering Pandharpur	2019-2020	1825
40	Academic, Internship , student/ faculty exchange , Research and publication,	Modern College of Arts, sciences, & Commerce Pune	MGM School of Biomedical,NM	Modern College of Arts, sciences, & Commerce Pune	2019-2020	1825

2020-2021

Link: https://www.mgmuhs.com/pdfs/AQAR_2020-21/Part-B/criteria_III/F-%203.7.2.pdf

Sr. No.	**Title of the Collaborative activity**	**Name of the collaborating agency with contact details**	**Name of the participants**	**Source of financial support**	**Year of collaboration**	**Duration**
1	Samples of 2009 H1N1 Influenza for investigations on RT PCR and report for the purpose of inter lab comparison	MIMER Medical College & B.S.T.R. Hospital, Dept of Microbiology, Talegaon, Pune	Dr. Sameer, Dr. Mansi, Ms. Sujata, Ms. Aafreen	MGM Medical & Hospital, Kamothe, NM	04.01.2021	1 year
2	Testing of 2009 H1N1 testing on Genexpert (cepheid) for the purpose of inter-lab comparison	SU-VISHWAS Diagnostic Lab, Nagpur	Dr. Harpriya, Dr. Sameer, Ms. Kadubai Thokal, Ms. Aafreen	MGM Medical & Hospital, Kamothe, NM	20.05.2020	1 year

3	Tertiary health care services	Primary Health Centre, Nere, Zilla Parishad, Raigad	Dr. Prasad Waingankar Dr. Mrunal Pimparkar Dr. Pradeep Sawardekar Dr. Madhavi Mankar Dr. Nisha Relwani Dr. Sunila Sanjeev Dr. Ratnaprabha Pedhambkar Dr. Ashlesha Tawade Dr. Kulkarni Noopur Mr. Kishore Raut Dr. Sailee Jadhav Dr. Radhika Kalyanshetty Dr. Rajkuwar Yerunkar Dr. Aswini Mohan Dr. Aviral Kashyap Dr. Inderjot Kaur Dr. Garg Mayur Sunil Dr. Waingankar Harsh Dr. Nevin Sabu Thomas Dr. Krishna Arcot Dr. Raushan Kumar Dr. Ramesh Mhatre Dr. Harshita Shah Dr. Vishal Vivekanand	MGM Medical & Hospital, Kamothe, NM	01.01.2021	5 years

4	Multispecialty outpatient services	Dr. Babasaheb Ambedkar Memorial Municipal Hospital, Khopoli, Raigad	Dr. Prasad Waingankar Dr. Mrunal Pimparkar Dr. Pradeep Sawardekar Dr. Madhavi Mankar Dr. Nisha Relwani Dr. Sunila Sanjeev Dr. Ratnaprabha Pedhambkar Dr. Ashlesha Tawade Dr. Kulkarni Noopur Mr. Kishore Raut Dr. Sailee Jadhav Dr. Radhika Kalyanshetty Dr. Rajkuwar Yerunkar Dr. Aswini Mohan Dr. Aviral Kashyap Dr. Inderjot Kaur Dr. Garg Mayur Sunil Dr. Waingankar Harsh Dr. Nevin Sabu Thomas Dr. Krishna Arcot Dr. Raushan Kumar Dr. Ramesh Mhatre Dr. Harshita Shah Dr. Vishal Vivekanand Jali	MGM Medical & Hospital, Kamothe, NM	01.11.2020	5 years
5	COVID-19 patients Treatment	Panvel Municipal Corporation (PMC)	All Clinical Staff (List Attached)	MGM Medical & Hospital, Kamothe, NM	28.04.2021	1 year

6	International Training Center (ATLC, PALS)	American Heart Association	Dr. Sameer Kadam Dr. Vishwas Sathe Dr. Suhasini Sonavdekar Dr. Sagar Sinha Dr. Deepika Sathe Dr. Richa Chinchkar Dr. Shweta Naik Dr. Ankita Joshi Dr. Mayank Dhir Dr. Ankit Biyani Dr. Minal Kanher Dr. Krishna Patele Dr. Pooja Agrawal Dr. Suraj Ahuja Dr Vernica Kala Dr Gayatri Jain Dr Nikita Ranjan	MGM Medical & Hospital, Kamothe, NM	24.01.2020	3 years
7	Research Project	Ambrosia Food Farm Co.	Dr. Jaishree G, Dr. Sager Sinha, Dr. Dubhashi, Dr. Sameer Kadam, Dr. Parineeta Samant, Dr. Amit Agarwal	MGM Medical & Hospital, Kamothe, NM	25.08.2020	1 year

8	Health Camp	Children of World India Trust	Dr. Vijay Kamale, Dr. Jitendra Dr. Bhaygashree, Dr. Revati, Dr. Vikram, Dr. Vikas, Dr. Sayed, Dr. Yemul, Dr, Kunal, Dr. Arunava, Dr. Akshai, Dr. Nazmuddin, Dr. Nikita, Dr. Tuhin, Dr. Dhruvi, Dr. K Nikhilesh, Dr. Avinash, Dr. Aastha, Dr. N Thivya, Dr. Kanmani, Dr. Urvee, Dr. Michelle, Dr. Priyanka (In rotation according to the schedule)	MGM Medical & Hospital, Kamothe, NM	01.12.2020	3 years
9	Integration of Extended Immune Monitoring (ExImM) and clinical parameters for early prediction of disease /progression, treatment planning and prophylaxis to improve COVID-19 prognosis	ICMR + ACTREC (TATA Hospital, Kharghar)	Dr. Shipli Sahu Dr. Navdeep, Dr. Parul, Dr. Gargi, Dr. Almas, Dr. Aparajita, Dr. Shweta	MGM Medical & Hospital, Kamothe, NM	10.09.20	2 years
10	For testing of H1N1 Influenza and SARS Cov-2 (COVID - 19)	Terna Diagnostics, Molecular Lab, Nerul	Dr. Harpriya, Dr. Sameer, Dr. Mansi	MGM Medical & Hospital, Kamothe, NM	16.09.20	1 year
11	Validate the AI Tool developed by MYB in reliably diagnosing COVID 19 cases by use of Xray images	More-Ya Biosciences Limited Liability Company (LLP), Pune	Dr. Harpriya, Dr. Sameer, Dr. Mansi	MGM Medical & Hospital, Kamothe, NM	03.08.20	5 years
12	Counseling and testing center for HIV	National AIDS control org. (NACO), Govt of India	Dr. Bai Mangesh Naik, Dr. D.H. Chawla, DR. Harpriya Kar, Dr. Bhageshree Seth, Rupali Gujar, , Sanjay Babar, Anil Dalvi ,Kalpesh Khawas	MGM Medical & Hospital, Kamothe, NM	01.10.2020	1 year

13	District Raigad - TB center	CEO, ZP Raigad, & District National Tuberculosis Elimination Programme society, Raigad	Dr. Potdar, Dr. Kulkarni, Dr. Shreeja, Dr. Sandeep, Dr. Karan	MGM Medical & Hospital, Kamothe, NM	01.04.21	3 years
14	For testing of H1N1 Influenza testing on RT PCR	Smt Kashibai Navale Medical College and General Hospital, Molecular Lab, Narhe Pune	Dr. Harpriya, Dr. Sameer, Dr. Mansi	MGM Medical & Hospital, Kamothe, NM	26.11.2020	1 year
15	To render health care to the users of Khopoli hospital & also training of medical & paramedical students, Post graduate, Residents, Interns, Nurses & other paramedical staff in community health care	Dr. Babasaheb Ambedkar Memorail Minicipal Hospital, Khopoli	Dr. Prasad Waingankar Dr. Mrunal Pimparkar Dr. Pradeep Sawardekar Dr. Madhavi Mankar Dr. Nisha Relwani Dr. Sunila Sanjeev Dr. Ratnaprabha Pedhambkar Dr. Ashlesha Tawade Dr. Kulkarni Noopur Mr. Kishore Raut Dr. Sailee Jadhav Dr. Radhika Kalyanshetty Dr. Rajkuwar Yerunkar Dr. Aswini Mohan Dr. Aviral Kashyap Dr. Inderjot Kaur Dr. Garg Mayur Sunil Dr. Waingankar Harsh Dr. Nevin Sabu Thomas Dr. Krishna Arcot Dr. Raushan Kumar Dr. Ramesh Mhatre Dr. Harshita Shah Dr. Vishal Vivekanand Jali	MGM Medical & Hospital, Kamothe, NM	01.11.2015	5 years
16	COVID-19 - Patient treatment	Navi Mumbai Municipal Corporation (NMMC)	All Clinical Staff (List Attached)	MGM Medical & Hospital, Kamothe, NM	17.04.2021	1 year
17	To give health care to Sports Men & Women as a part of traning to MGM's residents doctors of Sports Medicine	Karnala Sports Club	Dr. Pradeep S., Dr. Madhavi Mankar	MGM Medical & Hospital, Kamothe, NM	01.12.2020	1 year

18	Supply of Fresh Frozen Plasma (FFP)	Reliance Life Sciences Pvt. Ltd.	Dr. Iqbal Singh Dr. Dhote Shweta Wasudeo Dr. Udani Moni Mukesh Dr. Abhiniti Srivastava Dr. Vinita Gara Rao Dr. Satyam Sarkar Dr. Thorat Rajabhau	MGM Medical & Hospital, Kamothe, NM	01.09.2019	2 years
19	Supply of Blood & Blood product as a mother Blood bank to the Blood Stoage facility	MGM Hospital Research Centre CBD Belapur, Blood Storage centre	Dr. Iqbal Singh Dr. Dhote Shweta Wasudeo Dr. Udani Moni Mukesh Dr. Abhiniti Srivastava Dr. Vinita Gara Rao Dr. Satyam Sarkar Dr. Thorat Rajabhau	MGM Medical & Hospital, Kamothe, NM	07.10.2020	1 year
20	Blood Bank Component Facility	MGM New Bombay Hospital Vashi	Dr. Iqbal Singh Dr. Dhote Shweta Wasudeo Dr. Udani Moni Mukesh Dr. Abhiniti Srivastava Dr. Vinita Gara Rao Dr. Satyam Sarkar Dr. Thorat Rajabhau	MGM Medical & Hospital, Kamothe, NM	30.06.2021	5 years
21	COVID RTPCR Samples sent for QC	MGM New Bombay Hospital, Vashi	Dr. Harpriya, Dr. Sameer, Ms. Kadubai Thokal, Ms. Aafreen	MGM Medical & Hospital, Kamothe, NM	01.06.2021	1 year
22	Public-Private Partnership for HIV Testing	Maharashtra State Aids Control Society (MSACS)	Dr. Anahita, Dr. Urehekar, Dr. Samant, Dr. Kar, Dr. Sameer, Dr. Deepashree, Dr. Neha, Dr. Kanchan, Dr. Asha	MGM Medical & Hospital, Kamothe, NM	April, 2013	Till Date

23	HIV Viral Load & CD4CD8 Count	AIDS Health Foundation - India Cares (AHF) (Jyotics Care)	Dr. Anahita, Dr. Urehekar, Dr. Samant, Dr. Kar, Dr. Sameer, Dr. Deepashree, Dr. Neha, Dr. Kanchan, Dr. Asha	MGM Medical & Hospital, Kamothe, NM	29.04.2017	5 years
24	Public-Private Partnership for ART (PLHA)	ART Center	Dr. Anahita, Dr. Urehekar, Dr. Samant, Dr. Kar, Dr. Sameer, Dr. Deepashree, Dr. Neha, Dr. Kanchan, Dr. Asha	MGM Medical & Hospital, Kamothe, NM	01.12.2018	3 years
25	COVID RTPCR Samples	Haj & Umrah Medical Service Providers	Dr. Anahita, Dr. Urehekar, Dr. Samant, Dr. Kar, Dr. Sameer, Dr. Deepashree, Dr. Neha, Dr. Kanchan, Dr. Asha	MGM Medical & Hospital, Kamothe, NM	25.08.21	Till Date
26	Fellowship of students	Apollo Fertility, Apollo Specialty Hospital	Dr. Rajiv Sharma, Dr. Radhika Puntambekar	MGM Medical & Hospital, Kamothe, NM	2020	1 year
27	Health Care related Services	Star Health and Allied Insurance Company Ltd.	Hospital Staff	MGM Medical & Hospital, Kamothe, NM	02.09.2019	Till Termination
28	Medical and surgical expertise, Infrastructure facilities for cleft patients	Inga Health Foundation	Hospital Staff	MGM Medical & Hospital, Kamothe, NM	01.05.2021	3 years
29	Academic, Clinical training , Internship , Project work, student/ faculty exchange , Research	SRCC Centre of Child Development	Dept of Optometry MGM SBS (Rohit Gupta)	Nil	30.10.2021	1 year
30	Standarddisation of microchondrial depletions using qPCR and validating it on control and patients	Bai Jerbai Wadia Hospital for children Parel	MGM SBS (Dr Anjali Sabnis and Rose Jimson)	Nil	28.04.2021	Till Date
31	Standardization of Mitochondrial DNA deletion using long range PCR and validating it on control and patients	Bai Jerbai Wadia Hospital for children Parel	MGM SBS (Dr Anjali Sabnis and Pradnya Shahir	Nil	28.04.2021	Till Date
32	Study of rearrangement pattern of cMYC gene in high grade lymphomas	SRL Diagnostics Goregaon	MGM SBS (Dr Anjali Sabnis and Pooja Waghela	Nil	31.05.2021	Till Date

33	Biomarker testing for detection of spectrum of variants of ALK gene by Fluorescence in situ hybridization (FISH) in non-small scale lung cancer	SRL Diagnostics Goregaon	MGM SBS (Dr Anjali Sabnis and Tejaswini Mahajan	Nil	31.05.2021	Till Date
34	Project Work	Logical Life Sciences Pvt Ltd Pune	MGM SBS (Dr Mansee Thakur and Biotech students	Nil	11.05.2021	Till Date
35	Provide Diagnotics service to Patients treatment and other services including Microbiological services	MGM New Bombay Hospital, Vashi NM	MGM Medical College & Hospitals Central Laboratory MGM campus Kamothe Navi Mumbai (Dr Mansee Thakur, Dr Samir Pachpute)	Nil	01.04.2021	year
36	Provide Diagnotics service to Patients treatment and other services including Microbiological services	The Panvel Mahanagarpalika	MGM Medical College & Hospitals Central Laboratory MGM campus Kamothe Navi Mumbai (Dr Mansee Thakur, Dr Samir Pachpute)	Nil	24.04.2021	Till Date
37	Academic, Clinical training , Internship , Project work, student/ faculty exchange , Research	Lilac Insights Pvt. Ltd. Mahape Navi Mumbai	MGM SBS Kamothe	Nil	29.08.2020	Till Date
38	Provide Diagnotics service to Patients treatment and other services including Microbiological services	UDC Satellite Laboratory Pvt Ltd	MGM Medical College & Hospitals Central Laboratory MGM campus Kamothe Navi Mumbai (Dr Mansee Thakur, Dr Samir Pachpute)	Nil	17.07.2020	1 Year
39	Academic, Clinical training , Internship , Project work, student/ faculty exchange , Research	Progressive Education Societys Modern College of Art , Science & Commerce , Ganeshkhind Pune	Dept of Med Biotechnology MGM SBS (Dr Mansee Thakur)	Nil	07.10.2019	5 Years
40	Knowladge patner Inccubation and Establishing policy	Samruddhi TBI Foundation Sangli	MGM Institute of Health Sciences	Nil	09.01.2019	Till Date
41	Innovation & Inncubation manegemet plateform to establishment of technology commercialization	Jugaadrunda Innovations LLP Pune	MGM Institute of Health Sciences	Nil	5.12.2018	Till date
42	Academic, Clinical training , Internship , Project work, student/ faculty exchange , Research	Nirmala Niketan college of Home Sciences , New Marine Lines mumbai	MGM SBS (Dr Mansee Thakur)	Nil	04.04.2019	5 years

43	Academic, Clinical training , Internship , Project work, student/ faculty exchange , Research	Apollo fertility centre	MGM SBS (Dr Mansee Thakur,Dr Mini)	Nil	01.08.2019	3 years
44	Academic, Clinical training , Internship , Project work, student/ faculty exchange , Research	SVERI college of Engineering Pandharpur	MGM School of Biomedical Sciences (Dr Mansee Thakur)	Nil	2018	Till Date
45	Paper publication titled Agarwal BM, van Deursen R, Mullerpatan RP. Electromyographic evaluation of spine and lower extremity muscles during repeated and sustained bodyweight deep-squat. Trends in Sport Sciences, 2021, 28(1): 19-27.	International Society of Biomechanics	Dr.Rajani Mullerpatan, Dr.Bela Agarwal	Nil	2013-2021	8years
46	A Chapter in the book " Basic Biomechanics of the Musculosketal system" titled " Biomechanics of Indigenous Postures".	World Spine Care	Dr.Rajani Mullerpatan, Dr.Bela Agarwal, Dr.Triveni Shetty (PT), Dr.Anisha Gulati(PT), Dr,Suchita Rao(PT), Dr.juhi Bharnuke(PT)	Nil	2013-2021	8 years
	Fellowship in Clinical Biomechanics was introduced at MGM School of Physiotherapy, Navi Mumbai.	World Spine Care				
	Webinar on "Screening for Serious Pathology of Cervical Spine was organised by MGM School of Physiotherapy on 12th April 2021" Dr. Raghuprasad Varma & Dr. Chris Mercer contributed their clinical experience on international framework for red flags for potential serious spinal pathology and discussed thresholds for onward referral for suspected serious pathology of cervical spine	World Spine Care				
	Haldeman S, Nordin M, Tavares P, Mullerpatan R, Kopansky-Giles D, Setlhare V, Chou R, Hurwitz E, Treanor C, Hartvigsen J, Schneider M. Distance management of spinal disorders during the COVID-19 pandemic and beyond: Evidence-based patient and clinician guides from the global spine care initiative. JMIR public health and surveillance. 2021 Feb 17;7(2): e25484.	World Spine Care				
	Agarwal BM, van Deursen R, Mullerpatan RP. Electromyographic evaluation of spine and lower extremity muscles during repeated and sustained bodyweight deep-squat. Trends in Sport Sciences, 2021, 28(1): 19-27	World Spine Care				
47	Clinical testing of plantar tissue stiffness device ongoing- 30 participants tested till date,	IIT Bombay	Dr.Rajani Mullerpatan, Dr.Bela Agarwal, Dr.Triveni Shetty (PT), Dr,Suchita Rao(PT), Mr.Gavin Fernandes	IIT Bombay	2015-2021	6 years
	Students participated in eMEDHA 2021, and 2 students were awarded in the section Rehabilitation device Award, for demonstrating self-less team work, initiative, creativity and positive energy throughout their participation in medical device hackathon	IIT Bombay				
48	Clinical Trial	cliniinfinity Clinical Research Solution LLP	Dr. Anand Nikalje-02. Dr. Sayed Umar Quadri-03 Dr. Ashish Deshmukh	cliniinfinity Clinical Research Solution LLP	12.12.2020	10 years

49	Clinical Trial	Destination Pharmagens Healthcare Solution	Nill	Destination Pharmagens Healthcare Solution	01.12.2020	10 years
50	Clinical Trial	Aurangabad Health Care & Research LLP	Dr. Anand Nikalje	Aurangabad Health Care & Research LLP	27.01.2021	10 years
51	Clinical Trial	Metta Clinical Research Pvt.Ltd.	Nill	Metta Clinical Research Pvt.Ltd.	10.02.2021	10 years
52	Clinical Trial	Skyline CRS INDIA Pvt.Ltd	Nill	Skyline CRS INDIA Pvt.Ltd	23.12.2021	10 years
53	Clinical Trial	Biosphere Clinical Research Pvt. Ltd	Nill	Biosphere Clinical Research Pvt. Ltd	01.01.2020	10 years
54	Clinical Trial	Grapecity Research Solutions LLP	01. Dr. Anand Nikalje 02. Dr. Sayed Umar Quadri 03. Dr. Ashish Deshmukh. 04.Dr.Mohammad hasseeb. 05.Dr.Deepak Bhosle	Grapecity Research Solutions LLP	14.06.2019	5 years
55	Clinical Trial	Naralagiri Mogili Chandramma	Nill	Naralagiri Mogili Chandramma	01.01.2020	10 years
56	Clinical Trial	Q RED Clinical Research Services	Dr. Rajendra Bohra	Q RED Clinical Research Services	01.12.2019	10 years
57	Clinical Trial	JSS Medical Research India Pvt Ltd.	Dr. Anand Nikalje	JSS Medical Research India Pvt Ltd.	28.12.2020	Till Date
58	Clinical Trial	CliniExperts Research Services Private Limited	Dr. Ashihs Deshmukh	CliniExperts Research Services Private Limited	30.12.2020	Till Date
59	Clinical Trial	Biosphere Clinical Research Pvt. Ltd	Dr. Kelkar Vasanti Prabhakar	Biosphere Clinical Research Pvt. Ltd	18.02.2021	Till Date
60	Clinical Trial	HETERO LABS LIMITED	Dr. Umar Quadri	HETERO LABS LIMITED	18.05.2021	Till Date
61	Clinical Trial	HETERO Biopharma Limited	Dr. Anand Nikalje	HETERO Biopharma Limited	24.05.2021	Till Date
62	Clinical Trial	Tergene Biotech Pvt. Ltd	Dr. Mohammed Haseeb	Tergene Biotech Pvt. Ltd	06.04.2021	Till Date
63	Clinical Trial	Reliance Life Sciences Pvt. Ltd.	Dr. Anand Nikalje	Reliance Life Sciences Pvt. Ltd.	03.11.2021	Till Date
64	Clinical Trial	Novalead Pharma	Dr. Deepak Bhosle	Novalead Pharma	26.12.2019	Till Date
65	Clinical Trial	Serum lnstitute of lndia Pvt.Ltd	Dr. Deepak Tyade	Serum lnstitute of lndia Pvt.Ltd	04.09.2020	Till Date
66	Clinical Trial	DIGNOSEARCH	Dr. Deepak Tyade	DIGNOSEARCH	02.05.2020	Till Date
67	Clinical Trial	Cadila Health Care Limited	Dr. Mahendra Suryawanshi	Cadila Health Care Limited	09.11.2021	Till Date
68	Clinical Trial	Cadila Health Care Limited	Dr. Asish Deshmukh	Cadila Health Care Limited	15.11.2021	Till Date
69	Clinical Trial	JSS Medical Research Asia Pacific (Optimus Pharma Pvt. Ltd,)	Dr. Syed Umar Quadri	Optimus Pharma Pvt. Ltd.	21.06.2021	Till Date
70	Clinical Trial	Meril Life Science Pvt. Ltd.	Dr. Shivaji Pole	Meril Life Science Pvt. Ltd.	21.02.2020	Till Date
71	Clinical Trial	Abiogenesis	Dr. Syed Umar Quadri	Abiogenesis	12.02.2021	Till Date
72	Clinical Trial	SIRO Clinpharm Pvt. Ltd.	Dr. Shivaji Pole	SIRO Clinpharm Pvt. Ltd.	28.07.2020	Till Date

73	Clinical Trial	Covance India Pharmaceutical Pvt. Ltd.	Dr. Prashant Udgire	Covance India Pharmaceutical Pvt. Ltd.	15.11.2021	Till Date
2021-2022						
	Link:					
Sr. No.	**Title of the Collaborative activity**	**Name of the collaborating agency with contact details**	**Name of the participants**	**Source of financial support**	**Year of collaboration**	**Duration**
1	Supply of Fresh Frozen Plasma (FFP)	Reliance Life Sciences Pvt. Ltd. (Ms Bindu Nair - 9967607037)	Dr. Iqbal Singh Dr. Dhote Shweta Wasudeo Dr. Udani Moni Mukesh Dr. Abhiniti Srivastava Dr. Vinita Gara Rao Dr. Satyam Sarkar Dr. Thorat Rajabhau	MGM Medical & Hospital, Kamothe, NM	2019	2 years
2	ICTC Program	MSACS (022-24115619)	8- Faculty & 10 Students	MGM Medical & Hospital, Kamothe, NM	2013	2025
3	Public-Private Partnership for HIV Testing	Maharashtra State Aids Control Society (MSACS) MSACS (022-24115619)	Dr. Anahita, Dr. Urehekar, Dr. Samant, Dr. Kar, Dr. Sameer, Dr. Deepashree, Dr. Neha, Dr. Kanchan, Dr. Asha	MGM Medical & Hospital, Kamothe, NM	2013	Till Date
4	HIV Viral Load & CD4CD8 Count	AIDS Health Foundation - India Cares (AHF) (Jyotics Care) (022-25474911)	Dr. Anahita, Dr. Urehekar, Dr. Samant, Dr. Kar, Dr. Sameer, Dr. Deepashree, Dr. Neha, Dr. Kanchan, Dr. Asha	MGM Medical & Hospital, Kamothe, NM	2017	5 years
5	For testing of H1N1 Influenza testing on RT PCR	Smt Kashibai Navale Medical College and General Hospital, Molecular Lab, Narhe Pune (020-67537215)	Dr. Harpriya, Dr. Sameer, Dr. Mansee	MGM Medical & Hospital, Kamothe, NM	2021	1 year
6	Student Intership Program	Pfizer Limited a Public Limited Company (022-66932000)	Dr. Ashiwin Balasubramanian	MGM Medical & Hospital, Kamothe, NM	2022	2 Months

7	Student Intership Program	AstraZeneca Pharma India Pvt Ltd. Karnataka (Mr. Gagandeep Momi - 9205074255)	Dr. Harshit Zavier	MGM Medical & Hospital, Kamothe, NM	2022	2 Months
8	Conducts worskhop of train docters in the field of neuro-modulation , Cold storage facility and storage at fresh of cadaverat 20-degree celsius	Internatonal Neuromodulation Society, Jaslok Hospital and Research Centre, Mumbai (Dr. Priti Doshi: 98200 28686)	Dr. Anajali Sabnis Dr. Prakash Mane	MGM Medical & Hospital, Kamothe, NM	2021	1 year
9	Hospital Services to patients care	SEAL (Jinnama: 810868029 Rubbin: 9594903121)	Hospital Staff	MGM Medical & Hospital, Kamothe, NM	2022	02.05.2022 to 01.05.2025
10	Health Camp	Children of World India Trust Betty Mathai 9167209764	Dr. Vijay Kamale, Dr. Jitendra Dr. Bhaygashree, Dr. Revati, Dr. Vikram, Dr. Vikas, Dr. Sayed, Dr. Yemul, Dr, Kunal, Dr. Arunava, Dr. Akshai, Dr. Nazmuddin, Dr. Nikita, Dr. Tuhin, Dr. Dhruvi, Dr. K Nikhilesh, Dr. Avinash, Dr. Aastha, Dr. N Thivya, Dr.	MGM Medical & Hospital, Kamothe, NM	2020	3 years

11	Multispecialty outpatient services	Dr. Babasaheb Ambedkar Memorial Municipal Hospital, Khopoli, Raigad S.S. Thakur: 9422383539	Dr. Prasad Waingankar Dr. Mrunal Pimparkar Dr. Pradeep Sawardekar Dr. Madhavi Mankar Dr. Nisha Relwani Dr. Sunila Sanjeev Dr. Ratnaprabha Pedhambkar Dr. Ashlesha Tawade Dr. Kulkarni Noopur Mr. Kishore Raut Dr. Sailee Jadhav Dr. Radhika Kalyanshetty Dr. Rajkuwar Yerunkar Dr. Aswini Mohan Dr. Aviral Kashyap Dr. Inderjot Kaur Dr. Garg Mayur Sunil Dr. Waingankar Harsh Dr. Nevin Sabu Thomas Dr. Krishna Arcot Dr. Raushan Kumar Dr. Ramesh Mhatre Dr. Harshita Shah Dr. Vishal Vivekanand	MGM Medical & Hospital, Kamothe, NM	2020	5 years

12	International Training Center (ATLC, PALS)	American Heart Association (Mr. Srimon:7034506497)	Dr. Sameer Kadam Dr. Vishwas Sathe Dr. Suhasini Sonavdekar Dr. Sagar Sinha Dr. Deepika Sathe Dr. Richa Chinchkar Dr. Shweta Naik Dr. Ankita Joshi Dr. Mayank Dhir Dr. Ankit Biyani Dr. Minal Kanher Dr. Krishna Patele Dr. Pooja Agrawal Dr. Suraj Ahuja Dr Vernica Kala Dr Gayatri Jain Dr Nikita Ranjan	MGM Medical & Hospital, Kamothe, NM	2020	3 years
13	Integration of Extended Immune Monitoring (ExImM) and clinical parameters for early prediction of disease /progression, treatment planning and prophylaxis to improve COVID-19 prognosis	ICMR + ACTREC (TATA Hospital, Kharghar) (022-27405362)	Dr. Shipli Sahu Dr. Navdeep, Dr. Parul, Dr. Gargi, Dr. Almas, Dr. Aparajita, Dr. Shweta	MGM Medical & Hospital, Kamothe, NM	2020	2 years
14	Validate the AI Tool developed by MYB in reliably diagnosing COVID 19 cases by use of Xray images	More-Ya Biosciences Limited Liability Company (LLP), Pune (990765555)	Dr. Harpriya, Dr. Sameer, Dr. Mansi	MGM Medical & Hospital, Kamothe, NM	2020	5 years
15	District Raigad - TB center	CEO, ZP Raigad, & District National Tuberculosis Elimination Programme society, Raigad Vrushali(9822631881)	Dr. Potdar, Dr. Kulkarni, Dr. Shreeja, Dr. Sandeep, Dr. Karan	MGM Medical & Hospital, Kamothe, NM	2021	3 years
16	To give health care to Sports Men & Women as a part of traning to MGM's residents doctors of Sports Medicine	Karnala Sports Club (+91 90228 83361)	Dr. Pradeep S., Dr. Madhavi Mankar	MGM Medical & Hospital, Kamothe, NM	2020	1 year
17	Public-Private Partnership for ART (PLHA)	ART Center (022-24113097)	Dr. Anahita, Dr. Urehekar, Dr. Samant, Dr. Kar, Dr. Sameer, Dr. Deepashree, Dr. Neha, Dr. Kanchan, Dr. Asha	MGM Medical & Hospital, Kamothe, NM	2018	3 years
18	Health Care related Services	Health India TPA Services Pvt Ltd. (022 40881000)	Hospital Staff	MGM Medical & Hospital, Kamothe, NM	2019	Till Termination

19	Medical and surgical expertise, Infrastructure facilities for cleft patients	Star Health and Allied Insurance Company Ltd. (022 45203531)	Hospital Staff	MGM Medical & Hospital, Kamothe, NM	01.05.2021	3 years
20	Academic, Clinical training , Internship , Project work, student/ faculty exchange , Research	Heartfulness Education Trust, North Block N-34, Kanha Shanti Vanam, Mallapur, Telangana 509325, Dr Nivetita Shreyans :9821056529	Dr Mansee Thakur MGM SBS Navi Mumbai	NA	2021	1 yr
21	Academic, Clinical training , Internship , Project work, student/ faculty exchange , Research	SRCC Centre of Child Development 1A Keshavrao khadye marg , Haji Ali, Haji Ali Govt colony Mahalakshmi Mumbai, 400034, Dr Himika Gupta: 9742771110	Dept of Optometry MGM SBS (Rohit Gupta)	NA	2021	Till date
22	Standarddisation of microchondrial depletions using qPCR and validating it on control and patients	Bai Jerbai Wadia Hospital for children , Acharya Dhonde Marg ,Parel Mumbai 400012 , Dr. Lalit : 7506176166	MGM SBS (Dr Anjali Sabnis and Rose Jimson)	NA	2021	Till Date
23	Standardization of Mitochondrial DNA deletion using long range PCR and validating it on control and patients	Bai Jerbai Wadia Hospital for children , Acharya Dhonde Marg ,Parel Mumbai 400012 , Dr Lalit : 7506176166	MGM SBS (Dr Anjali Sabnis and Pradnya Shahir	NA	2021	Till Date
24	Study of rearrangement pattern of cMYC gene in high grade lymphomas	SRL Diagnostics ,Prime Square, 1-5 floors, Near Gaiwadi Industrial Estate, S.V.Road, Goregaon (W), Mumbai-400062, Maharashtra, India. Mumbai , Dr Anurita : 9820853368	MGM SBS (Dr Anjali Sabnis and Pooja Waghela	NA	2021	Till Date
25	Biomarker testing for detection of spectrum of variants of ALK gene by Fluorescence in situ hybridization (FISH) in non-small scale lung cancer	SRL Diagnostics ,Prime Square, 1-5 floors, Near Gaiwadi Industrial Estate, S.V.Road, Goregaon (W), Mumbai-400062, Maharashtra, India. Mumbai , Dr Anurita : 9820853368	MGM SBS (Dr Anjali Sabnis and Tejaswini Mahajan	NA	2021	Till Date
26	Project Work	Logical Life Sciences Pvt Ltd, Pune Office NO 1, First Floor, Shilam Heights Plot NO 36/1/1, Vadgaon Khurd, Pune, Maharashtra 411041 Dr Nishant :8698684792	MGM SBS (Dr Mansee Thakur and Biotech students	NA	2021	Till Date
27	Academic, Clinical training , Internship , Project work, student/ faculty exchange , Research	Lilac Insights Pvt. Ltd. Office no 301 & 302 sec 1 , Building no A-1 , Millennium Business park , Mahape Navi Mumbai 400710 , Dr Vidya :9820074155	MGM SBS Kamothe	NA	2020	Till Date

28	Academic, Clinical training , Internship , Project work, student/ faculty exchange , Research	Progressive Education Societys Modern College of Art , Science & Commerce , Ganeshkhind road, Pune Dr Vinay Kumar: 9767839708	Dept of Med Biotechnology MGM SBS (Dr Mansee Thakur)	NA	2019	Till Date
29	Knowladge patner Inccubation and Establishing policy	Samruddhi TBI Foundation, Near, Railway Station, Plot No. A1, Samruddhi IT Park, Sangli - Miraj Rd, Vishrambag, Sangli, Maharashtra Dr Mahesh Patil : 9762171471	MGM Institute of Health Sciences	NA	2019	Till Date
30	Innovation & Inncubation manegemet plateform to establishment of technology commercialization	Jugaadfunda Innovations LLP Pune , A-201 Mitrangan Baner Road Pune Dr Mahesh Patil : 9762171471	MGM Institute of Health Sciences	NA	2018	Till date
31	Academic, Clinical training , Internship , Project work, student/ faculty exchange , Research	Nirmala Niketan college of Home Sciences , 49 New Marine Lines Mumbai, 400020, Prof Anuradha Bakshi : 02222076503	MGM SBS (Dr Mansee Thakur)	NA	2019	Till Date
32	Academic, Clinical training , Internship , Project work, student/ faculty exchange , Research	Apollo fertility centre, Plot -13, Parsik Hill Road, Off Uran Road, Sector - 23, Mumbai, Maharashtra 400023 ·Dr Jay Shah : 7600030178	MGM SBS (Dr Mansee Thakur,Dr Mini)	NA	2019	Till Date
33	Academic, Clinical training , Internship , Project work, student/ faculty exchange , Research	Shri Vithal Education and Research Institute's (SVERI)College of Engineering , Gopalpur Ranjani Road Pandharpur , 413304 , Dr Prashant Pawar :9765394205	MGM School of Biomedical Sciences (Dr Mansee Thakur)	NA	2018	Till Date
34	Clinical testing of plantar tissue stiffness device ongoing- 30 participants tested till date, Students participated in eMEDHA 2021, and 2 students were awarded in the section Rehabilitation device Award, for demonstrating self-less team work, initiative, creativity and positive energy throughout their participation in medical device hackathon	IIT Bombay & MGM Instituite of Health Sciences, Navi Mumbai, +91 (22) 2572 2545	Dr.Rajani Mullerpatan, Dr.Bela Agarwal, Dr.Triveni Shetty (PT), Dr,Suchita Rao(PT), Mr.Gavin Fernandes	IIT Bombay	2015	6 years
35	Paper publication titled Agarwal BM, van Deursen R, Mullerpatan RP. Electromyographic evaluation of spine and lower extremity muscles during repeated and sustained bodyweight deep-squat. Trends in Sport Sciences, 2021, 28(1): 19-27.	MGM – International Society of Biomechanics & MGM Instituite of Health Sciences, Navi Mumbai. webmaster@isbweb.org	Dr.Rajani Mullerpatan, Dr.Bela Agarwal	NA	2013	8years

36	A Chapter in the book " Basic Biomechanics of the Musculosketal system" titled " Biomechanics of Indigenous Postures".	MGM-World Spine Care & MGM Instituite of Health Sciences, Navi Mumbai, info@worldspinecare.org	Dr.Rajani Mullerpatan, Dr.Bela Agarwal, Dr.Triveni Shetty (PT), Dr.Anisha Gulati(PT), Dr,Suchita Rao(PT), Dr.juhi Bharnuke(PT)	NA	2013	8 years
	Fellowship in Clinical Biomechanics was introduced at MGM School of Physiotherapy, Navi Mumbai.					
	Webinar on "Screening for Serious Pathology of Cervical Spine was organised by MGM School of Physiotherapy on 12th April 2021" Dr. Raghuprasad Varma & Dr. Chris Mercer contributed their clinical experience on international framework for red flags for potential serious spinal pathology and discussed thresholds for onward referral for suspected serious pathology of cervical spine					
	Haldeman S, Nordin M, Tavares P, Mullerpatan R, Kopansky-Giles D, Setlhare V, Chou R, Hurwitz E, Treanor C, Hartvigsen J, Schneider M. Distance management of spinal disorders during the COVID-19 pandemic and beyond: Evidence-based patient and clinician guides from the global spine care initiative. JMIR public health and surveillance. 2021 Feb 17;7(2): e25484.					
	Agarwal BM, van Deursen R, Mullerpatan RP. Electromyographic evaluation of spine and lower extremity muscles during repeated and sustained bodyweight deep-squat. Trends in Sport Sciences, 2021, 28(1): 19-27					
37	Online-Meetings were conducted for discussing a collaborative project in covid patients for funding 2021.	Kaivalyadham Yoga Institute & MGM Instituite of Health Sciences, Navi Mumbai, info@kdham.com	Dr.Rajani Mullerpatan, Dr.Bela Agarwal, Dr.Triveni Shetty (PT), Dr.Anisha Gulati(PT), Dr,Suchita Rao(PT), Dr.juhi Bharnuke(PT)		2021	Till date
	Through this MOU we intend to work together to participate in collaborative patient care, student training, research projects and other activities like conducting workshops, awareness camps etc and also to jointly evaluate and interpret the final outcome of combining respective expertise and resources .					
	Collaborative project proposal was submitted to AYUSH for funding titled " Biomechanical and Biochemical exploration of yoga in low back pain"					
38	Visit of two faculty member from SVERI Institute for discussion regarding development of a device to measure pediatric hand muscle strength and a device to measure respiratory muscle strength.	Shri Vithal Education and Research Institute(SVERI) & MGM School of Physiotherapy ,MGM Instituite of Health Sciences, Navi Mumbai, coe@sveri.ac.in/principal@coe.sveri.ac.in	Dr.Rajani Mullerpatan, Dr.Bela Agarwal	NA		09.02.2022

39	Collaboratively create a hollistic approach and ecosystem to support academic , research and innovation activities.	MGM- Mahatma Education Society's Pillai College of Engineering , pce@mes.ac.in	Dr.Rajani Mullerpatan, Dr.Bela Agarwal	NA	2022	09.05.2022
40	International Conference	Association for clinical neurology and Mental health ACNM	Farrukh Ali Sonal Biyani,Elham Chogle, siddhi dalvi ,gauravi desale, Vaishnavi Deshpande, Vishakha Gaikwad Kshitija,GhadgeTaymeena Ghanchi ,Shweta Ghodke, Rohan HulawalePranal KulkarniSaurabh Pravin Mahajan Parinita Mhatre,Mansi RathiIshwa Nathwani,Kshitija Ghadge, Cicely Rodrigues, Ali farrukh, Apurva Vaidya Shruti Soni ,Taymeena Ghanchi, Shweta Thorat,Monika Thombale,Parinita Mhatre, Shweta, Shweta Ghodke, Ketaki Ravindra Naik,Ishwa Nathwani,Mansi Rathi,Cicely Rodrigues,Amruta Shelke,Sakshi	SELF	2022	26,27-02-2022 to till date
41	Student Exchange	Sports Auhority Of India and MGM School Of Physiotherapy (09821085005)	(Dr. Ashwin Kshirsagar -Faculty), Ms. Samkisha Shedge, Shantanu Ahire, Pawan Solank	SELF	2021	09-10-21 & 09-10-2024

42	Student Exchange	Samagra Shikshan Abhiyan Aurangabad Muncipal Corporation Aurangabad and Saksham Sambhaji Nagar	Dr.Pallavi Palaskar(Faculty) Sakshi Shah, Deepti Shinde, Shweta Thorat, Ali Farrukh, Sonal Biyani, Elham Chogle, Tahmeen Ghanchi, Jeet Kanthariya, Monika Thombale, Apurva Vaidya, Ankita Deshmukh, Payal Padole, Pooja Jadhav, Sonali Asolkar, Pooja Chungdade, Riya Lahoti, Ankita Sahani, Bhagyashri Lahoti, Aleen Siddique, Anam Shaikh, Laxmi Pillai, Ashlesha Vaidya, Akash Tandale (23 Students)	SELF	2022	11-07-2022 to till date
43	Student Exchange	Sports Auhority of India and MGM School of Physiotherapy (09821085005)	(Dr. Ashwin Kshirsagar -Faculty) Mr. Rohit Bhavanthankar	SELF	2021	20.06.2018 & 1-7-2022
44	Student Exchange	Sports Auhority of India and MGM School Of Physiotherapy (09821085005)	(Dr. Ashwin Kshirsagar -Faculty) MS. Kharde Ekta	SELF	2021	19.07.2020 & 31-8-2022
45	Health Care related Services	Primary Health Care Adul and MGM School of Physiotherapy	Health Care Realted Service	MGM School of Physiotherapy, Aurangbad	2018	Till Date
46	Gragauates post graduates will attend clinical trainning at sport authority of Inida , Aurangabad	Sports Auhority of India and MGM School Of Physiotherapy (09821085005)	Sutdent Clinical Training	MGM School of Physiotherapy, Aurangbad	2021	till date

47	Student Exchange	Primary Health Care, warudkazi and MGM School of Physiotherapy (0240-2331572)	Dr. Snehal Thakur **(Faculty),** Vedeeka Goje, Trivendi Gosavi, Sakshi Shah, Deepti Shinde, Shweta Thorat, Ali Farrukh, Sonal Biyani, Elham Chogle, Tahmeen Ghanchi, Jeet Kanthariya, Monika Thombale, Apurva Vaidya, Ankita Deshmukh, Payal Padole, Pooja Jadhav, Sonali Asolkar, Pooja Chungdade, Riya Lahoti, Ankita Sahani, Bhagyashri Lahoti, Aleen Siddique, Anam Shaikh, Laxmi Pillai, Ashlesha Vaidya, Akash Tandale (25 Students)	SELF	2021	5-02-2021- To 05-02-2023
48	School Health Checkup Camp	MGM Gandhi Mission Sanskar Vidyalay Valung, Aurangabad	Dr. Nizzam Pathan Dr. Kashita Sharma Dr. Ananaya Anand Dr. Krishika Zha Dr. Saumya Gupta Dr. Ashiwini Kale Dr. Anuj Dixit Dr. Tejas Devtale Dr. Vishal Pahune	MGM Medical College, Aurangbad	2022	1 Year
49	School Health Checkup Camp	MGM Gandhi Mission Sanskar Vidyalay . Valung, Aurangabad	Dr. Nizzam Pathan Dr. Kashita Sharma Dr. Ananaya Anand Dr. Krishika Zha Dr. Saumya Gupta Dr. Ashiwini Kale Dr. Anuj Dixit Dr. Tejas Devtale Dr. Vishal Pahune	MGM Medical College, Aurangbad	2022	1 Year

50	School Health Checkup Camp	Royal Oaks World School (02402653779/8)	Dr. Vishal Pahune Dr. Shivani Patil Dr. Anamika Roy Dr. Disha Maske Dr. Pallavi Bharati Dr. Nawed Qureshi Dr. Mitali Bimby Dr. Sania Shaikh Dr. Ananya Anand Dr. Nikhil Dabale Mr. Sevalikar	MGM Medical College, Aurangbad	2022	1 Year
51	School Health Checkup Camp	First Step's School , Aurangabad (0240-2473375)	Dr. Rajesh Dase	MGM Medical College, Aurangbad	2022	
52	Sensitization workshop on Acrediation	Government Medical College and Hospital Aurangabad (0240-2402412)	Dr. Pravin Surywanshi	MGM Medical College, Aurangbad	2022	1 Year
53	Clinical Trial	Aurangabad Health Care & Research LLP (ahrllp20@gmail.com)	Dr. Anand Nikalje	Aurangabad Health Care & Research LLP	2021	10 years
54	Clinical Trial	Biosphere Clinical Research Pvt. Ltd(0240-6601423, 0240-6601174, Emal: pharmacology@mgmmcha.ore	Dr. Kelkar Vasanti Prabhakar	Biosphere Clinical Research Pvt. Ltd	2020	10 years
55	Clinical Trial	Canvass clinical Research Services Pvt Ltd. (Email. Id : info@ccrsindia .com 91-8208448630)	Dr. Deepak Bhosle	Canvass clinical Research Services Pvt Ltd.	2022	10 years
56	Clinical Trial	Destination Pharmagens Healthcare Solution (info@dphindia.co , 9870965482)	Dr. Deepak Bhosle	Destination Pharmagens Healthcare Solution	2020	10 years
57	Clinical Trial	Grapecity Research Solutions LLP(Sushil Choudhary	Dr. Deepak Bhosle	Grapecity Research Solutions LLP	2019	5 years
58	Clinical Trial	Med Tricare clinical research solution	Dr. Deepak Bhosle	Med Tricare clinical research solution	2022	10 years
59	Clinical Trial	Meticulous Healthcare and Research Services LLP (meticulous.smo@gmail.com,9766885171) Mr. Shaikh Yahiya Ali N	Dr. Deepak Bhosle	Meticulous Healthcare and Research Services LLP	2022	10 years
60	Clinical Trial	cliniinfinity Clinical Research Solution LLP(Email. ID cliniinfinity @gmail.com , 917276363685,7020783072)	Dr. Anand Nikalje- Dr. Sayed Umar Quadri- Dr. Ashish Deshmukh	cliniinfinity Clinical Research Solution LLP	2020	10 years
61	Clinical Trial	Metta Clinical Research Pvt.Ltd.(info@mettaclinical.com, 09545526358,9822222459)	Dr. Deepak Bhosle	Metta Clinical Research Pvt.Ltd.	2021	10 years
62	Clinical Trial	Oxygen Clinical Research Services (9284417019,	Dr. Deepak Bhosle	Oxygen Clinical Research Services	2022	10 years

63	Clinical Trial	Naralagiri Mogili Chandramma	Dr. Deepak Bhosle	Naralagiri Mogili Chandramma	2020	10 years
64	Clinical Trial	Q RED Clinical Research Services(9l 9665094458 dadhe.pratik@gmail.com)	Dr. Deepak Bhosle	Q RED Clinical Research Services	2019	10 years
65	Clinical Trial	Doclin Clinical Research Services(maruti.patil171@gmail.com, 9591358733	Dr. Deepak Bhosle	Doclin Clinical Research Services	2020	10 years
66	Clinical Trial	Skyline CRS INDIA Pvt.Ltd (E-mail: info@skylinecrsindia.com	Nill	Skyline CRS INDIA Pvt.Ltd	2021	10 years
67	Clinical Trial	Ardent Clinical Research PVT LTD.	Dr. Syed Umar Quadri	Aboigenesis	2020	5 year
68	Clinical Trial	Serum Institute of India Pvt. Ltd	Dr. Tayade Deepak Narayan,	Serum Institute of India Pvt. Ltd	2020	10 years
69	Clinical Trial	Grapecity Research Solution LLP.	Dr. Ashish Deshmukh	Reliance	2021	1 Years
70	Clinical Trial	Grapecity Research Solution LLP.	Dr. Anand Nikaje	Hetero	2021	2Years
71	Clinical Trial	Grapecity Research Solution LLP.	Dr. Anand Nikaje	Glenmark	2021	1 Years
72	Clinical Trial	George Clinical India Private.Ltd.	Dr.Sudhir Kulkarni	George Clinical India Private.Ltd.	2022	Till date
73	Clinical Trial	AstraZeneca	Dr. Prashant Udigre	AstraZeneca	2022	Till date
74	Clinical Trial	Glenmark Pharmaceuticals Ltd	Dr. Hafiz Deshmukh	Glenmark Pharmaceuticals Ltd	2022	Till date
75	Clinical Trial	Parexel International clinical Research Private Limited	Dr. Hafiz Deshmukh	Cipla Ltd	2022	Till date
76	Clinical Trial	Civil Hospital, Chikhalthana, RH Khultabad, PHC Ellora, PHC Daulatabad	70 students, 5 teachers	Civil Hospital, Chikhalthana, RH Khultabad, PHC Ellora, PHC Daulatabad	2022	Till date
77	Clinical Trial	ICON Clinical Research India Private Limited	Dr. Ashish Ramchandrarao Deshmukh	ICON Clinical Research India Private Limited	2022	Till date
78	Clinical Trial	Abiogenesis Clinpharm Private Limited	Dr. Syed Umar Quadri	Abiogenesis Clinpharm Private Limited	2021	Till date

1

महाराष्ट्र शासन

MSACS

NACO

जिल्हा एड्स कार्यक्रम नियंत्रण विभाग

वि.सा.सामान्य रुग्णालय,ठाणे.

दूरध्वनी क्रमांक:-	२५४७४९११	जिल्हा शासकिय रुग्णालय, पहिला मजला, ए.आर.टी सेंटर, टेंभीनाका, कोर्टाच्या शेजारी, ठाणे (पश्चिम) ४०० ६०१
फॅक्स नंबर :-	२५४७१४०९	

उपरोग्य सेवा

जा.क्र.जिरुठा/आस्था/समु/प्रशि/ /११

दिनांक :-०४/०२/२०११

प्रति,

वैद्यकिय अधिक्षक/अधिकारी/आय.सी.टी.सी इंचार्ज,
एम.जी.एम रुग्णालय, कळंबोली/डॉ.डि.वाय.पाटील मेडी.कॉलेज नेरुळ/
मध्यवर्ती कारागृह, ठाणे

विषय :- आय.सी.टी.सी टीम प्रशिक्षणास उपस्थित राहणे बाबत.

संदर्भ :- मा.उपसंचालक, आय.सी.टी.सी मराएनिसो वडाळा यांचे कडील पत्र क्र.मराएनिसो/आयसीटीसी/टिम ट्रेनिंग/११/१३८६-९४ दि.०१/०२/२०११

उपरोक्त संदर्भीय विषयान्वये आपणास कळविण्यात येते की, महाराष्ट्र राज्य एड्स नियंत्रण सोसायटी अंतर्गत कार्यरत आय.सी.टी.सी सेंटर मधील वैद्यकिय अधिकारी, समुपदेशक व प्रयोगशाळा तंत्रज्ञ अशा तीन व्यक्तींची टिम ट्रेनिंग **राज्य आरोग्य व कुटुंब कल्याण प्रशिक्षक केंद्र, पूणे** येथे दि.१०/०२/२०११ ते दि.१२/०२/२०११ पर्यंत आयोजीत करण्यांत आली आहे.

उपरोक्त प्रशिक्षणामध्ये आयसीटीसीचे दैनंदिन काम, रुग्णांना पुरविण्यात येणा-या सेवामध्ये कर्मचा-यांची भुमिका, NACP-III अंतर्गत एच.आय.व्ही नियंत्रणाकरिता सुरु करण्यात आलेल्या नविन सुविधा, रेकॉर्ड अदयायावत ठेवणे, अहवाल सादरीकरण व त्या अनुषंगाने आयसीटीसी केंद्राशी संबंधीत कर्मचा-यांची भूमिका याबाबत प्रशिक्षण देण्यात येणार आहे. तरी आपण व आपले सहकारी (आय.सी.टी.सी समुपदेशक व प्रयोगशाळा तंत्रज्ञ) प्रशिक्षणाच्या ठिकाणी हजर व्हावे तसा अहवाल या कार्यालयास सादर करावा ही विनंती.

सदरील प्रशिक्षणास उपस्थित राहणा-या अधिकारी व कर्मचा-यांना शासनाच्या नियमानुसार प्रवास खर्च देण्यात येईल.

जिल्हा शल्यचिकित्सक,ठाणे

प्रत माहितीसाठी सविनय सादर :-

१) मा.अधिष्ठाता, एम.जी.एम रुग्णालय, कळंबोली
२) मा.अधिष्ठाता, डॉ.डि.वाय.पाटील मेडी.कॉलेज नेरुळ, नवी मुंबई
३) मा.उपसंचालक, म.रा.ए.नि.सो, वडाळा मुंबई

भारतीय गैर न्यायिक

एक सौ रुपये Rs. 100

रु. 100 ONE HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA

GC 963458

28 FEB 2013

खरेदीदार

अ.नं. 132/2013 दिनांक 11/3/2013

नाव. एम.जी.एम मेडिकल कॉलेज -प्रथम

यांचेसाठी माधा काबे

खरेदीदार सही दिपक राजपूरकर

खरेदीचा दिनांक

पक्षकाराचे नांव-पनवेल, जि. रायगड.

उपकोषागार अधिकारी, पनवेल, जिल्हा रायगड

उपकोषागार अधिकारी
पनवेल - रायगड.

TRIPARTITE AGREEMENT FOR SERVICE DELIVERY ON INTEGRETED COUNSELING AND TESTING CENTRES (ICTCs)

Memorandum of understanding (MOU)
Between
National AIDS Control Organization (NACO)
Government of India
&
MGM Medical College and Hospital, Kamothe, Navi Mumbai

This Memorandum of Understanding is made on day of April 2013 by and between the director General, National AIDS Control Organization, Department of Health, Ministry of Health and Family Welfare, Government of India, 9th & 6th Floor, Chandralok Building, 36, Janpath, New Delhi 110 001 (herein referred to as "NACO") through the Project Director of Maharashtra State AIDS control Society, (hereafter referred to as "MSACS"), Shri Prakash Safde, I.A.S. Project Director, Acworth complex, R.A.Kidwai Marg, Wadala, Mumbai – 400031.

MGM Medical College and Hospital, a facility having its office at Kamothe Navi Maumbai Raigad, acting through Dr. P. P. Doke, the authorized signatory, hereinafter referred to as **MGM Medical College and Hospital,** which expression shall, unless repugnant to the context, include its successor in business, administrators, liquidators and assigns or legal representatives.

I. PURPOSE OF THE COLLABORATIVE PROJECT

The purpose of the agreement is to set up NACO certified facility integrated counseling and testing centre for HIV counseling and testing in a private sector/not for profit/non governmental organizations run health facility through a public private partnership. The aim is to provide access to quality HIV counseling and testing services to clients who access private/ not for profit health care system in both urban and rural areas of the country.

II RESPONSIBILITIES OF THE SACS.

1. To supply rapid HIV diagnostic kits (3 different antigens/ principles) in quarterly advance as per annual requirement to **MGM Medical College and Hospital,** subject to availability of above kits with SACS. While every effort will be made to provide uninterrupted supply of above kits, SACS will not held responsible for any shortage of above kits due to unforeseen circumstances.

2. To provide training of staff of ICTC (staff of facility) in HIV counseling and testing in NACO approved centers. If required more than one training will be provided by the SACS.

3. To supply protective kits for delivery of HIV positive pregnant woman as per requirement to if needed.

4. To provide TA/DA a per eligibility to ICTC staff of **MGM Medical College and Hospital,** for attending review meeting conducted by SACS as well as for collecting the HIV test kits, registers, formats etc. from the office of the SACS and for transport of coded blood sample or delivery of blood test records from **MGM Medical College and Hospital,** to the SRL (State References Laboratory-State/ district ICTC management authority) under the external quality assurance schemes (EQAS) as laid out in "Operational guidelines for Integrated Counseling and Testing Centre" published by NACO, Ministry of Health & Family Welfare, Govt. of India in July, 2007 or any newer version thereof

5. To supply PEP (Post-exposure Prophylaxis) drugs for protection of staff of ICTC in the event of accidental exposure to **MGM Medical College and Hospital,** as per requirement.

6. To supply IEC material required for an ICTC such as flip charts, posters, condom demonstration models, take home materials to **MGM Medical College and Hospital,** as per requirement.

7. To Supply condoms required for demonstration and distribution to clients coming to the ICTC as per requirement.

8. To supply prophylactic ARV drugs for prevention of transmission from HIV positive mother to their new born babies as per national protocol.

9. To evaluate the performance of the ICTC periodically as per monitoring and evaluation tools developed by NACO/SACS.

10. To provide Registers and Formats as per "Operational guidelines for Integrated Counseling and Testing Centre" published by NACO, Ministry of Health and Family Welfare, Govt. of India in July, 2007 or any newer version thereof.

III. RESPONSIBILITIES OF MGM MEDICAL COLLEGE AND HOSPITAL, KAMOTHE

1. To provide a room with suitable, sufficient and convenient space to be used for counseling purpose with adequate furniture, lighting and privacy and any other infrastructure required.

2. To provide a laboratory equipped with refrigerator, centrifuge, micropipette, needle cutter, etc for HIV testing and blood sample storing facility.

3. To designate existing staff or appoint new staff for the posts of counselor and laboratory technician in the ICTC. To also designate an existing Medical Officer as ICTC Manager.

4. To provide consumables such as needles, gloves, syringes, serum storage vials, micro tips, etc. of standard quality required for HIV testing to the ICTC.

5. To provide counseling and testing services in the ICTC to any client who approaches the ICTC without discrimination **either freely or on receipt of charge not exceeding Rs. 75/-** as per protocol laid out in the guideline text per "Operational guidelines for integrated Counseling and Testing Centre" published by NACO, Ministry of Health & Family Welfare, Govt. of India in July, 2007 or any newer version thereof. The charge will be used to defray cost for provision of the above services.

6. To entirely bear the costs related to staff salary, infrastructure and consumables required for the ICTC.

7. To respect the privacy of clients and maintain confidentially. Provide data protection systems to ensure that records of all those who are counseled and tested are not accessible to any unauthorized person.

8. To maintain quality assurance at the services delivery especially in HIV testing services as provided in the guideline text "Operational guidelines for Integrated Counseling and Testing Centre" published by NACO, Ministry of Health & Family Welfare, Govt. of India in July, 2007 or any newer version thereof . MGM Medical College and Hospital will be accountable for any substandard delivery of service.

9. To participate in EQAS (External Quality Assessment Scheme) as laid out in the above mentioned guideline text. MGM Medical College and Hospital will send samples in the first week of every quarter, for cross checking to SRL (State reference laboratory-state/ district management authority) once every quarter. The laboratory technician designated by MGM Medical College and Hospital to ensure that these samples are collected in the first week of January, April, July and October & sent to the SRL.

10. To provide data and information to the coordinating agency to perform their duties as per the instruction and direction from SACS.

11. To send monthly report to the SACS/DAPCU in CMIS format by 5th of every month in registers and records supplied by the SACS.

12. To use all the IEC materials, condoms, items required for laboratory use, protective kits for delivery, PEP (post exposure prophylaxis) drugs supplied by the SACS at the services delivery purpose by the MGM Medical College and Hospital.

13. To Maintain stock records for the all items and drugs provided by the SACS.

14. To maintain quality waste management of disposable items that is used in HIV testing.

15. To ensure that ICTC staff working in the blood collection room and laboratory will observe universal safety precaution (USP).

16. To ensure that ICTC staff are aware of the PEP procedure and display the name and contact information of the PEP focal point/ person as well as the location where the PEP drugs are stored.

17. To follow the national protocol for ARV prophylaxis for prevention of parent to child transmission of HIV (PPTCT).

18. To attend coordination/ review meetings conducted by SACS.

19. To ensure that no research or clinical trials are done on the clients who visit the ICTC or based on data of clients who visits the ICTCs.

20. To attend review meetings at the district level and SACS level as per the supervisory protocol that is provided in the "Operational guidelines for Integrated Counseling and Testing Centre" published by NACO, Ministry of Health & Family Welfare, Govt. of India in July, 2007 or any newer version thereof. To allow access to authorized NACO/SACS/DAPCU staffs who visit the ICTC to the premises and records of the ICTC.

21. To permit SACS to periodically test designated counselor and Lab Technician for their knowledge, attitude and skills.

22. To follow the testing methodology & algorithm as mention in the "Operational guidelines for Integrated Counseling and Testing Centre" published by NACO, Ministry of Health & Family Welfare, Govt. of India in July, 2007 or any newer version thereof, in the laboratory of **MGM Medical College & Hospital.**

23. To follow National AIDS Control Policy & State HIV/AIDS policy.

24. Test kits supplied by MSACS not to be used for routine screening of surgical patients of the facility.

IV. COMMENCEMENT

1) This Memorandum of Understanding shall become effective upon signature by the parties and certification of the facility site. It shall remain in full force and effect for a period of one year thereafter.

2) Further, the certification of the site of the collaborative testing project as "NACO/SACS designated HIV counseling and testing centre" shall run concomitantly with the present Memorandum of Understanding.

3) SAATHII, the implementing partner, authorized by MSACS will support the private sector on commencement and closely coordinate for smooth rollout.

V. RENEWAL OF AGREEMENT

1) This Memorandum of Understanding is renewable at the option of MSACS.

2) Three months prior to the expiry of the Memorandum of Understanding due to efflux of time SACS shall intimate **MGM Medical College & Hospital** if it intends to renew or not to renew the Memorandum of Understanding.

3) In the event that SACS decides not to renew the Memorandum of Understanding, **MGM Medical College & Hospital** hall give notice to the patients regarding the cancellation of its certification. In the event that SACS decide to renew the Memorandum of Understanding, the terms and conditions of this Memorandum of Understanding, as may be amended, will apply *de novo*.

VI. TERMINATION OF AGREEMENT

1) Any party may terminate this Memorandum of Understanding after giving three months notice to the other party at the address provided in this Memorandum of Understanding for correspondence or the last communicated for the purpose and acknowledges in writing by other party.

VII. BREACH BY MGM MEDICAL COLLEGE AND HOSPITAL

1) In case **MGM Medical College & Hospital** is not able to provide services as per agreement of defaults on the provision of this agreement or declines the patient to provide HIV counseling and testing services, it shall be liable for breach of agreement and breach of trust and other

VII. BREACH BY MGM MEDICAL COLLEGE AND HOSPITAL

1) In case **MGM Medical College & Hospital** is not able to provide services as per agreement of defaults on the provision of this agreement or declines the patient to provide HIV counseling and testing services, it shall be liable for breach of agreement and breach of trust and other consequences which may include black listing with SACS, NACO, MOHFW of Home affairs and external affairs.

IX. SETTLEMENT OF DISPUTES:

1) Any dispute of difference or question arising at any time between the parties hereto arising out of or in connection with or in relation to this agreement shall be referred to and settled by arbitration under the provision of the Indian Arbitration and Conciliation Act, 1996 or any modification or replacement thereof as applicable for the time being in India.

2) The arbitration shall be referred to an arbitrator nominated by Secretary Department of Legal Affairs, Ministry of Law and Justice, Govt. of India, Delhi. The arbitrator, if he so feels necessary, seek opinion of any healthcare personnel with experience of working in the field of HIV and care and treatment of PLHAs.

3) The place of arbitration shall be either New Delhi or the site of the collaborative laboratory, which shall be decided by the arbitral tribunal bearing in mind the convenience of the parties.

4) The decision of the arbitrator shall be final and biding on both the parties.

X. LAW APPLICABLE

This Memorandum of Understanding shall be construed and governed in accordance with the laws of India

XI. ADRESSES FOR CORRESPONDENCE

In witness thereof, the parties herein have appended their respective signatures the day and the year above stated.

Signed For and on behalf of MGM Medical College and Hospital

Dr. P. P. Doke
Med. Supdt.
MGM Medical College and Hospital

Signature.....
Date.....7/3/2012.....

Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE

In the presence of .....
Name.....

Signature
.....
Date.....

Signed for and on behalf of NACO

Project Director

MSACS

Signature.....

Date.....

In the presence of

Name ..... Dr. Tejaswini Khandapurkar

Signature..... T Khandapurkar

Date..... 8/3/2012

District Programme Officer
DAPCU Thane

District Programme Officer
DAPCU Thane

LETTER OF AGREEMENT

This Letter of Agreement (LoA)

Signed on

29th Day of April 2017

Between

AIDS Health Care Foundation – India Cares

&

MGM Institute of Health Sciences Trust, Navi-Mumbai

INTRODUCTION

India has one of the largest numbers of population living with HIV/AIDS in the world. Given the prevalence rate of 0.26 percent, 21 lakh people are estimated to be living with HIV/AIDS in the country[1]. To halt and reverse the epidemic it is imperative to ensure early testing and treatment and care.

AIDS Health Care Foundation (AHF) – India Cares and MGM Institute of Health Sciences Trust, Navi Mumbai, are hereinafter referred to together as "the parties"

Article 1

1. AIDS HEALTH CARE FOUNDATION – INDIA CARES

1.1 AIDS Healthcare Foundation (AHF) Established in 1987 in Los Angeles United States is one of the largest not-for-profit HIV & AIDS organizations in United States and is present in 38 countries in the world providing cutting edge medicine and advocacy regardless of their ability to pay. For more details visit website www.aidshealth.org.

1.2 "India Cares" under the aegis of AHF is established as a trust in Delhi. Collectively called AHF India Cares, the trust carries forward the vision and mission of AHF Global in India. AHF worldwide currently treats more than 7,12,675 HIV positive people free of cost. In India, we are providing free ART to more than 1600 people. Our prevention program includes free community based Rapid HIV testing and distribution of condoms.

Article 2

2. MGM INSTITUTE OF HEALTH SCIENCES TRUST, NAVI MUMBAI

2.1 The MGM Institute of Health Sciences Trust was established on 28th March 2006 with a futuristic vision to provide qualitative education by applying innovative and dynamic pedagogical techniques. Since inception, the Trust has focused on providing health care services, medical education with dedication and commitment.

[1] Technical Estimates NACO, 2015

2.2 Service to society at the grass root level has been the basic vocation of the Trust along with education. The Trust has been instrumental in providing prompt and efficient health care services to the economically weaker sections of the society. The Trust hospitals and Medical colleges underscore its commitment to human resource development and social health and welfare.

Article 3

3 RATIONALE FOR PARTNERSHIP

3.1 The total number of people living with HIV/AIDS (PLHA) in India is estimated at 21.2 lakhs in 2015. Despite the reduction in the overall prevalence, there are emerging vulnerabilities which need to be addressed. The epidemic in the country is changing according to emerging vulnerability factors related to poverty, migration, marginalization and gender. As per the Technical Estimates, 86% of those infected are in the age group of 15 to 49 years, which is one of the most productive segment of the society irrespective of the sectors, in which, they have engaged. The global objective to end the AIDS epidemic by 2030, is only possible with active and meaningful involvement of all stakeholders.

3.2 Vulnerability of HIV cannot be completely ignored among young people. In the absence of right guidance and information at the young age, they are more likely to have exposure to sexual experiments which may lead to high risk behaviors. The prevalent social stigma and discrimination is another challenge. Though National AIDS Control Program has appropriate strategies in reaching out high risk, vulnerable groups and youths to reduce new infections and reduce mortality rates, there is still a gap of around 12 lakh people against the estimated numbers who are not aware of their HIV status and continue to transmit HIV.[2] AHF India Cares have been striving to complement the efforts of the Government to reduce this gap by promoting community based rapid testing program and linking all to ART treatment. The scope

[2]Report of the Mid Term Appraisal of NACP IV

of community based rapid testing in reaching out to the unreached masses and offering the complete cascade of services is the objective of this partnership.

3.3 MGM Institute of Health Sciences Trust can play a crucial role in supporting the global objective of ending the AIDS epidemic by 2030 in partnership with AHF India Cares.

Article 4

4 SCOPE OF THE PARTNERSHIP

MGM Institute of Health Sciences Trust can complement to the objectives of AIDS Healthcare Foundation by

a) Enhancing coverage and reach of HIV prevention messages through the outreach program in the villages, among students, staff and faculty.

b) Provide subsidized diagnostics and treatment to people infected and affected by HIV which is in congruent to the organization's mission.

c) Through the medical colleges, it could be one of the first few private institutes to provide HIV fellowship training programs to medical practitioners in the region.

d) Provide training to medical practitioners on universal precaution, management of HIV/AIDS & TB and house based care.

e) Provide stigma free services to all the HIV infected and affected people.

f) Identify and provide free HIV testing services to the vulnerable and high risk people in the nearby communities.

Now, therefore, in consideration of the foregoing rationale and scope, the parties i.e. MGM Institute of Health Sciences Trust and AIDS Healthcare Foundation India Cares agree to cooperate and collaborate in the overall goal of halting and reversing of HIV epidemic in the following areas

Article 5

5 OBJECTIVE OF LoA

5.1 Reaching out to the large numbers of people on HIV/AIDS prevention, testing and treatment diagnostics and other related services with regardless of their ability to pay.

5.2 Provide training and fellowship programs to medical practitioners on Universal precaution and management of STI/HIV/AIDS.

5.3 Create awareness among the students, faculty and other allied staff members regarding STI/HIV/AIDS.

5.4 Providing stigma free prevention, testing, diagnostic and treatment service to all HIV infected an affected people including TB and Hepatitis patients.

Article 6

6 KEY DELIVERABLES

6.1 Issue advisory in all MGM Institute of Health Sciences Trust regarding the LoA and share the jointly develop work to all institutions for implementation and periodic monitoring.

6.2 Inclusion of content on Universal precaution, STI/HIV management and the need for impact mitigation of HIV appropriately in different courses thereby developing a cadre of trained HIV specialists in the country.

6.3 Incorporating HIV related prevention and testing services in all outreach activities under the MGM Institute of Health Sciences Trust.

6.4 Providing free or subsidized (as per agreement) diagnosis and treatment for people infected and affected with HIV based on mutual agreement.

6.5 Providing stigma free services to all infected and affected communities regardless of their ability to pay the Trust and during outreach programs at the community level.

6.6 Collaborate in all the upcoming and ongoing campaigns of AHF for example "fund the Fund "(to increase contributions of countries to the Global Fund for HIV/TB and Malaria), advocacy on drug pricing which aims to reduce the cost of life saving medicines, stopping the war on the bodies of women etc.

Article 7

7 ROLES OF BOTH PARTIES

7.1 ROLE OF MGM INSTITUTE OF HEALTH SCIENCES,TRUST

7.1.1 Advisory issued to all MGM Institute of Health Sciences Trust regarding the LoA and sharing of the broad annual action plan.

7.1.2 Advisory to start planning and development of the annual action plan of each institute with the objective set in the LoA for (Jan – Dec).

7.1.3 Advisory issued to all educational Institutions under MGM Institute of Health Sciences Trust to form youth health clubs for students promoting sexual reproductive health awareness, HIV/STI prevention programs and offer HIV testing and treatment services if needed.

7.1.4 To include information on STI/ HIV prevention & services, voluntary blood donation and prevention of intravenous drug use, in health-related courses and printed materials and to include HIV related questions in competitive examinations conducted at all levels.

7.1.5 Screening of movies/documentaries on HIV/AIDS in the institutions to sensitize them on issues related to HIV/AIDS and drug pricing.

7.1.6 Observing World AIDS Day, International condom day, day of the girl child, international transgender day and other relevant days.

7.1.7 Inclusion of HIV/AIDS topic in the induction and training programs of undergraduate & post graduate students and employees of Institutes.

7.1.8 Designing and implementation of short term courses/ fellowships on prevention and management of HIV to develop local resource pool

7.1.9 Outreach activities under the MGM Institute of Health Sciences Trust to include providing HIV related prevention and testing services with a focus of reaching the poor and marginalized sections of the society.

7.1.10 Provide free or subsidized (as per agreement) diagnosis (mutually agreed costs) and treatment for people infected and affected with HIV.

7.1.11 Provide stigma free preventing, testing, diagnostic and treatment services to all HIV infected and affected people.

7.1.12 Sharing of information periodically and regularly as mentioned in the implementation of the LoA.

7.1.13 Reflection of activities undertaken in the LoA in the website and annual report of MGM Institute of Health Sciences Trust.

7.1.14 Sensitization of staff and students in dealing with the issues of LGBTQI communities and establish service centre exclusively for them

7.2 ROLE OF AHF India Cares

7.2.1 Provide technical support to implement prevention and testing services in the different Institutes of MGM Institute of Health Sciences Trust.

7.2.2 Provide technical support for capacity building of all employees and students under MGM Institutes to include HIV/AIDS as a topic in their induction and other training program.

7.2.3 Provide technical support in developing courses on prevention and management of HIV/AIDS and to obtain accreditation for the same as per regulatory bodies guidelines (MGMIHS/NACO/MCI/UGC)

7.2.4 Provide condoms and rapid test kits for prevention and testing services in house and outreach programs.

7.2.5 Monthly payment of bills based on the jointly agreed subsidized costs of diagnostic and treatment for the infected and affected population.

7.2.6 Provide training to medics, paramedics and community outreach staff on community based HIV rapid testing program.

7.2.7 AHF will provide technical support in form of human resources, logistics and management of biomedical waste during outreach activities in community.

7.2.8 AHF will operate satellite clinic in MGM Medical College & Hospital, Navi-Mumbai to provide health care services & support to patients living with HIV.

7.2.9 Establishments of state of art - ART centre In MGM Medical College & Hospital, Navi-Mumbai.

7.2.10 Establishment of state of art -ART Centre in MGM Medical College & Hospital Aurangabad Campus.

7.2.11 AHF through provide through JCC, Kalamboli will provide care & support for destitute women living with HIV.

7.2.12 Periodical and regular replenishment of commodities like condoms and HIV rapid test kits based on the indents submitted by MGM Institute of Health Sciences Trust.

7.2.13 Provide technical assistance to establish service centers and provide services for LGBTQI under different Institutes of MGM Institute of Health Sciences Trust.

Article 8

8 EXECUTION OF LoA

8.1 Parties will set up a joint working group, with the officials in the two institutions within 7 working days after signing of the LoA for its implementation.

8.2 The meeting of the Joint Working Group will be held every quarter for the first 2 years and later bi-annually.

8.3 The first meeting of the joint working group will develop the list of services that will be provided free and the costing of the subsidized services.

8.4 The joint working Group will also review cost and need for revision annually.

8.5 The joint working group will be responsible in developing annual work plans (Jan -Dec) and its regular monitoring for the successful implementation. The working group will also propose mid-course correction and implement the same.

8.6 This LoA will be operative with effect from the date 29th April 2017and any alteration / modifications can be carried out with the consent of both parties.

8.7 The individual projects envisaged under this LoA will be formulated based on Log Frame Analysis indicating resources sharing / budgets.

8.8 LoA can be invalidated with three months' prior notice on either side.

The parties herein have appended their respective signatures the day and the year above stated.

SIGNED FOR AND ON BEHALF OF MGM INSTITUTE OF HEALTH SCIENCES TRUST, NAVI-MUMBAI.

1. DR. RAJESH GOEL
   REGISTRAR, MGMIHS
   NAVI-MUMBAI.

2. DR. S N KADAM
   TRUSTEE, MGMIHS,
   NAVI-MUMBAI.

MGM INSTITUTE OF HEALTH SCIENCES NAVI MUMBAI Reg No F-5465

SIGNED ON 29TH APRIL 2017

SIGNED FOR AND ON BEHALF OF AIDS HEALTH CARE FOUNDATION.

1. DR V SAM PRASAD
   COUNTRY PROGRAM DIRECTOR
   AIDS HEALTH CARE FUNDATION – INDIA CARES

2. MS TERRI FORD
   CHIEF OF GLOBAL ADVOCACY& POLICY
   AIDS HEALTH CARE FOUNDATION

SIGNED ON 29TH APRIL2017

4

भारतीय गैर न्यायिक

एक सौ रुपये Rs. 100

रु. 100 ONE HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA ◐ 2021 ◐ ZF 558265

ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्यांनी त्याच कारणासाठ
मुद्रांक खरेदी केल्यापासून ६ महिन्यात वापरणे बंधनकारक आहे.
अनु.क्र. 33808 दि. 23-12-2021 मु.शु.रक्कम 100
दस्ताचा प्रकार Affidavit
दस्त नोंदणी करणार आहेत का ? होय/नाही.
मिळकतीचे वर्णन
मुद्रांक विकत घेणाऱ्याचे नाव Molecular Laboratory SKNMC GH
पत्ता Narhe Pune
दुसऱ्या पक्षकाराचे नाव MGM Medical college, New
हस्ते व्यक्तीचे नाव व पत्ता Vinayak Jadhav Mumbai.

23-12-21
मुद्रांक विकत घेणाऱ्याची सही

श्री. संगल आकाश नेवसे
[illegible]
परवाना क्र. 2201101

20 DEC 2021
प्रथम मुद्रांक लिपीक कोषागार पुणे कार्यालय

MEMORANDUM OF UNDERSTANDING

The original memorandum of understanding is entered in to on **27th November 2021** between The Dean MGM Medical College & Hospital's Central Laboratory, Maharashtra state (India), referred to as party no.1

AND

Professor & Head, Dept. of Microbiology, Molecular Laboratory Smt. Kashibai Navale Medical College and General Hospital, Narhe Pune, Maharashtra, here in referred to Party no.2.

21.01.22
Dean
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

WHEREAS Party no.1,is an Institute that provides patients treatment and other medical services including Microbiological services. The geographical region served is Maharashtra & Central India.

The party no 2 provides diagnostics service to patients hailing from Pune.

The memorandum of understanding is formulated between the parties of the following covenants.

PURPOSE:

In order to render more compressive range of services to its patients, Party no 2 is desirous to outsourced samples of 2009 H1N1 Influenza to party no 1for investigations on RT PCR and report for the purpose of inter lab comparison

The samples will be sent quarterly for this purpose both the parties have mutually agreed to render the services mention above on following terms and conditions

1. Services covered under this MOU

A) The party no 2 shall send samples to party no 1 only for testing of H1N1 Influenza testing on RT PCR for purpose of interlab comparison

B) The charges for H1N1 Influenza **test shall be Rs. 5000/-.**

2. Duration

A) The parties hereby agree that effective date of mutual agreement shall be from the date of signing this memorandum of understanding and the same will be valid till 26/11/2024

3. Confidentiality

A) The party shall maintain confidentiality of all patient's health information and medical records with in accordance with prevailing law of land.

B) That in eventuality of instrument breakdown or any damage to the particular machine or instrument of the Molecular Laboratory of both parties, it will be open for parties to send all the samples for which the investigation is usually carried out at the respective Molecular Laboratory of Party no 1or party no 2 as the case may for investigations

In witness where of party no 1 and party no 2 have been herein sign this memorandum of understanding at Navi Mumbai in presence of following witness

M.G.M Medical & Hospital
Kamothe, Navi Mumbai - 410209

Dr. Ashwin Balasubramanian, Internship Work Report

Work period: Feb-March 2022.

I am Dr. Ashwin Balasubramanian, currently pursuing an M.D. degree from the Department of Pharmacology, MGM Medical college, Navi Mumbai. In November 2021, I had applied for an internship program in Pfizer Mumbai. After an interview, I was selected and offered an internship in Medical Affairs at Pfizer Mumbai for 2 months from 1st Feb 2022 – 31st Mar 2022.

During my internship, I was working with the Rare Disease medical team under the supervision of Dr. Hitesh Muley, Medical Lead, Rare Diseases, Pfizer India. After initial round of discussion and expectation setting, I was assigned the following objectives:

The **objectives** to be achieved:

1. To understand the role and functioning of Medical Affairs in Pfizer India.
2. To learn methods, approaches and policies for internal and external stakeholder interactions related to medical activities.
3. To understand the process to review scientific aspect of promotional/scientific material in line with the policies.

To achieve the above objectives, I was given a formal training around the SOPs and work instructions pertaining to above objectives. A detailed induction plan was given to understand various functions and their roles and interactions with Medical Affairs. I also interacted with my fellow colleagues to understand their function and role. I was also given some responsibilities to achieve the above-mentioned objectives. During this entire tenure, I was in constant touch with Dr. Hitesh for guidance and information required.

Sessions attended:

Sr.No.	Sessions Attended	Learnings
1	**Rare Disease Plan of Action 2022 meeting**	The different parts of a plan of action and how the various stakeholders in the company for eg. Medical, regulatory, legal, sales, marketing, access, digital, etc. interact.
2	**Basics of RWE studies**	How to conduct a RWE study in India and challenges faced when conducting it.
3	**Introduction Artificial intelligence and Machine learning**	I learned about the untapped potential of Artificial Intelligence and Machine Learning, the existing use-cases and achievements for AI/ML in diagnosis of diseases, and future directions for this exciting and new field
4	**Medical Affairs meeting**	The new evolving and transforming role of Medical Affairs was explored through interactions with colleagues in breakout sessions.

Assignments completed:

Sr.No.	Assignments completed	Learnings
1	**Literature search to understand the latest development in Growth Hormone Deficiency in India.**	To collate data in a systematic unbiased, manner using detailed checklists.
2	**Prepared a presentation on recent updates in the management of Growth Hormone disorders.**	To present the entire information in a way that is holistic, non-promotional and prevents misunderstanding.
3	**Conducted a session on the evolving role of Medical Affairs in KOL management for Rare Disease and Internal Medicine medical team.**	There are different types & levels of KOLs depending on segmentation. The KOL journey should be kept in mind when planning engagements.
4	**Interacted with 5 cardiologist KOLs in relation to Rare Disease focus group medical meetings.**	Importance of having complete knowledge about the topic of discussion when interacting with a high-level KOL.
5	**Supported in execution of Centre of Excellence kickstart meeting involving cardiologists from 19 institutes and preparation of Eliquis Masterclass.**	The logistic requirements and challenges before, during, and after a meeting with multiple high-level KOLs.
6	**Attended all weekly Rare Disease review meetings.**	Understood the ways of how a team is assigned tasks and how important it is to complete them in time for growth as a team and as an individual.
7	**Collaborated with Pfizer colleagues for successful execution of the Cultural Event in the Medical Affairs meeting.**	I learned to interact with colleagues of different verticals in an informal setting.

Though my experience in Pfizer I gained an understanding of the four Pfizer values. Courage, Excellence, Equity, and Joy. Switching to onsite work from a work-from-home situation during these COVID times, I understood **Courage.** Engaging with my colleagues and delivering on tasks for critical meetings, I understood **Excellence.** Working with the Rare Disease team for an under-served population, I understood **Equity.** Collaborating with Pfizer colleagues the successful execution of Cultural Event in the Medical Affairs meeting, I understood **Joy.** I humbly thank Dr. Hitesh, and Pfizer India for this wonderful learning experience and all the support and encouragement.

Yours' Sincerely,

31/3/2022.

Dr. Ashwin Balasubramanian.

महाराष्ट्र MAHARASHTRA ◐ 2021 ◐ ZS 296575

18 APR 2022

पुरवठ्याचा दिनांक
कोषागाराचे नांव-पनवेल,
जि. रायगड.

उप कोषागार अधिकारी
पनवेल - रायगड

Memorandum of Understanding (MOU)

Between

MGM Medical College and Hospital, Kamothe, Navi Mumbai (FIRST PARTY)

&

SEAL (Social & Evangelical Association For Love), Vangani, Nere, New Panvel (SECOND PARTY)

THIS Memorandum of Understanding is made on this 2nd May 2022.

MGM Medical College & Hospital, Navi Mumbai, having registered office at Sector : 1, Kamothe, Navi Mumbai 410209, hereinafter called First Party MGMMCH (which term shall deemed to mean and include its successor-in-interest, permitted assign, agents and executors) through their Authorized signatory. The agreement may get changed as per requirement with consent of both the parties.

AND

SEAL (Social & Evangelical Association For Love), Vangani, Nere, New Panvel

- Doctors from dept of Geriatrics in Co-ordination with Rural Health Training Centre, Nere team of MGM to visit every Tuesday– to screen patients and needed patients will be admitted in a ward which is allocated for SEAL

- All other patients also can be shown to the doctors on Tuesday – whoever needs further follow and admission will be referred to MGM.

- The Specialty Visit will be Skin / ENT / Ophthalmology / Paediatrics will be once a week. The geriatric dept of MGM Medical college will co-ordinate for smooth functioning of the patient care of the 2nd party.

- During admission in MGM , common medicines will be provided from hospital. Specific medicines if not in MGM medical store, may have to be procured by SEAL. Also all implants etc required for treatment may procure by the Seal.

- At least one male and female attendant be with the patients during the stay

- One Co-ordinator will work with the team in MGM as volunteer, for all co-ordination, admission, treatment and other needs. ID card provision for the volunters . They will be introduced to all Social workers and Doctors and all departments so that to get better co-ordination in treatment of patients.

- The transport to & fro of patients will be bored by first party.

- The In Patient will be admitted in Hospital Beds in the respective General Wards and will be treated free of cost (Bed charges, Generic Medicine, Hb, CBC, LFT, RFT & OT charges, food) however the specialised investigation /test will be cost effective. Medicine, Consumable, & splints will be bound by the second party. However OPD IPD & Doctors consultation will be completely free.

- This MOU is valid for a period of 3 yrs from 2nd May 2022 to 1st May 2025 subject to the feedback and changeable by either party with one month notice period / intimation.

Dr. G.S. Narshetty
Dean
MGM Medical College,
Kamothe, Navi Mumbai

Dean
MGM Medical College & Hospital
Kamothe, Navi Mumbai-410209

HOD Geriatric
MGM Medical College
Kamothe.

Fr. K.M. Philip,
Director
SEAL Ashram

03/06/'22

Date :

Place :

Extension of Memorandum of Understanding (MoU)

BETWEEN

MAHATMA GANDHI MISSION MEDICAL COLLEGE, KAMOTHE, NAVI MUMBAI, UNDER MGM INSTITUTE OF HEALTH SCIENCES,

AND

DR. BABASAHEB AMBEDKAR MEMORIAL MUNICIPAL HOSPITAL, KHOPOLI DISTRICT - RAIGAD

महाराष्ट्र MAHARASHTRA ◑ 2019 ◑ 10 MAY 2021 AS 808066

पुरवठ्याचा दिनांक
उपकोषागाराचे नांव-पनवेल,
जि. रायगड.

उप कोषागार अधिकारी
पनवेल - रायगड

उप कोषागार कार्यालय
पनवेल-रायगड

BETWEEN

MAHATMA GANDHI MISSION MEDICAL COLLEGE, NAVI MUMBAI
under MGM INSTITUTE OF HEALTH SCIENCES
AND

Dr. Babasaheb Ambedkar Memorial Municipal Hospital, Khopoli, District - RAIGAD

THIS MoU is made at Navi Mumbai and comes in effect **immediately in continuation of previous MoU of 1st November 2015** between Dr. Babasaheb Ambedkar Memorial Municipal Hospital, Khopoli, District - RAIGAD, Here in referred as the **FIRST PARTY**

AND

MGM MEDICAL COLLEGE, KAMOTHE, NAVI MUMBAI hereinafter referred as **SECOND PARTY**

M.G.M. MEDICAL COLLEGE NEW MUMBAI 410209 KAMOTHE

AND WHEREAS THE FIRST PARTY is seized and possessed of sufficiently entitled to the Municipal Hospital, Bajarpeth, Khopoli hereinafter referred to as the said premises which is in their exclusive possession being in need of Medical Personnel including doctor/doctors/ paramedicals to manage the multispecialty outpatient services, laboratory services and Secondary and Tertiary health care services to the users of their hospital has approached **SECOND PARTY**.

AND WHEREAS SECOND has agreed to manage their hospital by way of providing the services of doctors and paramedical staff at the said PREMISES as Urban Health Training Centre (as specified hereunder) having Academic Control by Dean in the said premises, upon same terms and conditions as per earlier MoU in effect from 1st November 2015.

NOW THIS AGREEMENT WITNESSETH AS UNDER:-

Both the parties agree to extend the earlier MoU which was in effect from 1st November 2015 to 30th October 2020 for a further period of 5 years from 01st Nov. 2020 to 30th October 2025 upon same terms and conditions..

IN WITNESS THEREOF THE PARTIES HERETO have executed this agreement in the manner herein on this 15th May 2021

SIGNED SEALED AND DELIVERED

By the within named "FIRST PARTY"

Competent Authority

Dr. Babasaheb Ambedkar Hospital, Khopoli,
Khopoli Municipal Council, Khopoli

Chief Medical Officer
Khopoli Municipal Council

CHIEF OFFICER
Khopoli Municipal Council

Witnesses-

1.
2.

SIGNED SEALED AND DELIVERED

SECOND PARTY

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

Dean
MGM Medical College, Navi Mumbai
Under MGM Institute of Health Sciences
Kamothe, Navi Mumbai

Witnesses-

1. Dr. Prasad Naiyarkar
2. Dr. Sunita Sajeev

ATTESTED BY ME
R. C. DIGPAL
ADVOCATE & NOTARY
MUMBAI
21 MAY 2021

7

महाराष्ट्र MAHARASHTRA ◐ 2019 ◐ WF 670418

11 NOV 2020

MEMORANDUM OF UNDERSTANDING

Between

MGM MEDICAL COLLEGE & HOSPITAL
(CONSTITUENT UNIT OF MGMIHS)
Sector 1, Kamothe, Navi Mumbai-410209,
Tel.No 022-27432471,022-27432994,Email.mgmmcnb@gmail.com Website: www.mgmuhs.com

AND

MORE-YA BIOSCIENCES Limited Liability Company(LLP)
Sr.No.71/72,Sneh Park Co.op.Hsg.Society
Baner, Pune, Maharashtra 411045

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

This Memorandum of Understanding (**"MOU"**) made on this 3rd of August, 2020 by and between the **Mahatma Gandhi Mission Institute of Health Sciences** through its constituent Institute, MGM Medical College & Hospital **(MGMIHS/MGM Medical College)** having its office at MGM Educational Campus, Sector 1, Kamothe, Navi Mumbai, 410209 and **MORE YA BIOSCIENCES Limited Liability Company(LLP)** having its registered office at Sr.No.71/72, Sneh Park Co.op. Hsg. Society, Baner, Pune, Maharashtra 411-045 (hereinafter referred to as the "**MYB**") which expression shall, unless it be repugnant to the context or meaning thereof, includes its successors and permitted assigns) of the Second Part.
MGMIHS and MYB each individually and collectively referred to as "Party" and "Parties" respectively herein.

(A) **Whereas** MGMIHS is a deemed to be University, recognized under the University Grants Commission Act. MGMIHS runs and administers educational institutions and medical colleges in Navi Mumbai and Aurangabad including the Mahatma Gandhi Missions Medical College and Hospital at Kamothe, Navi Mumbai. The aims and objects of MGMIHS are to establish educational institutes and hospital with the required modern facilities and infrastructure, to provide good quality education, medical education/facilities etc to the society and public at large, to help promote education, medical education and provide good quality medical facilities at reasonable rates etc.

(B) **And Whereas** MYB is a LLP founded and headed by Mr Varunraj More. MYB is a limited liability company registered in India MYB though being a startup company has developed a software by the name "AI Tool" which helps detect and reliably diagnosing COVID-19 cases by use of X-Ray images. The validation process of the said software is required to be done.

(C) **And Whereas** COVID-19 which began with the reporting of unknown causes of pneumonia in Wuhan, Hubei province of China on December 31, 2019, has rapidly become a pandemic. This new virus spread from Wuhan to most countries in the world by March 2020. The ongoing pandemic is expected to be the most severe pandemic in recent history. The disease is named COVID-19, and the virus is termed SARS-CoV-2.

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

(D) **And Whereas India** has seen more than 15,00,000 confirmed cases and more than 34,000 deaths from this disease as of July 29, 2020. This virus's name SARS-CoV2 describes its most common symptom: **"Severe Acute Respiratory Syndrome,"** where patients' lungs are usually the first to suffer damage. The typical clinical features of COVID-19 include fever, cough, sore throat, headache, fatigue, muscle pain, and shortness of breath. The most accurate test for COVID-19 is a real-time reverse transcription-polymerase chain reaction (RT-PCR). However, its use is limited by low availability, high costs, and longer delays in getting the diagnosis. Chest radiological imaging such as computed tomography (CT) and X-ray have vital roles in early diagnosis and treatment of this disease. The Chest radiological imaging method if validated and used will serve as an cost effective alternative to the other test, help in early detection and prevention of damage to the lungs.

(E)And Whereas MYB has developed an **AI tool** in reliably diagnosing COVID-19 cases by use of X-Ray images. MYB is looking to collaborating/associating itself with reputed universities, institutes having the required infrastructure, facilities and know how to validate the AI tool. MYB has requested MGMIHS to *validate the software tool.*

(F)**And Whereas** MGMIHS is a reputed institute having the required facilities, infrastructure etc and has been in and associated with the medical field and medical research. MYB has approached MGMIHS, through the MGM Medical College and Hospital with a request to validate theAI tool at the MGM Medical College and Hospital with the help of the retrospective data available with the MGM Medical College and Hospital Kamothe navi Mumbai.

(G) Whereas the parties propose to undertake the validation process of the AI Tool with the help of the Chest radiological imaging of X-ray of patients affected with the COVID 19 virus. *Under the MOU , MGMIHS through the MGMMCH will* validate the "AI tool" developed by MYB in reliably diagnosing COVID-19 cases by use of X-Ray images. The parties propose to use the X-Ray images available with the MGM Medical College and Hospital, Navi Mumbai **(the retrospective data)**.

(H)And Whereas pursuant to various meetings and discussions the MGMIHS and MYB have agreed to execute and enter in this MOU with a objective to spell out and define the scope of work, duties, responsibilities etc of both the parties and specific role of each party in testing, developing and validating the AI tool developed by MYB and the work to be undertaken in respect thereof in the future.

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

NOW THEREFORE THESE PRESENTS WITNESSETH AND IT IS AGREED BY AND BETWEEN THE PARTIES HERETO AS FOLLOWS:

1. **SCOPE, OBJECTIVES AND BENEFITS OF MOU:**

(a) The MGM Medical College and Hospital Navi Mumbai will test and validate the AI tool developed by MYB, in reliably diagnosing COVID-19 cases by use of X-Ray images (the retrospective data) from the MGM Medical College and Hospital, Navi Mumbai and the MGM College and Hospital Aurangabad. MGMIHS will validate the software developed by MYB. The validation will be in the form of A Performa (Annexure 1 hereto) which has been approved in the Ethics committee. Further the parties agree and accept that MGMIHS can utilize the validation/ soft ware for patients diagnosis, for academic, research and publication purposes etc.

(b) The parties agree and accept that the MOU, will able MYB to gets its AI Tool software validated from MGMIHS and MYB may provide access at the discretion of MYB to MGMIHS to use the software for its research purposes, hospitals and patients diagnosis etc.

2. **TERMS AND CONDITIONS OF THE MOU AND TERMINATION:-**

(a) The MOU is for a period of **-5** /years. The parties may renew/extend the MOU for a further period upon such terms and conditions which are mutually agreeable to the parties.

(b) **Termination:** Either party shall have the right to terminate the MoU by giving a 30 days (notice period) notice to the other party. Once the termination notice is given no activity will be conducted by and between the parties.

3. **Responsibilities/Duties/Obligations of Parties :**

(A) Responsibility of MGM Medical College & Hospital, Navi Mumbai:

(i) MGM Medical College & Hospital will provide data (retrospective data) of covid-19 patients which will be collected from the patient's medical record. The same will include basic demography data, clinical data-symptoms, any signs of lung involvement on auscultations, SPO2, Standard X-Ray chest obtained as per the site operating procedure to ensure data collection and Site radiologist report and the RT PCR reports.

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(ii) Data collection will be the responsibility of the investigating team of MGMIHS. The Investigating team consists of the Principal investigator and the Co-investigators of the MGM Medical College & Hospital of MGMIHS. The investigators will be responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported. All source documents will be completed in a neat, legible manner to ensure accurate interpretation of data. Hardcopies of the study visit worksheets will be provided for use as source document worksheets for recording data.

(iii)he Clinical data will be entered into the MYB supported web based data platform. The data system includes password protection and internal quality checks, such as automatic range checks to identify data that appear inconsistent, incomplete, or inaccurate. The clinical data will be entered directly from the source documents. Investigating team of MGM will enter the data.

(iv)To compare the accuracy of COV-Ai tool vs site radiologist vs. blinded independent radiologist to classify COVID-19 related lung involvement correctly.

(v)To assess the accuracy of COV-Ai tool to classify COVID-19 related lung involvement in various patient subgroups based on triaging in the hospital.MGM will validate the soft ware too depending on the various levels of Covid 19 i.e patients will be divided according to their severity so the tool will validate it for the various levels of severity.

(B) Responsibilities of MORE-YA BIOSCIENCES :-

(i) MYB will provide the software COV-Artificial intelligence-based tool (COV-Ai) to predict COVID-19 related lung involvement.

(ii) To assess the accuracy of COV-Ai to classify COVID19 related lung involvement in suspected cases.

(iii)To assess the accuracy of COV-Ai in patients with laboratory-confirmed COVID-19 infection.

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(C) Responsibilities of both the Parties:

Confidentiality/secrecy

(i) The confidentiality and privacy of the data of the Covid-19 patients will be strictly held in trust by the parties, the participating investigators, the staff of both the parties and all participants or people involved in the project.

(ii) The data collected under this project or the data used under this project shall be the property of the MGMIHS and the same ought to be kept confidential by the parties. The parties shall be bound by the terms of confidentiality in respect of all the data (main or incidental) to the studies under this MOU or studies under this MOU. MYB agrees and undertakes not to use the data for any other purpose whatsoever.

All case report forms and other data (including without limitation, written, printed, graphic, video and audio material, and information contained in any computer data base or computer readable form) generated by the Study Site in the course of conducting the Study (the "Data") shall be the property of the study sponsor, which may utilize the Data in any way it deems appropriate, subject to and in accordance with applicable privacy laws. Any copyrightable work created in connection with performance of the Study and contained in the Data (except any publication by the Principal investigator) shall be property of the study sponsor

(iii) The parties agree and undertake to hold in strict confidence the data that could be used to identify a specific study participant within the research team.

(iv) The parties agree that no personally identifiable information from the study or any document used during the study will be released to any unauthorized third party. Release if required for the purpose of the study shall be made after receiving written approval and prior consent of both the parties. The parties agree and undertake that all the research activities, work will be carried out/conducted in MGM Hospital, Kamothe, Navi Munbai & MGM Hospital Aurangabad. The same shall be a private and confidential set up. Any deviation or relaxation as regards the confidentiality clause or any matter affecting (directly or indirectly) the confidentiality shall need the prior written approval of the MGM Ethical Committee.

(v) The parties agree and undertake that the study participant's contact information will be securely stored at each clinical site for internal use during the study. The same shall be under the control and in the custody of Electronic Data Processing (EDP) section of MGM.

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4. **Fees:** MGMIHS has agreed to do the validation without charging any fees and considers the same as a contribution of MGMIHS towards the fight against COVID-19 pandemic.

5. **General Conditions :**

(i) There will be quarterly meetings between the parties to audit the work to ensure that the aims and objects of the MOU are meet and the issues/ difficulties if any are addressed. A report of the meetings shall be filed with the Scientific Advisory Committee (SAC)of the MGM Hospital Navi Mumbai and MGM Hospital Aurangabad. The decision of the committee in respect thereof shall be final and binding.

(ii) **Data/Records:-**At the end of the study, all data and records will be kept/stored in a secure location i.e Electronic Data Processing (EDP) section of MGM. The data will be stored for a period of 5 years and shall be under the review of the Scientific Advisory Committee.

(iii) The study documents will be retained for a minimum of 2 years or until at least 2 years have elapsed since the formal discontinuation of clinical development of the study intervention. The said documents shall be retained by and in custody of MGMIHS. The parties agree that no records/data will be destroyed without the written consent of both the parties.

(iv) **Protocol deviations**: The parties agree that it shall be the responsibility of the Principal investigator to use continuous vigilance to identify and report protocol deviations within 7 working days of identification of the protocol deviation. *The* deviations if any from the planned protocol, shall be placed before the Ethics committee of MGMIHS. If any adverse effects are notices the adverse effects need to be informed to the Ethics committee for research on human subjects. The decision of the Ethics Committee shall be final.

(v) All deviations will be addressed in study source Documents/protocol.

(vi) Publication and data sharing policy: The parties agree that all publication shall be a joint publication and due weightage shall be given to both the parties.

(vii) The data collected from the MGM Hospital of Navi Mumbai, will be the sole property of the MGMIHS. At the end of the study, one or more manuscripts for joint publication may be prepared in collaboration between the Investigator(s) MGMIHS and the MYB.

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(viii) Any publication of results must acknowledge all sites/centers, this being the multicentre project. The other site/center being MGM Medical Hospital Aurangabad. The results from other site must be reported in entirety in a responsible and coherent manner and results from subsets should not be published in advance or without clear reference to the primary publication of the entire study.

(ix) The parties agree and accept that MGMIHS and MYB have the right to publish data of the study independently. MGMIHS will include name of MYB in its publications and MYB will include the name of MGMIHS in their publication.

(x) If the matter considered for publication is deemed patentable by the MYB due weightage should be given to MGMIHS the name of MGMIHS will be in the Patent as a co-investigator however they will not share any revenue with MGMIHS as it a soft wear that has been put together by MYB , MGMIHS is only validating. The soft wear MYB will give the soft wear free for use to MGM Group Of Hospitals for covid -19 Patient diagnosis.

(xi) MGMIHS retains its ownership of the data related with patients of Covid19 for the use by MGMIHS stake holders for the research and other purposes.

6. **NOTICES**

Any notices given under this Agreement will be in writing and delivered by e-mail or speed post or by hand addressed to the parties as follows:

MGMIHS:-

Address: Sector 1, Kamothe Navi Mumbai-410209, Tel No: 022-27432471 / 27432994
Fax: 022-27431094
Email: mgmuniversity@mgmuhs.com / mgmuniversity@yahoo.co.in

MORE-YA BIOSCIENCES

Director of More-YaBiosciences.
Sr.No.71/72, Sneh Park Co-operative Hsg.Society, Baner, Pune,
Maharashtra - 411045, **INDIA,**
TEL.: 9890765555 E-MAIL: vgore@more-ya.com

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Kamothe, Navi Mumbai - 410209

7. MISCELLANEOUS

a) Assignment

Neither party may assign this MOU or the rights their under without the prior written consent of the other party.

b) Severability

If any provision of this MOU becomes or is declared illegal, invalid, or unenforceable, such provision will be divisible from this MOU and will be deemed to be deleted from this MOU. If such deletion substantially alters the basis of this MOU, the parties will negotiate in good faith to amend the provisions of this MOU to give effect to the original intent/object of the parties under this MOU.

c) Order of Precedence.

In the event of any inconsistency between the terms of this MOU and the documents referenced or incorporated herein or any other document, correspondence or MOU concerning this Project between the Parties and/or their employees, the terms of this MOU will prevail.

d) Entirety.

This MOU represents the entire agreement and understanding between the parties with respect to its subject matter and supersedes any prior and/or contemporaneous discussions, representations, or agreements, whether written or oral, of the parties regarding this subject matter.

e) Amendments.

The Amendments or changes to this MOU must be in writing and signed by duly authorized representatives of both the parties. No amendment or modification of this MoU shall be valid unless the same is made in writing by both the parties or their authorized representatives and specifically stating the same to be an amendment of this agreement. The modification/changes shall be effective from the date on which they are made / executed unless otherwise agreed to.

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f) Independent Entities.

MGMIHS and MYB are independent parties and neither is an agent, joint venture partners, or partner of the other.

g) Dispute Resolution.

In event of dispute or claim between the parties concerning the interpretation of any provision of this agreement or the performance of any of the terms/obligations of/under this Agreement, such matter or matters in dispute shall be first settled amicably by mutual discussion between the Vice Chancellor / Registrar of MGMIHS and MYB failing which through the Arbitration process. Both the parties after due discussion shall appoint an Arbitrator for resolving the dispute arising out of this Agreement. The Arbitration shall take place in Navi Mumbai.

Now, therefore, for and in consideration of the foregoing premises the parties have signed the Memorandum of Understanding on 30th Nov., 2020. **PARTIES**

Dean	Director
MGM MEDICAL COLLEGE & HOSPITAL **CONSTITUENT UNIT OF** **MGM Institute Of Health Sciences,** **(Deemed to be University u/s 3 of UGC Act 1956)** Grade "A" Accredited by NAAC Sector 1, Kamothe, Navi Mumbai – 410209	**Varun Gore** **MORE-YA BIOSCIENCES** Sr.No.71/72, Sneh Park Co-operative Hsg. Society, Baner, Pune, Maharashtra - 411045. E-mail: vgore@more-ya.com Website: www:more-ya.com

Registrar
MGM Institute of Health Sciences
(Deemed to be University u/s 3 of UGC Act 1956)
Grade "A" Accredited by NAAC, Sector 1, Kamothe, Navi Mumbai – 410209

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Kamothe, Navi Mumbai - 410209

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भारतीय गैर न्यायिक

एक सौ रुपये Rs. 100

रु. 100 ONE HUNDRED RUPEES

भारत INDIA

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA ◐ 2020 ◐ YT 419061

29 JUL 2021

खरेदीचा दिनांक
उपलब्धतेचे नांव-रायगड,
जि. रायगड.

उप कोषागार अधिकारी
रायगड - रायगड

MEMORANDUM OF UNDERSTANDING

Between

Chief Executive Officer, Zilla Parishad,Alibag, District-Raigad& District National Tuberculosis Elimination Programme Society, Alibag, District-Raigad.

AND

MGM Medical College & Hospital, Kamothe, Tal- Panvel, District- Raigad

This MOU is executed on 1st April 2021 between **CHIEF EXECUTIVE OFFICER, ZILLA PARISHAD,ALIBAG, DISTRICT-RAIGAD & DISTRICT NATIONAL TUBERCULOSIS ELIMINATION PROGRAMME SOCIETY, ALIBAG, DISTRICT-RAIGAD** having its office at Parijat Society, Raiwadi Complex, Plot No.14, Shribag, Tal Alibag, Dist. Raigad Pin 402201 (Hereinafter called **"the Grantor**, which expression shall unless exclude by or repugnant to the context include its successors in-interest, executors, administrators and legal representatives) And **MGM MEDICAL COLLEGE & HOSPITAL, KAMOTHE, TAL PANVEL, DIST. RAIGAD** hence forth referred to as PPP Partner, having its office at Plot No.1and 2, Sector-1,Kamothe, Tal Panvel, Dist. Raigad acting through its Hereinafter called **"the Grantee**", which expression shall unless excluded by or repugnant

st. Tuberculosis Officer
Raigad-Alibag

Dr. Kiran Patil (I.A.S.)
Chairman
District Integrated Health & Family Welfare Society, Raigad
Chief Executive Officer

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to the context include its successors it, interest, executors, administrators and legal representatives).

WHEREAS the Grantor plans to implement "NTEP (National Tuberculosis Elimination Programme) i.e.District DR. TB center with Indoor & Outdoor facilities through Grantee on partnership (PPP partner).

AND WHEREAS the Grantor has agreed to engage the services of the Grantee, subject to terms and as hereunder.

1. D.DR.TB center (~~under~~ Indoor): The activities would be implemented in the District/s of **Raigad, Maharashtra** for performance of the following activities in accordance with NTEP policy;

2. Project Location

The PPP Partner would be providing the services as specified above at the following location/ (s) as decided in consultation with concerned CTO/DTO.

a. Urban/ Rural: **Urban/ Rural.**
b.District/TU/Block/(s):**Whole Raigad District including Panvel Corporation Area.**
c. Urban Wards/ Panchayats covered: Yes.
d. Population Covered: App. 30 lacs.

3. Period of Co-operation:

The PPP Partner agrees to perform all activities outlined in the guideline for partnerships in above mentioned area. The duration of cooperation will be fromday signing of MOU or the day of the starting the activity / function whichever is later.

Contract assigned for a period of three year **1st April 2021 to 31st March 2024**, renewable as per the needs of the programme, subject to satisfactory performance. The contract should be renewed every year on 1st April. The Contract can be terminated by the District Health Society/ State Health Society or the PPP Partner any time with one month prior notice by either side.

4. Terms, conditions and specific services during the period of the MOU.

A. The District Health Society shall (please strike out whichever is not applicable)

i. Provide financial and material support to the PPP for carrying out the activities as mentioned in the partnership guideline.
ii. Provide relevant copy of technical guidelines, updates, manuals & circulars, etc.)

iii. Provide NTEP drugs, logistics and laboratory consumables for use as per NTEP policy as outlined the partnership guideline.

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Dr. Kiran Patil (I.A.S.)
Chairman
District Integrated Health & Family Welfare Society, Raigad
Chief Executive Officer

iv. Periodically review the performance and activities being undertaken by the PP Partner

B. MGM will: -

i. Perform all activities as agreed upon and signed under the partnership as mentioned below.

1. Institute should be tertiary care hospital with the pulmonologist will be available round the clock.
2. Separate designated clinic for MDR TB patients management should be available and comply with the National Guidelines for Air –borne infection control for outpatient settings
3. Relevant specialists like Pulmonologist, Physician, Psychiatrist, Dermatologist & gynecologist etc should be available.
4. D.DR.TB center Committee to be formed with the above group of doctors.
5. To renovate (in keeping with the National Airborne Infection Control Guidelines and National Guidelines for Programmatic Management of Drug Resistant TB (PMDT) provided for the purpose) and designate a special clinic area designated for MDR TB out patient service with earmarked well ventilated preferably open air waiting area separate from other waiting areas, away from clinics managing immune suppressed and vulnerable cases where the patients who will be eligible to avail D.DR.TB services under NTEP will be fast tracked, segregated and counseled in accordance with NTEP guidelines.
6. Doctors and Nursing staff should be available from institute round the clock consultation services made available , if required by the patients.
7. Management of adverse drug reactions (ADRs) as per National PMDT Guidelines.

Indoor D. DR. TB Center scheme :

The terms and condition are as follows.

1. To designate a special ward compliant with national AIC guidelines and at least 10 beds earmarked for indoor management of DRTB patients according to National PMDT Guidelines.
2. Routine clinical laboratory investigation facility to be made available for pretreatment evaluation and monitoring.
3. Doctors and Nursing staff should be available from institute round the clock to the DRTB patients.
4. **Ancillary drugs should be provided by MGM Hospital as per DR TB center Committee's advised services / facilities to diagnose and manage adverse drug reaction (ARDs) as per National PMDT Guidelines.**
5. Services /facilities to diagnose and manage the comorbid condition
6. Records and reports to be maintained for PMDT registration, follow up, referral and transfer (if required) \of patients as per guidelines update the same on the day basis using Nikshay.
7. Quarterly reports to be submitted electronically.

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Kamothe, Navi Mumbai - 410209

Dr. Kiran Patil (I.A.S.)
Chairman
District Integrated Health & Family Welfare Society, Raigad
Chief Executive Officer
Raigad Zilla Parishad, Alibag

8. All doctors in the hospital should be following Standards for TB care in India and notify all TB cases through Nikshay.
9. Ensure coordination with implementing District officers and staff as well as laboratory for proper follow up of patients till outcome.
10. The Drug Resistant Tuberculosis Patients seeking treatment at DRTB Centre of MGMIHS will not be charged for any & all complications related to the tuberculosis (e.g. Pneumothorax, Hemoptysis, Respiratory Failure)

    However any emergency not connected / related to tuberculosis requiring intervention (e.g. stroke, acute myocardial infarction, acute kidney injury, D.K.A., Dialysis). The expenses should be borne by patient.
11. The diagnostics services to be provided by the partner organization would include at least.

Sr. No.	Investigations	Minimum No. of times test will be done	Rate for tests (In Rs.)
1	Complete Blood Count (CBC)	1	138
2	Blood Sugar (RBS)	1	25
3	LFT. (SGOT/SGPT/Billirubin)	1	275
4	Blood Urea Nitrogen (BUN)	1	55
5	Serum Creatinine	1	56
6	TSH	6	125
7	Urine Routine & Microscopy	1	39
8	Urinary Pregnancy Test (UPT)	1	69
9	Chest X-Ray	3	70
10	ECG	1	100
11	Sr. Electrolytes	1	365
12	Audiometry (PTA)	1	120
13	ESR	1	65
14	Sr. Uric Acid	1	70
15	Urea	1	105
16	HIV	1	75
17	HBSAG	1	130
18	HCV	1	275
19	Sr. Magnesium	1	300
20	USG-Abdomen & Pelvis	1	265
21	Sr. Calcium	1	70
22	Renal Function Test (RFT) With Electrolyte	1	440
23	Indoor stay for maximumdays	7days	
24	Bed Charges, Meals, Breakfast etc.	Included.	
25	Ancillary drugs for management \of adverse drug reaction and co morbidities	As required	

12. The DR TB Centre cannot deny services to any eligible patient from the geographical area assign to the centre.
13. This does not restrict the DR TB Centre from extending any further services to the patients,if clinically deemed necessary.

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Raigad-Alibag

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MGM Medical College & Hospital

Dr. Kiran Patil (I.A.S.)
Chairman
District Integrated Health &

14. DR TB Centre committee doctors will have to be trained in PMDT at National Level.
15. Management of MRD/XRD TB patients is to be done as per NTEP Guidelines second line anti TB drugs will be provided from NTEP.
16. The performance review of the PPM partner would be done bi annually and in case lack of satisfactory performance the contract may be terminated by either party with one month written notice.

5. Grant-in-Aid

The reimbursement of bills of indoor DRTB patients will be done by the District National Tuberculosis Elimination Program society, Raigad under NHM District Health Society after submission of monthly bills of indoor patient by the MGM Medical College Hospital, Kamothe, Tal Panvel, Dist. Raigad to the Office of District Tuberculosis Officer, Raigad (Parijat Society, Raiwadi Complex, Plot No.14, Chendhare, Shreebag No.2, Alibag, Dist. Raigad.

Sr. No.	Service Name	Rates per day	Remarks
1)	Consultation Charges OPD	Rs.200/- One Time per patient	For Consultation (One Time)
2)	IPD Specialist Visit Charges (Consultation Charges)	Rs.250/- per day per patient	For Specialist Visit (Consultation Charges)
3)	Indoor Charges Package Cost Per day	Rs.1000/- per day per patient	Include Pre-Treatment Evaluation (As per List) Bed Charges, Meals, Breakfast and Ancillary drugs etc.
	Total Rate for one patient for one day	Rs.1450/- per day per patient	Patient should not be charged at any cost for MDR TB Indoor treatment

Note:-1) From 2nd day onwards charge will not exceed Rs.1250/- per day per Indoor patient.
2) Indoor Charges Package Cost per day (if Pre-treatment evaluation done outside) is Rs.800/- per day per patient.

1. Package cost per day for admitted MDR-TB Patients will be Rs.1000/- including pre-treatment evaluation (as per above list), bed charges, meals, breakfast and all necessary ancillary drugs etc.
2. In house Specialist Consultation charges would be applicable at Rs.250/day/per patient for indoor patients.
3. Rs.800/- per day if pre treatment investigation is done at the district level or outside and patient is admitted to the ward hospital.
4. To provide Training, formats and registers for PMDT.
5. To Provide access & training to NIKSHAY for online data management and patient tracking.

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6/9/2021
Dist. Tuberculosis Officer
Raigad-Alibag

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

Dr. Kiran Patil
Chairman
District Integrated Health & Family Welfare Society, Raigad
Chief Executive Officer
Raigad Zilla Parishad, Alibag

6. Fund Management.

Funds under this MOU shall be placed at the disposal of the Grantee in separate account opened by it, subject to its furnishing to the Grantor a letter of commitment containing such conditions as may be approved by the Grantor from the bank that the bank shall not exercise a lien over the said account or may right to set off or adjust any amount due to payable under any loan or credit arrangement which the Grantee may be having or may have with the bank against the amounts standing to the credit of the Grantee in the said amount.

The Grantee shall install and maintain separate books of accounts on cash basis accounting along with proper vouchers for expenditure incurred and with details of outstanding liabilities, if any. The Grantor shall have the right to inspect by its authorized officers of independent agencies the books of accounts and other records relating to the project fund kept by the Grantee any time during the agreement period or thereafter.

7. Grievance Redressal Mechanism

All grievances will be addressed within a period of thirty days by DTOof the concerned district. Final decision will rest with district Health Societies. Annual review would be a platform for addressing grievance of PPM partners.

8. Right over Information/data

All documents, information, statistics and data collected by the Grantee in the discharge of the obligation under the MOU incidental or related to it (whether or not submitted to the Grantor) shall be the joint property of the Grantor, and the Grantee.

9. Indemnity

The Grantee hereby agrees to always keep the Grantor indemnified and harmless from all claims /demands / action and proceedings which may arise by reason of any activity undertaken by Grantee if the activity is not in accordance with the approved guidelines.

This MOU shall be enforceable in courts situated at [Mumbai, Maharashtra] ; any suit or application for enforcement of the above shall be filed in the competent court at Mumbai and no other district of Maharashtra or outside Maharashtra shall have any Jurisdiction in the matter.

10. Termination Mechanism

The partnership may be terminated by either side through written notice of one month. In case services of PPM partner are discontinued, unspent balance, if any will be refunded by the partner.

If the Grantor at any stage decides that the Grantee has misutilised the amounts (or any part thereof) already received from the Grantor or has fraudulently claimed any covenants, stipulation or obligations hereunder a commits a breach of any of the terms, conditions or provision of this MOU on its part to be observed and performed, or it at any stage reasonable ground exist to apprehend the breach of

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Dist. Tuberculosis Officer
Raigad-Alibag

Dr. Kiran Patil (I.A.S.)
Chairman
District Integrated Health &
Family Welfare Society, Raigad

the terms and condition of the MOU in future or that the continuance of this project may be prejudiced or be in jeopardy he/she may revoke this MOU wholly or partially and ask the Grantee to refund the amount received till then along with interest accrues, if any after giving at least fifteen days' notice and an opportunity of being heard to the Grantee.

11. The programmatic and financial review of the partnership will be conducted every quarter.

12. Necessary approval of State Health Society has been obtained: Yes

M.G.M. MEDICAL COLLEGE NEW MUMBAI 410209 KAMOTHE

Signature of authorized signatory
Dr G. S. Narshetty
Dean,
MGM Medical College & Hospital,
Kamothe, Navi Mumbai.

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

Seal

Signature of authorized signatory
Chief Executive Officer, Zilla Parishad
Raigad & District National Tubersulosis Elimination Programme Society,
Alibag, District Raigad.

Dr. Kiran Patil (I.A.S.)
Chairman
District Integrated Health & Family Welfare Society, Raigad
Chief Executive Officer
Raigad Zilla Parishad, Alibag

Dist. Tuberculosis Officer
Raigad-Alibag

9

M O U
between

National AIDS Control Organisation, Ministry of Health and Family Welfare, Government of India

&

Mahatma Gandhi Mission's Medical College & Hospital, Kamothe, Navi Mumbai -410 209

This Agreement is made on 1 day of December 2018 by and between Ccompetent Authority, National AIDS Control Organisation, Ministry of Health and Family Welfare, Government of India, 9th Floor, Chandralok Building, 36, Janpath, New Delhi 110 001 (hereinafter referred to as "NACO (First Party) ")

AND

Mahatma Gandhi Mission's, Medical College, Navi Mumbai (hereinafter referred to as ("Second Party"), run by Mahatma Gandhi Mission, a Public charitable Trust bearing registration number - F- 674(Nanded) having its registered office at – Nanded acting through Dean, MGM Medical College, Kamothe, Navi Mumbai – 410 209, the authorised signatory, hereinafter referred to as "Second Party", which expression shall, unless repugnant to the context, include its successor in business, administrators, liquidators and assigns or legal representatives.

WHEREAS NACO (first Party) is providing first line antiretroviral treatment (hereinafter referred to as ART) to persons living With HIV/AIDS (hereinafter referred to as PLHAs) in India through designated public hospitals as per the guidelines issued by the NACO (first Party) from time to time:

AND WHEREAS NACO (first Party) coordinates the aforementioned provision of ART at designated public hospitals by limiting the selection, procurement, distribution and rational use of drugs, including antiretroviral drugs, and prescribing guidelines for treatment of opportunistic infections and provision of ART;

AND WHEREAS NACO (first Party) is desirous of extending the provision of ART to more PLHAs in collaboration with not-for-profit non-governmental organisations;

Draft approved
① Noted for Update 24/12/18
② MS.
③ Dean.

AND WHEREAS Mahatma Gandhi Mission's, Medical College, Navi Mumbai (hereinafter referred to as ("Second Party") an Organization registered under the MGM Trust Registration. It has established a centre to extend AIDS related treatment, care and other services to its employees and their families living with HIV/AIDS and to extend these services to PLHA's in the nearby areas as a part of their corporate social responsibility;

AND WHEREAS the parties hereto had set up a collaborative ART project since 01/12/2018 (*month & year)* and hereby reduce the terms of the agreement to writing;

NOW THEREFORE THIS AGREEMENT WITNESSES AS FOLLOWS:

I. PURPOSE OF COLLABORATIVE ART PROJECT

The purpose of the present Agreement is to continue the collaborative ART project between NACO (first Party) and second Party that had been a model for high quality provision of ART and associated healthcare and medical management of PLHAs in Maharashtra, India.

II. RESPONSIBILITIES OF NACO

1) NACO (first Party) shall continue to organize refresher training or provide support for training of personnel of second Party involved in the collaborative ART project.

2) NACO (first Party) shall provide to second Party regular updates on National ART guidelines from time to time as earlier.

3) NACO (first Party) and second party shall form a committee comprising of representative from NACO (first Party), Nodal Officer / Director of second Party, which shall supervise and monitor the collaborative ART project to ensure provision of quality services.

4) NACO/SACS will continue to provide drugs on a [three] monthly basis on receipt of a requisition/s from second party and certificate of utilization of drugs in a prescribed format supplied earlier.

III. RESPONSIBILITIES of second party

Second party had set up a centre at MGM Medical College & Hospital, Kamothe Navi Mumbai, Maharashtra State and has appointed Dr. Umakant Deshpande, as Nodal Officer for the official contact for the collaborative ART Project.

1) Second party represents that it provides various health services to PLHAs, a description of which is set out at Schedule III to the present Agreement.

2) Second Party undertakes that it will comply with all the laws for the time being in force in India in the running of the ART centre as done earlier. Second Party has obtained all necessary government approvals and have appointed the necessary staff with the requisite technical qualifications.

3) Second Party strictly follows the National ART guidelines (drug regimen as well as physical standards) issued by NACO (first party) from time to time, follow the terms of reference for staff including qualifications as specified by NACO (first Party) and has ensured that mechanisms needed for good treatment adherence are in place.

4) Second party shall respect the autonomy and privacy of the patients, and to this end provides pre- and post-test counseling, obtains written informed consent from the patient prior to a test or treatment, and maintains confidentiality of the patients on the principle of shared confidentiality.

5) Second Party shall provide for data protection systems to ensure that the confidential records of the patients are computerized and are protected so that they are not accessible to any unauthorized person.

6) Second Party shall provide a copy of all medical records to the patients on their request.

7) Second Party shall provide all health services related to provision of ART and treatment of opportunistic infections, including those listed in Schedule III, free of cost to patients who require treatment. Second Party shall not deny services to any person living with HIV on any ground. The ARV drugs used for community will be supplied by NACO/SACS.

8) Second Party shall maintain all the registers and reporting formats as per NACO (first party) ART guidelines. They will send report of all adverse drug reactions to NACO (first party).

9) Second Party shall use standard NACO (first Party) Monitoring and Evaluation tools.

10) Second party shall provide standard, regular monthly reports of patient numbers and relevant details for the previous month to NACO (first party) by the 4th of each month in prescribed formats in accordance with the guidelines laid down by NACO (first Party) from time to time. NACO (first Party) will be free to use the data so sent to them in an anonymous manner.

11) Second party shall provide details of the ART team at their centre along with the names and technical qualifications of the staff in case of any change to NACO (first party) from time to time.

12) Second party shall entirely bear the costs related to the staff's salary (doctors, counselors, pharmacist, nurses, medical records officer and administrative staff) and the cost related to the infrastructure. Second party represents that it has enough funds to run the programme for the next three / five years. Second party will permit NACO (first party) to inspect its documents relating to the balance sheets, profit and loss accounts, grants and donors, financial and other documents so that NACO (first party) can verify the representation of sustainability of the collaborative ART project.

13) NACO/SACS will provide drugs for ART on receipt of a requisition/s from second party and certificate of utilization of drugs in a prescribed format supplied earlier.

14) Second party has already established a network with NGOs involved in HIV care and support as well as with the Indian Network for People Living With HIV/AIDS or PLHA groups in the area for increasing access to treatment and for follow-up support.

15) The designated representatives of second party shall continue to attend the coordination meeting with NACO (first party) at their own costs.

16) Second party shall not permit research or clinical trial, whether relating to the allopathic system of medicine or any alternate system of medicine or any combination thereof, at the designated ART centre, except with the approval of the Drugs Controller General of India for the conduct of such clinical trial. Further, in the event of an approved clinical trial, the Party of the Second Part will ensure that ethical protocols are complied with.

17) Use of any data obtained by second party during the course of its collaborative ART project shall be done in an anonymised manner such that the identity of the patients enrolled at the collaborative ART project is not revealed in any manner.

18) Second party shall maintain the records for a period of five years from the time that this Agreement is terminated or lapses by efflux of time.

19) Second party shall constitute a grievance redressal mechanism. ***[A model grievance redressed mechanism is annexed hereto.]*** Further, second party shall forward to NACO (first party) in an anonymised manner the nature of complaints received and action taken thereon on a monthly basis.

20) Second party shall continue to provide space, CD 4 machine and staff for the ART center.

IV. COMMENCEMENT

1) This Agreement shall become effective upon signature by both the Parties and It shall remain in full force from the last date of renewal till completing of 3 yrs of agreement.

V. RENEWAL OF AGREEMENT

1) This Agreement is renewable at the option of NACO (first party) and second party.

2) Six months prior to the expiry of the Agreement due to efflux of time NACO (first party) shall intimate second party if it intends to renew or not to renew the Agreement.

3) In the event that second party decides not to renew the Agreement, second party shall intimate three month in advance to NACO (first party) about its inability to continue to provide treatment free of charge to the patients enrolled. If second party fails to continue to provide treatment free of charge or expresses its inability to do so, they shall give notice to the patients and NACO (first party) about this and refer the patients to the nearest government hospital providing treatment for opportunistic infections and ART, as directed by NACO (first party). Further, upon such referral, second party shall forthwith forward a copy of all medical records of the patients to such hospital and to NACO (first party) or a person designated by NACO (first party) to receive such medical records. Thereupon, NACO (first party) will be responsible for ensuring that the patients continue to receive the drugs.

4) In the event that NACO (first Party) desires to renew the Agreement, the terms and conditions of this Agreement, as may be amended, will apply *de novo*. It is made expressly clear that in that event, second party will have to re-apply for and re-obtain certification.

5) Both parties shall ensure that there is no treatment interruption of the patients.

VI. TERMINATION OF AGREEMENT

1) The second party shall ensure that the infrastructure and manpower at centre is provided as per operational guidelines and in event of any deficiencies / reduction/withdrawal of space or staff, NACO (first party) (GOI) will exercise its option to terminate the agreement unilaterally

2) Any party may terminate this Agreement without giving any reasons after giving three months notice to the other party at the address provided in this Agreement for correspondence or the address last communicated for the purpose and acknowledged in writing by the other party.

3) On such notice of termination being received by any party, second party shall intimate NACO (first party) about its inability to continue to provide treatment free of charge to the patients enrolled. If second party cannot continue to provide treatment free of charge, they shall give notice to the patients and NACO (first party) about this and refer the patients to the nearest government hospital providing treatment for opportunistic infections and ART, as directed by NACO (first party). Further, upon such referral, second party shall forthwith forward a copy of all medical records of the patients to such hospital and to NACO (first party) or a person designated by NACO (first party) to receive such medical records. Thereupon, NACO (first party) will be responsible for ensuring that the patients continue to receive the drugs.

VII. BREACH BY second party

1) In case second party is not able to provide services as per agreement or defaults on the provision of this Agreement or declines the patients to provide medication or directly or indirectly makes any charges for the treatment of opportunistic infections or ART or otherwise enters into any malpractices, it shall be liable for breach of agreement and breach of trust and other consequences which may include black listing with NACO (first party), MOHFW, Ministry of Home affairs and External Affairs. This action shall also be intimated to their parent/ International NGO also for necessary action by them.

2) If second party is found to have made any charges for the treatment which was to be given free of charge under this Agreement or to have not provided the medicines to the named patients or to have otherwise misappropriated the funds or goods released by NACO (first party) to second party, then without prejudice to any other right or consequence or mode of recovery, NACO (first party) may recover the amount thereof from second party and/or its office bearers as arrears of land revenue.

VIII. SETTLEMENT OF DISPUTES

1. Any dispute or difference or question arising at any time between the parties hereto arising out of or in connection with or in relation to this Agreement shall be referred to and settled by arbitration under the provisions of the Arbitration and Conciliation Act, 1996 or any modification or replacement thereof as applicable for the time being in India.

2. The arbitration shall be referred to an arbitrator nominated by Secretary Department of Legal Affairs, Ministry of Law and Justice, Govt. of India Delhi. The Arbitrator may, if he so feels necessary, seek opinion of any health care personnel with experience of working in the field of HIV and care and treatment of PLHAs.

3. The place of arbitration shall be either New Delhi or the site of the collaborative ART project, which shall be decided by the arbitral tribunal bearing in mind the convenience of the parties.

4. The decision of the arbitrator shall be final and binding on both the parties.

LAW APPLICABLE.

This Agreement shall be construed and governed in accordance with the laws of India.

IX. ADRESSES FOR CORRESPONDENCE

In witness thereof, the parties herein have appended their respective signatures the day and the year above stated.

Signed For and on behalf of	Signed For and on behalf of
Mahatma Gandhi Mission's, Medical College, Navi Mumbai (Dr. Umakant Deshpande Nodal Offi Dr U. N. Deshpande Associate Professor Medicine Dept. MD Medicine MGM Medical College & Hospital Kamothe Reg. No. 32248 Signature Date...1-1-2019.. In the presence of Name and Signature (Mrs. Harapriya Kar) Date ...1/1/2019.....	Competent authority NACO Signature ..... Date..... In the presence of Name and Signature ..... Date.....

[In case the contract is entered into by the President through the NACO, this needs to comply with the Rules of Business laid down in this behalf.] : Competent Authority , NACO

SCHEDULE I

MODEL LIST OF DRUGS TO BE PROVIDED BY NACO TO Second Party

S.no	LIST OF ARV DRUGS
	Adults
1.	Zidovudine300mg + Lamivudine 150mg
2	Zidovudine300+Lamivudine150+Nevirapin200
3	Tenofovir 300 mg+ Lamivudine 300 mg+ Efavirenz 600 mg
4	Tenofovir 300 mg+ Lamivudine 300 mg
5	Nevirapine tablet/Suspension 200 mg/50 mg
6	Efavirenz 200 mg, 600 mg
7	Lopinavir 400 mg /ritonavir 100 mg
8	Atazanavir 300 mg/ ritonovir 100mg
	Paediatric
9	Tablet.Zidovudine 60+ Stavudine 30
10	Tablet.Zidovudine 60+ Stauvudine 30+Nevirapine 50
11	Tablet.Abacavir 60+ Lamivudine30
12	Tablet.Efavirenz 50 mg
13	Lopinavir/ ritonovir 100/25 tablet
14	Lopinavir / ritonovir syrup

SCHEDULE II

MODEL FOR A ONE YEAR AGREEMENT

Year	Centre	Number of PLHAs for whose treatment stock is to be provided
2018-19		

SCHEDULE III

MODEL OF DESCRIPTION OF SERVICES PROVIDED / PROPSOED TO BE PROVIDED

Address of site	Mahatma Gandhi Mission's, Medical College, Kamothe, Navi Mumbai
Outpatient	As per Statistics attached
Days	Monday to Saturday
Timings	08.30 am to 03.30 pm(As per hospital timings)
Inpatient care	24 Hours
Number of patients registered	As per Statistics attached
Number of patients receiving ART	As per Statistics attached
Average number of patients attending OPD everyday	As per Statistics attached
Criteria followed in administering ARVs	As per NACO Guidelines
Treatment for OIs	As per NACO Guidelines
First line regimen	TLE/EFV
Description of follow-up of patients	As per NACO Guidelines
Facilities available	As per NACO Guidelines for ART Center
Personnel and their qualifications	As per NACO Guidelines for ART Center

ANNEXURE

MODEL GRIEVANCE REDRESSAL MECHANISM

[Note: This portion has been taken from the draft law on HIV/AIDS and it would be advisable for MGM Medical College & Hospital, Navi Mumbai *to constitute a grievance redressal mechanism at the outset.]*

(a) Second party shall appoint a person of senior rank, working full time in the organisation, as the Complaints Officer, who shall, on a day-to-day basis, deal with complaints received from an aggrieved person or an authorised representative of such person.

(b) Every aggrieved person or an authorised representative of such person, who has a grievance against the second party about the services provided or refused, has the right to approach the Complaints Officer to attend to such complaint and shall be informed of such rights by second party.

(c) The Complaints Officer may inquire *suo motu*, and shall inquire, upon a complaint made by any aggrieved person or authorised representative of such person, into the complaint.

(d) The Complaints Officer shall act in an objective and independent manner when inquiring into complaints made.

(e) The Complaints Officer shall inquire into and decide a complaint promptly and, in any case, within seven working days. Provided that in cases of emergency, the Complaints Officer shall decide the complaint within one day.

(f) The Complaints Officer, if satisfied that there has been an unfair/arbitrary refusal of services or deficiency in the services provided, shall (i) first direct second party to rectify the cause of the grievance, (ii) then counsel the person alleged to have committed the act and require such person to undergo training and social service. Upon subsequent violations by the same person, the Complaints Officer shall recommend to second party to, and the institution shall, initiate disciplinary action against such person.

(g) The Complaints Officer shall inform the complainant of the action taken in relation to the complaint.

Assistance to ART Centres in various sectors under NACP

Component	Public Health Sector	Remarks
	Medical Colleges, Distt. Hosp.	
Land	Available	
Infrastructure Development	√	Under NACP-III
Equipment (CD4 machine)	√	
Additional Human Resources	√	
Diagnostic Kits (HIV/CD4)	√	
ARV Drugs (First Line)	√	
Drugs for Opportunistic Infections	Can be done as per cost effective/ Govt rates	
Training of key personnel	√	TA/DA by sponsoring agency
IEC material	√	
Operational Costs	√	

10

HEALTH INDIA's Copy

Health India TPA Services Pvt. Ltd.

HEALTH INDIA™
TOWARDS GOOD HEALTH

(T.P.A License No. 022)

Anand Commercial Co. Compound, 103 – B, L.B.S. Marg, Gandhi Nagar, Vikhroli (W), Mumbai – 400 083
Tel :-022 6686 7575 (80 Lines) Fax:-022 4247 1911/ 1957 * Email – provider@healthindiatpa.com * Website : www.healthindiatpa.com

SERVICE AGREEMENT

This Service Agreement made at Kamothe on dated 06/09/2014 between **HEALTH INDIA TPA SERVICES PVT. LTD.** a company duly registered under The Companies Act, 1956, located at Commercial Union House, 2nd floor, Wallace Street, Fort, Mumbai-400001, hereinafter referred to as '**HEALTH INDIA**' (which expression shall unless it be repugnant to the context or meaning thereof shall deem to mean and include its successors and assignees) and MGM MEDICAL COLLEGE & HOSPITAL, KAMOTHE (Hospital / ~~Nursing Home~~ / ~~Day Care~~ Centre) hereinafter referred to as 'Provider' (which expression shall unless it be repugnant to the context or meaning thereof shall deem to mean and include its successors or assignees).

WHEREAS, **HEALTH INDIA** is a **Third Party Administrator (TPA)** providing Healthcare related services to its beneficiaries and clients and for this purpose **HEALTH INDIA** has created a network of service providers.

Health India TPA Services Private Limited agrees to provide the necessary medical services on the terms and conditions, hereinafter appearing:

It is now agreed by and between the parties as follows:

IDENTIFICATION

1. For the purpose of identification **HEALTH INDIA** shall provide each beneficiary with an Identity Card bearing his/ her recent photograph, name and date of birth or an Identity Card without photograph but bearing beneficiary's signature. The beneficiary will produce this card at the time of admission for the purpose of identification.

PROCEDURE FOR ADMISSION

2. Request for hospitalization should be made by the beneficiary / provider / consultant as per the admission format specimen provided (Hospitalization Request Letter). On receipt of such request and after due scrutiny, **HEALTH INDIA** will issue a **Payment Guarantee Letter (PGL)** specifying beneficiary's entitlement of benefits. The **PGL** will be either faxed to the Provider or hand delivered by the beneficiary and produced at the time of admission.
   The Provider will not provide cashless benefit to any HEALTH INDIA beneficiary without PGL.

3. The purpose of hospitalization and the monetary limit of expenses that could be incurred will be indicated on the Payment Guarantee Letter. In the event of anticipated expenditure exceeding the specified limit the Provider will inform **HEALTH INDIA** in advance and seek authorization for incurring additional expenses. In the event that **HEALTH INDIA** declines and / or fails to inform

HEALTH INDIA TPA SERVICES PVT. LTD.

DHI MISSION HOSPITAL

the Provider, the Provider may incur such additional expenses on its own account and recover the same, directly from the beneficiary.

4. If the expenses incurred are over and above the amount guaranteed by **HEALTH INDIA** in the **Payment Guarantee Letter**, the Provider will recover the same directly from the beneficiary / patient.

5. Expenses incurred by the beneficiary for non-medical items such as Special attendant charges, telephone, snacks, food and beverages etc. must be directly collected from the beneficiary. **HEALTH INDIA** will not be responsible for making payments for items mentioned above.

6. The Provider will arrange to supply all medicines; injections, surgical materials and disposable items required for treatment of the beneficiary and include them in the final bill stating cost of each item. In case the provider does not have the facility to provide such items the provider shall arrange to obtain such items from outside (submit pharmacy / medical store bill). For procuring such items the provider shall issue proper prescriptions on its letterhead mentioning the date, name and ID number of the beneficiary.

7. In case the Provider does not have facility to carry out some of the diagnostic tests required for treatment of the beneficiary, the Provider shall arrange to carry out these tests at other Diagnostic Centers and include the charges of such tests in the Final Bill, mentioning cost of each test. Requisition for such test should be made on hospital letterhead mentioning the date, name and ID number of the beneficiary (Diagnostic centers bill should be attached).

8. After the beneficiary is discharged from the Hospital, the Provider shall submit the following documents to **HEALTH INDIA** within 7 working days:
   - Final bill: It should mention details of charges payable for necessary medical services provided and also the units of each service as per the latest submitted & approved tariff. It should not include charges such as that of telephone, snacks, beverages, barber etc, which are not covered in the Insurance policy. **The beneficiaries' signatures should authenticate the bills.**
   - Original copies of investigation reports / prescriptions, pharmacy bills (along with original bills if done from outside).
   - Original discharge card summarising symptoms with their duration, clinical findings, investigations, overall treatment, diagnosis and follow-up treatment,
   - Claim form duly signed by the patient.
   - Any other documentary evidences statutorily required under the law.

PAYMENTS

9. All payments in respect of the Final bills will be made by **HEALTH INDIA** directly to the Provider within a period of 30 days from the date of receipt of the Final bill, along with all relevant documents mentioned in clause 8 of this Service Agreement.

GENERAL

MAHATMA GANDHI MISSION HOSPITAL * KAMOTHE *

HEALTH INDIA TPA SERVICES PVT. LTD.

Medical Superintendent

10. The Provider shall furnish to **HEALTH INDIA** the Detailed Schedule of charges for various services. The Provider will charge **HEALTH INDIA** beneficiaries on such rates that have been agreed upon. The Provider cannot change the rates without approval from **HEALTH INDIA**.
11. The Provider would ensure that the bills are in no way exaggerated. The Provider would ensure that there is no malpractice or fraud by itself, its doctors or by its staff.

12. **HEALTH INDIA**'s authorised representative / Doctor are entitled to visit and verify the record books of the Provider as and when necessary. The Provider agrees to extend necessary co-operation during such visits.

13. The Provider will have no objection for using its name, and other relevant material in advertisement, promotional literature, brochure, website etc. sponsored by **HEALTH INDIA**.

14. The **HEALTH INDIA** beneficiary will be provided medical treatment by the panel of consultants attached to the provider hospital according to the practice parameters and clinical protocols established by the provider.

15. **HEALTH INDIA** will not interfere in the treatment and medical care provided to its beneficiaries. **HEALTH INDIA** will not be in any way held responsible for the outcome of treatment or quality of care provided by the Provider.

16. The Provider shall alone be liable to pay any costs, damages and/or compensation demanded by the beneficiaries for poor, wrong or bad quality of the test reports or treatment given to the beneficiary by the Provider while executing the assignment of **HEALTH INDIA**.

17. The Provider undertakes to protect the secrecy of all data of **HEALTH INDIA** beneficiary/s and trade or business secrets of **HEALTH INDIA**, and shall not share the same with any unauthorized person for any reason whatsoever with or without any consideration.

18. This Agreement shall come into force with effect from the MOU Signed date and remain in force for a period of **Three years** until terminated by either party by giving to the other not less than two months prior written notice.

19. The schedule of charges submitted by the hospital will be applicable for a period of **two years**, with effect from the date of MOU Signed and any changes henceforth has to be on terms and conditions agreed between both the parties.

20. The Bill must be as per the agreed schedule of charges. Any higher amount will be deducted from the bill.

21. In the event of termination of the Agreement **HEALTH INDIA** will be responsible for payment of bills of **HEALTH INDIA** authorized beneficiaries admitted prior to the date of termination of this Agreement.

HEALTH INDIA TPA SERVICES PVT. LTD.

MAHATMA GANDHI MISSION HOSPITAL * KAMOTHE *

Medical Superintendent

Medical Superintendent
M.G.M. Hospital, Kamothe

HEALTH INDIA's Copy

22. I) Provider hereby agrees to give ~~15%~~ 0% discount on the total bill excluding medicines & consumables to **HEALTH INDIA** beneficiary. II) 17% as early payment discount (early payment discount will be valid if Health India pay the settled amount within 15 working days from the date of receipt of the final bill, along with all relevant documents mentioned in clause 8 of this service agreement).

23. Any disputes, claims arising out of this agreement are subject to arbitration and jurisdiction of Mumbai Courts.

24. Any amendments in the clauses of this Service Agreement can be effected as an addendum, after the written approval from both the parties.

In witness thereof this agreement was executed by or on behalf of the parties the day and year first before written.

Signed and delivered by the within named:

Provider MGM MEDICAL COLLEGE & HOSPITAL, KAMOTHE

Through Dr/ Shri./ Smt. Dr. K.R. Satpathy Sign

Date: 6/9/14

Medical Superintendent
M.G.M. Hospital, Kamothe

For

HEALTH INDIA TPA Services Pvt. Ltd.

Through Dr/ Shri./ Smt. Sabhajit Singh. Sign

Date: 23/02/2015

Regd. Office: Commercial Union House, 2nd Floor, 9, Wallace Street, Fort, Mumbai – 400 001.
Tel.: 2207 0869 / 2207 2482 * Fax: 91-22-2207 3204 * Email: contact@healthindiatpa.com *

தமிழ்நாடு तमिलनाडु TAMILNADU

13821
27.2.18

BN 638321

R. RAGUPATHI
STAMP VENDOR, LIC. C3/4839/83
No. 37, VILLAGE ROAD, NOW KNOWN
No. 79/81, VALLUVARKOTTAM HIGH RO
NUNGAMBAKKAM, CHENNAI-600 03
MOBILE: 9445114347

STAR HEALTH AND ALLIED INSURANCE CO. LTD. STAR CORPORATE OFFICE CHENNAI-34

MEMORANDUM OF UNDERSTANDING

Hospital Code: Hos-85952

This Agreement made Chennai this 2nd Aug 2019

BETWEEN

STAR HEALTH AND ALLIED INSURANCE COMPANY LTD., a Company incorporated under the Companies Act 1956 and having its Registered & corporate office at no 1 New Tank Street, Nungambakkam, Chennai-600 034, hereinafter referred to as {Star Health} which expression shall unless it be repugnant to the context or meaning thereof shall deem to mean and include its successors and assigns of the ONE PART.

AND

MGM Medical College Hospital and having its Registered office **Plot No: 1 & 2, Sector-1,Near Mumbai - Pune Express Highway,Kamothe,Navi Mumbai-410209,Maharashtra** hereinafter referred to as (PROVIDER) which expression shall unless it be repugnant to the context or meaning thereof be deemed to mean and include its successors and assignee's of the OTHER PART. WHEREAS, Star Health is an insurance company Licensed under IRDA to transact health, Accident and Overseas Medical Insurance, providing Healthcare Insurance coverage to its Clients (hereinafter referred to as "the Beneficiary") and for these purposes Star Health has created a network of service providers.

for Star Health and Allied Insurance Co.Ltd

Authorised Signatory

STAR HEALTH AND ALLIED INSURANCE CO. LTD. STAR CORPORATE OFFICE CHENNAI-34

Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE

MAHATMA GANDHI MISSION HOSPITAL KAMOTHE

WHEREAS

1. Provider means a hospital or nursing home or day care center (herein after referred as "Provider") duly recognized and authorized by appropriate authorities to impart heath care services to the public at large.

2. Insurer is registered with Insurance Regulatory and Development Authority to conduct insurance business including health insurance business.

3. Provider has expressed its desire to join Insurer's network of Providers and has represented that it has requisite facilities to extend medical facilities and treatment to beneficiaries as covered under Health Insurance Policies on terms and conditions herein agreed.

4. Insurer has on the basis of desire expressed by the Provider and on its representation agreed to empanel the Provider as empanelled provider/network provider for rendering complete health services.

DEFINITION

A. Health Services shall mean all services necessary or required to be rendered by the Institution under an agreement with an insurer in connection with "health insurance business" or "health cover" as defined in regulation 2(f) of the IRDA (Registration of Indian Insurance Companies) Regulations, 2000 but does not include the business of an insurer and or an insurance intermediary or an insurance agent.

B. Beneficiaries shall mean the person/s that are covered under the health insurance policy issued by the [insurance company].

C. Confidential Information includes all information (whether proprietary or not and whether or not marked as 'Confidential') pertaining to the business of the Company or any of its subsidiaries, affiliates, employees, Companies, consultants or business associates to which the Institution or its employees have access to, in any manner whatsoever.

D. Smart Card/identification card shall mean Identification Card for health insurance policy issued by the Insurer or by its representative TPA.

Now this agreement witnessed as under:

Article 1: Effective Date

1.1 The Parties hereby agree that the effective date of the Agreement shall be the date on which the agreement is signed. This agreement shall be in force until otherwise terminated as provided for in this MOU.

Article 2: General Provision

2.1.1 The Provider shall treat Star Health beneficiaries in a courteous manner and according to good business practices.

for Star Health and Allied Insurance Co.Ltd

Authorised Signatory

STAR HEALTH AND ALLIED INSURANCE CO. LTD. CORPORATE OFFICE CHENNAI

Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE

MAHATMA GANDHI MISSION HOSPITAL KAMOTHE

2.1.2 The Provider will extend priority admission facilities to the beneficiaries, whenever possible.

2.1.3 The provider will have his facility covered by proper indemnity policy including errors, omission and professional indemnity insurance and agrees to keep such policies in force during entire tenure of the agreement.

2.1.4 Provider shall ensure that the best medical treatment/ facility is extended to the beneficiary.

2.1.5 Provider shall endeavor to have an officer in the administration department assigned for insurance/contractual patient and the officers will eventually learn the various types of medical benefits offered by the different insurance plans.

2.1.6 Provider shall allow Star Health official to visit the beneficiary and also to check the indoor papers/treatment being given to the beneficiary. Star Health shall not interfere with the medical treatment of the patient. However the medical team of Star Health reserves the right to discuss the treatment plan with the treating doctor. Access to billing and medical records and indoor papers will be allowed to Star Health as and when necessary or asked for with prior appointment.

2.1.7 Provider agrees to display their status of preferred provider of Star health at their reception/admission desks along with the display and other materials supplied by Star Health whenever possible for the ease of Star Health beneficiaries.

2.1.8 Star Health also reserves right to inspect the premises of your hospital at any point of time without any prior intimation, for obtaining relevant information or to view the facilities available for the treatment of the beneficiary.

Article 3: Identification of Beneficiaries

3.1.1 The beneficiaries will be identified by the provider on the basis of an ID card issued to them bearing the logo and the wordings of Star Health. The ID card shall have photograph or signature or thumb impression of the beneficiary. In certain cases of large corporate where ID cards are not issued by Star health, Beneficiary may have only the Authority letter/Pre certification issued by Star health along with the employee ID of the corporate.

3.1.2 For the ease of the beneficiary, the provider shall display the recognition and promotional material, network status, and procedures for admission supplied by Star Health at prominent location, preferably at the reception and admission counter and Casualty/Emergency departments. A provider also needs to inform their reception and admission facilities regarding the procedures of admission and obtaining Preauthorization as per the article 4

3.1.3 It is desirable to take a photocopy of the ID card, to be submitted later with the bill or to keep as proof of the beneficiary being treated.

Article 4: Provider Services - Admission Procedure

4.1. Planned Admission

Request for hospitalization on behalf of the beneficiary may be made by the hospital provider/consultant attached to the provider as per the prescribed format. The preauthorization

for Star Health and Allied Insurance Co.Ltd

Authorised Signatory

Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE

form would need to give the beneficiary's proposed admission along with the necessary medical details and the treatment planned to be administered and the breakup of the estimated cost.

Authorization certificate will mention the amount guaranteed, class of admission, eligibility of beneficiary or various sub limits for rooms and board, surgical fees etc. wherever applicable, as per the benefit plan of the insured. Provider must take care to ensure admission accordingly.

4.2 Emergency admission

4.2.1 The Parties agree that the Provider shall admit the Beneficiary (ies) upon the production of the ID card issued by Star Health and shall ensure that no Beneficiary is required to make advance deposits of any amount as a precondition or condition of admission, when the Beneficiary is carrying a valid ID card issued by Star health.

4.2.2 In case of vehicular accident, if the victim was under the influence of alcohol or inebriating drugs, if detected or suspected, since the insurance benefit is not available, the provider shall treat the admission as per their normal practice and not under cashless or being entitled to indemnity from insurer.

4.2.3 In case of other emergencies, Provider upon deciding to admit the Beneficiary should inform/ intimate over phone immediately to the 24 hours Star Care Center helpdesk or the local/ nearest Star health office.

4.2.4 Star Health agrees and undertakes to have their medical team to get in touch within 8 hours of the provider telephonic intimation and issue the authorization for admission under cashless.

4.2.5 Immediately but not later than a period of 12 hours from the time of admission a preauthorization form is forwarded which would give the details like present illness/past history, diagnosis, and estimated cost of treatment along with first prescription collected from patient.

4.2.6 On receipt of the preauthorization form for the beneficiary giving the details of the ailments for admission and the estimated treatment cost which is to be forwarded within 12 hours of admission, Star Health undertakes to issue the confirmation letter for the admissible amount within 12 hours of the receipt of the preauthorization form.

4.2.7 In case the ailment is not covered or given medical data is not sufficient for the medical team to confirm the eligibility, Star Health can deny the guarantee of payment which shall be addressed to the Insured under copy to the Provider. The provider will have to follow their normal practice in such case.

4.2.8 Denial of Authorization/ guarantee of payment in no way mean denial of treatment. The provider is requested to deal with each case as per their normal rules and regulations

4.2.9 Authorization certificate will mention the amount guaranteed class of admission, eligibility of beneficiary or various sub limits for rooms and board, surgical fees etc. wherever applicable, as per the benefit plan of the insured. Provider must take care to ensure compliance.

for Star Health and Allied Insurance Co.Ltd

Authorised Signatory

STAR HEALTH AND ALLIED INSURANCE CO. LTD. CORPORATE OFFICE CHENNAI

Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE

MAHATMA GANDHI MISSION HOSPITAL KAMOTHE

4.2.10 The guarantee of payment is given only for the necessary treatment cost of the ailment covered and mentioned in the request for hospitalization. Non-covered items like Telephone usage, TV, relatives' food, hospital registration fees, documentation fees etc. and such of the non-covered items as prescribed by the IRDA guidelines under "List of expenses generally excluded ("non-medical") must be collected directly from the insured. Any investigation carried out at the request of the patient but not forming the necessary part of the treatment also must be collected from the patient.

4.2.11 In case the sum available is considerably less than the estimated treatment cost, Provider should follow their normal norms of deposit/ running bills etc., to ensure that they realize any excess sum payable by the beneficiaries not provided for by indemnity. Star Health upon receipt of the bills and document would release the guaranteed amount.

Article 5: Fee Schedule

5.1.1 Provider has submitted the fee schedule in the format, which shall be the basis for the treatment cost of various procedures and forming part of the MOU as given in the Annexure. The preauthorization form and billing will be made only on the stated accepted Tariff.

5.1.2 Provider has agreed to the continuation of the agreed tariff for a minimum period of Three years from the date of signing of the agreement considering that Star Health is the Stand-alone Health Insurer.

5.1.3 Any revision in the fee schedule will be submitted to Star health at least 30 days prior to the effective date. Star health reserves the right to discontinue the contract if dissatisfied with the revised tariff not agreed for.

Article 6: Check list for the provider at the time of Patient Discharge.

6.1 Original discharge summary, original investigation reports, all original prescription & pharmacy receipt etc. must not be given to the patient. These are to be forwarded to billing department who will compile the same and forward along with the bill to Star Health.

6.2 The Discharge card/Summary must mention the duration of ailment and duration of other disorders like hypertension or diabetes and operative notes in case of surgeries.

6.3 Signature of the patient / beneficiary on final hospital bill must be obtained.

6.4 Claim form of the Insurance Company must be presented to the beneficiary for signing and identity of the patient/ beneficiary again confirmed.

Article 7; Billing Procedure

7.1 Intimation of the impending discharge of the beneficiary need to be advised before the discharge of the patient to enable the Star Health medical team to be present at the discharge to assist the beneficiary. The Final bill would need to be made available to Star Health along with the discharge summary at the time of discharge of the patient.

7.2 The Final Bill has to be prepared by the Hospital as per the "Standard Format for Provider Bills" contained in Schedule IV of Insurance Regulatory and Development Authority (Health Insurance) Regulations, 2013 (attached) and made available to Star Health along with the discharge summary,

for Star Health and Allied Insurance Co.Ltd

Authorised Signatory

Medical Superintenden
M. G. M. HOSPITAL, KAMOTH

Indoor case papers, Investigation reports and other documents mentioned in the authorization letter at the time of discharge of the patient. Hospital should note that

i. Original discharge summary, original investigation reports, original prescription and pharmacy receipts etc., must not be given to the patient. These are to be forwarded to Billing department who will compile the same and forward along with the Bill to Star Health.

ii. In case of patient requiring the discharge summary / reports, he can be asked to take photocopies of the same at his own expense.

iii. The Discharge card / summary must mention the duration of ailment and duration of other disorders, if any, like Hypertension or Diabetes (operative notes in case of surgeries). The clinical detail furnished in the Discharge Summary should be sufficiently informative including the procedure.

iv. Signature of the patient / insured must be obtained on final hospital bill, including doctor daily visit charges, surgical fees, etc.

v. Claim form of the Insurance Company must be presented to the beneficiary for signing and identity of the patient / insured again confirmed.

vi. Copy of the beneficiary ID card issued by Star Health with the ID number legible must be obtained from the insured and must accompany the final bill.

7.3 The bills must be as per the agreed schedule of fees and any higher amounts charged shall be deducted. Any non-covered treatment/ Investigation cost must be recovered from the beneficiary.

7.4 The final docket for onward submission to Star Health for immediate payment must contain the following:

- Copy of beneficiary ID card with legible ID number.
- Copy of the first prescription collected from the beneficiary.
- Copy of preauthorization letter, beneficiary acceptance letter and duly signed claim form.
- Original final bill with detailed break up of miscellaneous, consumables & other charges.
- Original and complete discharge card/ summary mentioning the duration of ailment and duration of other disorders like hypertension or diabetes if any.
- Original investigation reports with corresponding prescription/ request.
- Pharmacy bill if supplied by hospital with corresponding request.
- Any other statutory documentary evidence required under law.
- Status of deposit paid if any by beneficiary
- Any other documents that may be required by Star Health in connection with the Claim

Article 8: Payment Terms and conditions

8.1 Star Health agrees to pay all the eligible bills within 15 days of the receipt at their head office address in Chennai along with all the original relevant documents.

for Star Health and Allied Insurance Co.Ltd

Authorised Signatory

STAR HEALTH AND ALLIED INSURANCE CO. LTD. CORPORATE OFFICE CHENNAI

Medical Superintendent

MAHATMA GANDHI MISSION HOSPITAL KAMOTHE

8.2 In case certain billed items are not correlated with corresponding report, due intimation for the items not correlated would be given within seven days of the receipt the bill. The provider shall provide the requisite reports within seven days thereof and the bill shall be settled accordingly. In case, there is no response for the correlating report the amount not correlated would be deducted from the final bill and no further papers thereafter shall be entertained. Payments will be done by and at par payable cheque of Star Health.

8.3 Payments to the providers can be made by Star Health by electronic funds transfer based on relevant details submitted by the Provider or by cheque/draft, as may be agreed upon by both the parties; all the payments are subject to deduction of tax at source as per applicable laws and shall be reconciled periodically by both the parties.

8.4 Payment and bank deposition would be construed as due receipt if a provider omits to send a stamped receipt of the payment received immediately on receipt of the cheque.

Article 9: Limitations of liability and indemnity

9.1 Star Health will not interfere in the treatment and medical care provided to its beneficiaries. Star Health will not be in any way held responsible for the outcome of treatment or quality of care provided by the provider.

9.2 Star health shall not be liable or responsible for any acts, omission or commission of the Doctors and other medical staff of the Provider.

9.3 Notwithstanding anything to the contrary in this Agreement, neither Party shall be liable by reason of failure or delay in the performance of its duties and obligations under this Agreement if such failure or delay is caused by acts of God, Strikes, lock-outs, embargoes, war, riots civil commotion, any orders of governmental, quasi-governmental or local authorities, or any other similar cause beyond its control and without its fault or negligence.

9.4 In case Star Health is unable to pay within 30 days of receipts of bills and relevant documents in original, Star health shall pay interest to the provider @ prevailing interest rates

Article 10: Confidentiality

10.1 All the stakeholders undertake to protect the secrecy of all the data of Star Health beneficiary/ies and trade or business secrets of Star Health and shall not share the same with any unauthorized person for any reason whatsoever within or without any consideration.

Article 11: Termination

Star Health shall reserve the right to terminate and/or to modify the agreement by giving 30 days notice if-:

11.1 The Provider violates any of the terms and conditions of this agreement; or

11.2 The Provider increases fee schedule without prior information to STAR HEALTH.

for Star Health and Allied Insurance Co.Ltd

Authorised Signatory

STAR HEALTH AND ALLIED INSURANCE CO LTD. CORPORATE OFFICE CHENNAI

Medical Superintendent

11.3 Star Health comes to notice of any fraud, misrepresentation, inadequacy of service or other non-compliance or default on the part of the Provider, on the basis of information ascertained by and/or available with the Company at any point of time..

11.4 Star Health observes cases of overstay and over provisioning without adequate explanation.

11.5 Provider can terminate the agreement after giving 30 days notice to Star Health.

Article 12: Discount

12.1A discount of 0 % on Inpatient services, 0 % on outpatient service and 0 % to be extended on all the packages, except — to the Members by the provider.

Article 13: Non-exclusivity

13.1 Star health reserves the right to appoint other provider/s for implementing the packages envisaged herein and provider shall have no objection for the same and vice-versa.

Article 14: Jurisdiction

14.1 Any dispute, claim arising out of this Agreement are subject to arbitration and jurisdiction of Chennai courts only.

14.2 Any amendments in the clauses of the Agreement can be effected as an addendum, after the written approval from both the parties.

Article 15: Others

15.1.1 Subject to the terms and conditions of the Health Insurance coverage, the Company reserves the right to deny any claim made by the hospital on behalf of the Insured.

15.2 The Provider shall ensure that the proposed treatment and the costs claimed against each treatment is reasonable, appropriate and within the defined code of conduct under medical terminology.

Annexures to the Memorandum of Understanding:

1 Pre-Authorization Request Form
2 Claim Form
3 Guidelines, Summary & Detailed billing Form along with IRDA coding details
4 IRDA Guidelines :
  4.1. List of Expenses Generally excluded ("Non-Medical")
  4.2. Procedure for Cashless Facility
  4.3. Standard contents and guidelines for preparing discharge summary
  4.4. Procedure for de-empanelment

for Star Health and Allied Insurance Co.Ltd

Authorised Signatory

STAR HEALTH AND ALLIED INSURANCE CO. LTD. CORPORATE OFFICE CHENNAI

MAHATMA GANDHI MISSION HOSPITAL KAMOTHE

Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE

In witness thereof this agreement was executed by or on behalf of the parties the day and year first before written.

Signed and delivered by within named:

Provider: MGM Medical College Hospital
Hospital code: Hos-85952

Through Sri/ Smt. Swati Madhav Sign _____

In presence of Sri/ Smt. K. R. Sakgotra Sign _____

Medical Superintendent
M. G. M. HOSPITAL, KAMOTHE

Star Health and Allied Insurance company ltd:

Through : Dr. Madhumathi Ramakrishnan (AVP)

Sign : for **Star Health and Allied Insurance Co.Ltd.,**

Authorised Signatory

In presence of : Dr.J. Dhandayuthapani (AGM)

Sign: for **Star Health and Allied Insurance Co.Ltd.,**

Authorised Signatory

STAR HEALTH AND ALLIED INSURANCE CO. LTD. STAR CORPORATE OFFICE CHENNAI

महाराष्ट्र MAHARASHTRA ◐ 2019 ◐ AU 730498

22 SEP 2020

मुद्रांक दिनांक
मुद्रांकशुल्क भरणारे नाव-पत्ता वेतन,
जि. रायगड.

मुद्रांकशुल्क अधिकारी
पनवेल - एकमद.

मुद्रांकशुल्क अधिकारी, पनवेल
जिल्हा रायगड

Memorandum of Understanding for Academic Research & Development

This Memorandum of Understanding (**MOU**) is made and executed on this day of 10th September 2020.

BY AND BETWEEN

TMC-ACTREC, Mumbai having address at TMC-ACTREC, Paymaster Shodhika, Sector 22, Kharghar Navi Mumbai - 410210 (hereinafter referred to as "**TMC-ACTREC**" which expression shall unless it be repugnant to the context or meaning thereof be deemed to include its successors and permitted assigns) of the FIRST PART;

AND

Mahatma Gandhi Mission Institute of Health Sciences through its Constituent Unit the Mahatma Gandhi Mission's Medical College & Hospital, having address at Plot No. 1 & 2, Sector-1, NH-4 Junction, Kamothe, Navi Mumbai, PIN 410209

Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

ACTREC NAVI MUMBAI TMC

25 SEP 2020

जोडपत्र - २/ Annexure -II

मुद्रांक विक्री नोंदवही अनु-क्रमांक १४९९० . दि. ......

दस्ताचा प्रकार .... (M.O.U) ......

दस्त नोंदणी करणार आहेत का होय/ नाही ~~X~~

मिळकतीचे थोडक्यात वर्णन ....

मुद्रांक विकत घेणाऱ्याचे नाव व सही एम. जी. एम. मेडिकल. कॉलेज.

हस्ते असल्यास त्याचे नाव पत्ता व सही .... संतोष [illegible]

दुसऱ्या पक्षकाराचे नाव ....

मुद्रांक शुल्क रक्कम 100

श्री. मंगला कृष्णा पगडे
स्टॅम्प वेंडर, कळंबोली
दुकान नं. बी ९, सेक्टर ३ई/ए,
कळंबोली, जि. रायगड
परवाना क्र. ६/१९९६-९७

परवाना मुद्रांक विक्रेत्याची सही
परवाना क्रमांक
मुद्रांक विक्रेत्याचे ठिकाण व पत्ता

ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्यांनी त्याच कारणासाठी मुद्रांक खरेदी केल्यापासून ६ महिन्यात वापरणे बंधनकारक आहे.

22 SEP 2020

(hereinafter referred to as "MGMIHS/**MGMMCH**" which expression shall unless it be repugnant to the context or meaning thereof be deemed to include its successors and permitted assigns) of the SECOND PART;

WHEREAS the Tata Memorial Centre (TMC) is a fully funded Government-in-Aid institution of Department of Atomic Energy situated at Parel, Mumbai-400 012, the TMC-ACTREC (Advance Centre for Treatment, Research and Education is the state-of art R & D Satellite of TMC hereinafter referred to **TMC-ACTREC**.

WHEREAS the Hematopathology Laboratory at ACTREC is studying the immune cell profiling and serum cytokine levels in peripheral blood by Flow Cytometry as well as interaction of inflammatory proteins and their levels in mucosal cells from the nasal/oral swab using molecular techniques such as PCR in COVID-19 patients jointly with Indian Council of Medical Research (ICMR) Immunoprofiling Consortium.

AND WHEREAS MGMMCH having the required infrastructure, expertise and facilities, has been designated as a COVID hospital/center **and permitted** to test, admit and treat the COVID-19 patients.

AND WHEREAS THE TMC-ACTREC has approached the MGMIHS with a proposal and sought the COVID 19 patient data available with the MGMMCH. The said data will be used to carry out collaborative joint activities/research studies. MGMMCH after due consideration of the proposal, the importance of the research activities to the general public health and well being and considering the urgent need and requirement to undertake the activity, has agreed to participate in the activity.

AND WHEREAS the collaboration among the two institutions will provide a unique opportunity to determine immune cell subsets levels, inflammatory serum cytokine levels and proteins related immune response from nasal/oral mucosal membrane as well as their kinetics with SARS-CoV-2 infection status and COVID-19 disease progression over the infection period. The parties are aware that a successful study will develop the unique immune-cell signature specific to the pathogenesis COVID-19 disease and its severity, which will eventually help and assist in better management of COVID-19 patients.

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AND WHEREAS the ICMR is a sponsor of this study. TMC-ACTREC and MGMMCH have authorized Covid-19 ward for the treatment of COVID-19 patients and hence, both institutions are collaborating as a part of ICMR Immunoprofiling Consortium for Covid-19.

AND WHEREAS the parties are interested and intend to focus on joint research activities relating to the multi-dimensional in-depth evaluation of immune-cell subsets and inflammatory cytokine levels using multicolor flow cytometry to develop an immune-cell signature as well as mucosal immune-response related proteins which will allow to study the severity and prognosis of disease in COVID-19 patients.

AND WHEREAS the Hematopathology Laboratory at **TMC-ACTREC** has an expertise of multicolor flow cytometric immunophenotyping and has developed a multi-dimensional immune-cell profile assay and cytokine assays and has a state-of-the-art flow cytometry facility and has experience in various immunological studies in human subjects.

AND WHEREAS the TMC-ACTREC and MGMMCH have decided to collaborate and to do jointly a research project to study the multi-dimensional in-depth evaluation of immune-cell subsets and inflammatory cytokine levels using multicolor flow cytometry to develop an immune-cell signature as well as mucosal immune-response related proteins which will allow to study the severity and prognosis of disease in COVID-19 patients.

AND WHEREAS patient's samples collected under this study will be used (after obtaining the required patient consents) for above mentioned COVID-19 related research studies only.

NOW THIS MOU WITNESSETH AND IT IS HEREBY AGREED BY AND BETWEEN THE PARTIES HERETO AS FOLLOWS:

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M.G.M. Medical [illegible] & Hospital
Kamothe, Navi Mumbai - 410209

ACTREC NAVI MUMBAI TMC

WORK RESPONSIBILITIES:

(A) RESPONSIBILITIES OF TMC-ACTREC

1. **TMC-ACTREC's** Hematopathology Laboratory shall do the multicolor flow cytometric immunophenotyping and cytokine assays in peripheral blood and study of nasal/oral mucosal proteins in COVID-19 patients jointly with Indian Council of Medical Research (ICMR) Immunoprofiling Consortium.

2. **TMC-ACTREC's** Hematopathology Laboratory shall provide the vacutainers to collect peripheral blood and nasal/oral swab collection kits to MGMMCH and transport facility of these samples from MGMMCH to TMC-ACTREC.

3. The patient's details, samples and the data of research conducted will be safely stored in **TMC-ACTREC** and will be shared with Indian Council of Medical Research (ICMR) Immunoprofiling Consortium.

4. **TMC-ACTREC** will share the results of the study with MGMMCH after completion of the project.

5. **TMC-ACTREC** will not share this data with anyone other than Indian Council of Medical Research (ICMR) and ICMR Immunoprofiling Consortium.

6. **TMC-ACTREC** will share a part of patient's samples with Narayana Nethralaya Foundation (NNF), Bangalore which is a member of ICMR Immunoprofiling (IP) consortium.

7. **TMC-ACTREC** will allow the post-graduate students (maximum two students in a day) from MGM to observe the processing and analysis performed as a part of this study.

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Kamothe, Navi Mumbai - 410209

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(B) RESPONSIBILITIES OF MGMMCH

1. **MGMMCH** shall enroll patients with SARS-CoV-2 infection and will collect peripheral blood and nasal/oral swabs at time points as specified in the project proposal. MGMMCH will keep follow up as required by project proposal.

2. **MGMMCH** will share all the clinical and treatment details of the patients enrolled in this study as and when required by TMC-ACTREC.

3. **MGMMCH** will not use any of the data provided by TMC-ACTREC for any other purpose/publication without obtaining prior written permission from Hematopathology Laboratory, TMC-ACTREC.

B. PUBLICATION POLICY:

1. Any publication resulting from this work will have authorship from all the two participating institutes and members of ICMR Immunoprofiling (IP) consortium depending upon the contribution in particular aspect.

2. Dr. Prashant Tembhare from TMC-ACTREC and Dr. Shilpi Sahoo from MGMMCH will have the authority to decide the authors of their respective groups which will be in accordance with the contribution of the authors.

C. REPORTING:

The Institutional Ethics Committee (IEC) of the parties hereto shall have the authority to evaluate effectiveness and adherence to the agreement and the periodicity of evaluations every year.

D. FUNDING:

1. Funds will be mainly required for vacutainer tubes and nasal/oral swab collection kits and transportation of the patient's samples from MGMMCH to TMC-ACTREC. TMC-ACTREC will provide vacutainer tubes, nasal/oral swab collection kits and personal protection equipment (PPE) kits required for this study to MGMMCH. TMC-ACTREC will transport the patient's samples from

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MGMMCH to TMC-ACTREC. Data storage infrastructure at **TMC-ACTREC** will be used for managing the data related activities. Hence for any partner storage of data will be done by individual partner's own fund.

2. The study is funded by ICMR as a part of Immunoprofiling (IP) consortium for COVID-19.

E. CONFIDENTIALITY AGREEMENT:

The parties hereto acknowledge that, in the course of their activities under this MOU, it may be necessary for one party to provide documentation, technical and/or intellectual property to the other party. All Confidential Information provided or disclosed by either party hereunder shall remain the property of the furnishing party, and shall be held in strict confidence by the receiving party, its officers, employees, agents and all concerned persons unless the furnishing party otherwise consents in writing or unless disclosure of such Confidential Information is required by law. This clause will survive for five years the expiry of the MOU.

F. FINALITY:

This Memorandum of Understating embodies the entire agreement and understanding between the parties hereto relating to the subject matter hereof and there are no understandings, agreements, conditions or representations, oral or written, expressed or implied, with reference to the subject matter hereof that are not merged herein or superseded hereby. No modification hereof shall be of any force or effect unless reduced to writing and signed by the parties claimed to be bound thereby.

G. TERM AND TEMINATION:

This MOU shall become effective from the later date of execution hereof and will remain in effect until 10/9/2022 unless modified or terminated by giving one month advance written notice by either party.

H. SUCCESSORS AND ASSIGNMENT:

None of the parties hereto shall assign their rights or obligations under this Memorandum of Understanding to any third party or parties without the prior written consent of the other party. The provisions of this Memorandum of Understanding shall inure to the benefit of, and shall be binding upon, the successors and permitted

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K.G.M. Medica[illegible] Hospital
Kamothe, Navi Mumbai - 410209

ACTREC NAVI MUMBAI TMC

assigns of the parties hereto. Succession/transfer of this project related data shall not be done without the written consent of the other party and the ICMR approval.

I. SEVERABILITY:

If any term of this Memorandum of Understanding is held by a Court of competent jurisdiction to be invalid or unenforceable, then this MOU including all of the remaining terms, will remain in full force and effect as if such invalid or unenforceable term had never been included.

J. NO IMPLIED WAIVER:

Either party's failure to insist in any one or more instances upon strict performance by the other party of any of the terms of this MOU shall not be construed as a waiver of any continuing or subsequent failure to perform or delay in performance of any term hereof.

K. INDEMNITY:

The parties hereto shall indemnify and hold indemnified and harmless each other, and their employees, bonafide visitors and patients from and against all allegations, claims, actions, suits, demands, damages etc. which arise out of, relate to or result from any act or omission of the parties hereto during the period of this MOU.

L. NOTICES:

Any communication to be given in connection with this MOU shall be in writing and may be sent by duly acknowledged email, personal delivery or by registered post addressed to the parties at the addresses mentioned hereinabove: -

1. Dr Prashant Tembhare
   Clinician Scientist and Associate Professor
   Hematopathology Laboratory, TMC-ACTREC,
   Sector 22, Kharghar,
   Navi Mumbai 410210.
   Telephone: 02227405362 Fax: 02227405148
   E-mail: ptembhare@actrec.gov.in; docprt@gmail.com

Signature:

Date 09/10/2020

ACTREC NAVI MUMBAI TMC

Dean
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

2. Dr. Shilpi Sahu

Professor and Head

Department of Pathology, MGMMCH

Plot No. 1 & 2, Sector-1, NH-4 Junction, Mumbai- Pune Hwy,

Kamothe, Navi Mumbai, Maharashtra 410209

Telephone: +91-22 27437833

E-mail: mgmpathologyhod@gmail.com

Signature: for SINHA MMC 20110201 (General Medicine), DNB (General Medicine) Care), EDIC (European Diploma in Intensive C Unit & Assistant Professor, Emergency Medical College & Hospital, Kamothe, Navi M Date

M. Independent Entities.

MGMCH and TMC-ACTREC are independent parties and neither is an agent, joint venture partners, or partner of the other.

N. DISPUTE RESOLUTION:

In the event of any disputes or differences arising out of or in connection with this MOU whether during subsistence of this MOU or thereafter, the matter shall be referred to the Sole Arbitrator, who shall be mutually appointed by the parties, for arbitration, whose decision shall be final and binding on the parties. The proceedings before the Sole Arbitrator shall be governed by the provisions of the Arbitration and Conciliation Act 1996 and amendment thereof from time to time. The place of such arbitration should be Mumbai, conducted in English and cost of such arbitration will be equally shared by all parties.

O. COUNTER PARTS:

This Agreement may be executed in two or more identical counterparts, all of which shall be considered one and the same MOU and shall become effective when counterparts have been signed by each party and delivered to the other party.

P. GOVERNING LAW: The Parties hereto realize that the Registered Office of the **TMC-ACTREC** is in Mumbai and have mutually agreed that despite this MOU being executed by the other party (MGMMCH) in Navi Mumbai, for convenience and notwithstanding that part of the cause of action may arise anywhere in India, this Agreement shall be governed and construed in accordance with the laws of India under the jurisdiction of Mumbai Courts.

ACTREC NAVI MUMBAI TMC

Dean. M.G.M. Medi... Hospital Kamothe, Navi Mumbai - 410209

IN WITNESS WHEREOF, the parties hereto have caused this **Memorandum of Understanding** to be executed by their duly authorized representatives as of the date first above written.

Signed, Sealed & Delivered by:

TMC-ACTREC, Mumbai

Through:

Dr. Navin Khattry, Deputy Director, ACTREC

Dr. Navin Khattry
M.D.,D.M.
Dy. Director, CRC
Advanced Centre for Treatment Research & Education in Cancer (ACTREC)
Tata Memorial Centre,
Kharghar Navi Mumbai-410210. India

ACTREC NAVI. MUMBAI TMC

Dr. Sudeep Gupta,

Director of ACTREC, TMC

Dr. Sudeep Gupta
MBBS, MD, DM
Director,
Advanced Centre for Treatment Research & Education in Cancer (ACTREC)
Tata Memorial Centre,
Kharghar Navi Mumbai-410210. India

Date: 10.09.2020

Place: Kharghar, Navi Mumbai

Witness:

Name and signature

Signed, Sealed & Delivered by:

MGMMCH

Through

Dr. G S Narshetty, Dean MGMMCH

Dean.
M.G.M. Medic[illegible] & Hospital
Kamothe, Navi Mumbai - 410209

Authorized signatory

Date: 10.09.2020

Place: Kamothe, Navi Mumbai

Witness: _____

Name and signature

Memorandum of Understanding (MoU)

BETWEEN

MAHATMA GANDHI MISSION MEDICAL COLLEGE,UNDER MGM INSTITUTE OF HEALTH SCIENCES,KAMOTHE

(Deemed University u/s. 3 of UGC Act, 1956)

AND

PRIMARY HEALTH CENTRE, NERE
Zilla Parishad
DISTRICT - RAIGAD

महाराष्ट्र MAHARASHTRA ◐ 2018 ◐ AN 364552

16 DEC 2019

पुरवठ्याची दिनांक
उपकोषागाराचे नाव-पनवेल,
जि. रायगड.

उप कोषागार अधिकारी
पनवेल - रायगड

कोषागार कार्यालय पनवेल-रायगड

BETWEEN

MAHATMA GANDHI MISSION MEDICAL COLLEGE, under MGM INSTITUTE OF HEALTH SCIENCES, KAMOTHE, NAVI MUMBAI

AND

PRIMARY HEALTH CENTRE, NERE, DISTRICT – RAIGAD

THIS MoU is made at Navi Mumbai and comes in effect from 1st January 2021 between PRIMARY HEALTH CENTRE, NERE, DISTRICT – RAIGAD, Here in referred as the **FIRST PARTY**

AND

MGM MEDICAL COLLEGE, KAMOTHE, NAVI MUMBAI hereinafter referred as **SECOND PARTY**

AND WHEREAS THE FIRST PARTY is seized and possessed of sufficiently entitled to the Primary Health Centre (PHC) at Nere Village hereinafter referred to as the said premises which is in their exclusive possession being in need of Medical Personnel including doctor /doctors / paramedics to manage the multispecialty outpatient services, laboratory services and Secondary and Tertiary health care services to the users of their hospital has approached **SECOND PARTY**.

M.G.M. MEDICAL COLLEGE NEW MUMBAI 410209 KAMOTHE

जोड पत्र–2/Annexure-II

अ. क्रं. 20038 मु. शु. रक्कम 500/- 24/12/2019

दस्ताचा प्रकार M.O.U

दस्त नोदणी करणार आहेत का : होय/नाही

मिळकतीचे थोडक्यात वर्णन _____

_____

मुद्रांक विकत घेणाऱ्याचे नाव MGM Medical College

दुसऱ्या पक्षकाराचे नाव PHC

हस्ते/वकीलचे नाव व पत्ता Pradip

मुद्रांक विकत घेणाऱ्याची सही _____

सौ. धनश्री एस. बोंद्रे
ऑफिस नं.1, साईशरण कॉम्प्लेक्स,
1ला मजला, सेक्टर–6, खांदा कॉलनी,
नवीन पनवेल(प.) जि. रायगड.
परवाना कं. –7/1996 –97

ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्यांनी त्याच कारणांसाठी मुद्रांक खरेदी केल्यापासुन 6 महिन्यात वापरणे बंधनकारक आहे.

AND WHEREAS SECOND PARTY has agreed to manage their hospital by way of providing the services of doctors and paramedical staff at the said PREMISES(as specified hereunder) upon certain terms and conditions, which are accepted by both the parties who agreed with the following terms in writing and confirm the same

NOW THIS AGREEMENT WITNESSETH AS UNDER:-

1. The first party hereby grant unto the SECOND PARTY their permission to use and occupy the said PREMISES to render health care to the users of Primary Health Centre, Nere, constituent sub-centres and in its entire filed practice area and also training of medical and Para medical students, postgraduate residents, interns, nurses and other paramedical staff in community health care and also educate them the primary health teaching with effect from 1st JANUARY 2021 for a period of minimum 5 years.
2. The SECOND PARTY shall use the PREMISES for the specific purposes as outlined in Para "The said premises will be designated as Rural Health Training Centre (RHTC)" .
3. The FIRST PARTY will provide all the facilities to the SECOND PARTY to the existing infrastructure of hospital including OPDs, Wards, Operation theatre, X-ray, Dressing room, injection room, Labor room for treatment of patients, also provide to hold health talks, health checkup camps, exhibitions and training and any other required space as suggested by the Regulatory body.
4. SECOND PARTY will provide the services of a Qualified Medical Practitioners, Residents and interns from various specialties as and when required in future
5. SECOND PARTY will also provide outreach services to the vulnerable population and community health work like community health education activities, health camps as planned by your concerned authorities.
6. The FIRST PARTY will also allow SECOND PARTY to conduct research activities approved by Institutional ethics committee at PHC, Sub-centres and field practice area allocated to PHC.
7. For all the academic, research and extension activities mentioned above the Department of Community Medicine of MGM Medical College, Kamothe, Navi Mumbai will be coordinating agency and the faculty of the level of Assistant Professor and above designated as "RHTC – In Charge" will be coordinating with Medical Officer of PHC for day to day functioning.
8. The Academic Control for functioning of RHTC, which is affiliated to Government will be with SECOND PARTY while the First Party will continue to function as per the Government norms.
9. The FIRST PARTY will ensure that staff of the PHC, ASHA and Anganwadi Sevikas will work in close co-ordination with SECOND PARTY for the provision of outreach, treatment and referral services and SECOND PARTY will attempt to do the value addition to these services for the betterment of the community.
10. The FIRST PARTY will provide accommodation (well furnished minimum 2 rooms)in the said premises for Residential doctors and interns .

M.G.M. MEDICAL COLLEGE NEW MUMBAI 410209 KAMOTHE

11. The FIRST PARTY has no objection to the use of said premises and the data as Health, Training and Research centre for all residents including department of Community Medicine, and also authorize the said college to reflect the same in documents submitted to the regulatory authorities such as MCI/Nursing and other councils.

12. In case the FIRST PARTY is eager to establish any other specialty in their locality the SECOND PARTY will extend the services.

13. The FIRST PARTY shall ensure that the statuary requirements of licenses, approvals from the concerned Government and local Civil Authorities, necessary for operations and treatment of all kinds of patients are obtained regularly.

14. The SECOND PARTY shall extend the services of the Medical and Para Medical Staff to provide Health care only during the appointed hours. Beneficiaries shall make their own arrangement for emergency care including provision of the ambulance for transportation. Apart from primary Health Care patient who needs secondary and Tertiary including emergency, will be treated at Secondary party's Teaching hospital at Kamothe/Kalamboli on concessional charges.

15. This agreement can be terminated by either party by giving3 months notice without mentioning any reason for the termination.

16. All medico legal cases will be dealt with Medical Officer of Primary Health Centre, Nere.

17. The FIRST PARTY will be providing all Medicines, Medical instruments in OPD, IPD, OT and Labor room as per the requirement and the maintenance as per the requirement.

18. Any dispute relating to this agreement shall be subject to jurisdiction of courts at Raigad district only.

IN WITNESS THEREOF THE PARTIES HERETO have executed this agreement in the manner herein on this 1st January2021.

SIGNED SEALED AND DELIVERED

District Health Officer
Raigad Zilla Parishad, Alibag

RAIGAD ZILLA PARISHAD RZP ALIBAG

By the within named "FIRST PARTY"

Competent Authority – DISTRICT HEALTH OFFICER

PRIMARY HEALTH CENTRE, Nere,

Taluka – Panvel, District - Raigad

Witnesses-

1.

2. तालुका आरोग्य अधिकारी पनवेल

THO PANVEL

MEDICAL OFFICER
P. H. C. NERE
Tal. Panvel, Dist. Raigad

SIGNED SEALED AND DELIVERED

SECOND PARTY

Jan 2021.
Dean.
M.G.M. Medical College & Hospital
Kamothe, Navi Mumbai - 410209

Competent authority - DEAN

MGM MEDICAL COLLEGE under MGMIHS

Kamothe, Navi Mumbai

M.G.M. MEDICAL COLLEGE NAVI MUMBAI 410209 KAMOTHE

Witnesses-

1. Dr. Prasad Waingankar
2. Dr. Ashlesha Tawde

ATTESTED BY ME

R. C. DIGPAL
ADVOCATE & NOTARY
MUMBAI

21 MAY 2021

American Heart Association.

International Training Agreement

Company Information:

International Training Center ("ITC"):	Mahatma Gandhi Mission Medical College and Hospital
Address:	MGM Medical College and Hospital, Plot No. 01 Sector 01 Kamothe, Navi Mumbai, Maharashtra 410209, India
Form of Organization:	Not for Profit / University

This Agreement is between the American Heart Association, Inc. ("AHA"), a New York not-for-profit corporation, having its principal offices at 7272 Greenville Avenue, Dallas, Texas 75231-4596, and ITC.

IN CONSIDERATION of the mutual promises contained herein, the parties agree as follows:

1. Term: Beginning Date: January 24, 2020. Ending Date: January 24, 2023. This Agreement will be in effect for a period of Three (3) calendar years. It may be renewed for additional one (1) year periods by letter issued from AHA.

2. AHA ECC Courses to be Taught by ITC:

Basic Life Support	Advanced Cardiac Life Support
Provider Course(s)	Provider Course(s)
Instructor Course(s)	Instructor Course(s)

3. Geographic Territory: India

4. Insurance: $28,024.69 US

ITC will obtain and maintain at its expense, commencing upon the beginning date of this Agreement and during its entire term, liability insurance from a qualified insurance carrier, as set out above. This policy will specify that it may not be modified or canceled by the insurer, except after thirty (30) days prior written notice by the insurer. Upon execution of this Agreement ITC will provide the AHA with a certificate of insurance showing the required coverage.

5. Copyrights: ITC acknowledges and agrees that the AHA owns all copyrights in the ECC Materials, and ITC may not copy, or permit others to copy, distribute, perform or make derivative works based upon the ECC Materials, Course Completion Cards, or eCards.

6. Marks: ITC acknowledges the AHA's trademark rights and ownership of the name "American Heart Association", the heart-and-torch trademark and slogans (e.g., "Life is Why") (hereinafter "AHA Marks"). ITC will not use or display the AHA Marks. ITC shall not apply for any trademark registrations with respect to any AHA Marks or any marks similar to the AHA Marks.

7. Entire Agreement: This Agreement, including the terms and conditions set out on Page Two, contains the entire agreement between the parties relating to the rights granted and the obligations assumed.

EXECUTED by the parties on the date(s) set out below.

American Heart Association, Inc.	**International Training Center**
Signature:	Signature:
Name: Keith Jansen	Name: GURUNATH S NARSHETTY
Title: SVP, International	Title: DEAN
Date: January 24, 2020	Date: 18-02-2020

MGM Medical College & Hospital SKILLS LAB

INCHARGE
MGM SKILLS LAB
DATE: 25/01/2020

DIRECTOR
MGM SKILLS LAB
DATE: 25/01/2020

Definitions:

(a) "Program Guidelines" means the current *Guidelines for Cardiopulmonary Resuscitation and Emergency Cardiovascular Care*, Program Administration Manual: Guidelines for Program Administration and Training (hereinafter "PAM"), and *AHA Instructor's Manuals*, as they may be amended and/or supplemented by the AHA from time to time.

(b) "Course Completion Cards" or "Cards" are defined as documents made available or provided by AHA, and which indicate a student's successful completion of a specified Course.

(c) "Course" or "Courses" are defined as those courses that follow the curricula of the AHA and teach emergency cardiovascular care according to the Program Guidelines.

(d) "ECC Materials" are defined as emergency cardiovascular care textbooks and materials published by the AHA.

(e) "eCards" means those electronic records that Training Centers may distribute to, or provide access to, students pursuant to Program Guidelines to indicate that the student participated in or successfully completed a Course.

(f) "Instructors" are individuals who have successfully completed AHA authorized Provider and Instructor training and who are authorized by ITC to teach Provider courses to other individuals.

(g) "Training Sites" are organizations engaged or authorized by ITC to teach Courses under the auspices of ITC.

9. **ITC Role and Responsibilities:**

(a) ITC will teach Courses only within the Geographic Territory, and agrees to do so in compliance with the Program Guidelines.

(b) ITC may contract with other entities (hereinafter "Training Sites") who agree to teach Courses under the direction and guidance of ITC. ITC assumes full responsibility for the actions and performance of the Training Sites, and will ensure that Training Sites teach in compliance with the Program Guidelines.

(c) Periodically, as requested by the AHA, ITC will provide the AHA with a current and accurate list of Training Sites, Instructors, the number of students taught, and such other information as may be requested by AHA but only to the extent allowed by local law and the terms of any applicable consent, if required.

(d) ITC will insure that each student has individual possession of an authorized Course-specific textbook before, during, and after training.

(e) ITC will be responsible for the issuance and security of Course Completion Cards and eCards as outlined in the Program Guidelines: (i) ITC will establish a system for ensuring that Cards are issued only to authorized Training Sites. (ii) ITC and its authorized Training Sites will only issue the appropriate course-specific Course Completion Card or eCard to each student who successfully completes the applicable Course.

(f) ITC will obtain any and all required licenses, permits or documentation and is solely responsible for compliance with all laws and regulations applicable to training activities conducted under this Agreement. ITC will obtain any required or appropriate consent from each student before sharing that student's name and Course completion information with the AHA through AHA's online systems (which systems may include data storage outside of ITC's Territory).

10. **Relationship of Parties:**

The parties acknowledge and agree that each is an independent entity and, as such, neither party may represent itself as an employee, agent, or representative of the other; nor may it incur any obligations on behalf of the other party.

11. **Termination:**

(a) The Agreement may be terminated by either party, without cause, upon sixty (60) calendar days' prior written notice.

(b) Either party may terminate this Agreement if the other party breaches any term or condition of this Agreement and fails to cure the breach within thirty (30) calendar days after receipt of written notice by the non-defaulting party. The following will also constitute breach or default under this Agreement: (i) Failure to exist or operate as a legal entity or to maintain an office address; or (ii) Assignment for the benefit of creditors, becoming generally insolvent, being placed in receivership or the filing by or against a party of a petition for bankruptcy or for entity reorganization under any bankruptcy act or similar statute.

(c) The AHA may terminate this Agreement upon written notice if it determines, in its sole discretion, that any of the activities permitted or contemplated under this Agreement pose a significant legal or business risk to the AHA.

(d) Notwithstanding anything to the contrary in this Agreement, AHA may terminate this Agreement if ITC or any Training Site conducts Courses in any country on which the United States government or other governmental entity (except those that are contrary to United States' laws), that (i) imposes sanctions that would prevent the AHA from conducting Courses either directly or indirectly in the country or (ii) for which ITC, Training Site or AHA must obtain a license from the applicable government to conduct Courses. If the United States government should impose sanctions on any country named in the Geographic Territory, the AHA at its option may (i) immediately terminate this Agreement as to that country in which event ITC and its Training Sites will immediately cease conducting Courses in the country, or (ii) may immediately terminate this Agreement in its entirety upon written notice to ITC.

(e) ITC will not distribute any AHA Course Completion Cards or eCards or designate itself, in any manner or any place, as an authorized ECC training center of AHA after this Agreement has been terminated or expired. In addition to any remedies by law or in equity available to AHA, ITC will pay the AHA Two Hundred Dollars (200 US$) as a penalty for each Course Completion Card issued after termination or expiration of this Agreement. Upon termination or expiration of this Agreement, AHA shall have no liability or obligations to ITC, and ITC shall retain no rights under this Agreement.

12. **Warranties:**

(a) ITC warrants and represents to the AHA that as of the effective date and at all times during the term of this Agreement: (i) ITC, its agents, affiliates, members, representatives, distributors, contractors, and Training Sites will be in compliance with this Agreement, the provisions of the U.S. Foreign Corrupt Practices Act and all applicable U.S., local, state and federal laws and regulations, and applicable laws or regulations of any jurisdictions whose laws may apply; (ii) ITC is not a tobacco company, or a tobacco company corporate subsidiary or parent, nor does it receive revenue from tobacco products. "Subsidiary" and "parent" are defined as an entity in which there exists a direct or indirect Five Per Cent (5%) or greater ownership interest by a tobacco company.

(b) EXCEPT AS EXPRESSLY SET OUT IN THIS AGREEMENT, THERE ARE NO WARRANTIES, EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE.

13. **Indemnification and Liability:**

(a) ITC will indemnify, defend and hold harmless the AHA and its directors, officers, employees, agents, distributors, members, volunteers, successors and assigns from and against all suits, proceedings, actions, demands, claims, losses, liability, damages or expenses (including reasonable attorneys' fees and legal costs) arising from (i) ITC's performance or breach of its obligations under this Agreement, (ii) ITC's operation activities and/or distribution of Course Completions Cards, (iii) any breach or alleged breach of ITC's representations or warranties, (iv) any act or omission of ITC in any country in the Geographic Territory, and (v) any act or omission of Training Sites, Instructors, ITC's affiliates, agents, partners or representatives.

(b) The AHA will not be liable for any indirect, special, consequential or incidental damages, including lost profits or any other kind of damages, even if it has been warned of the possibility of such loss or damage. In no event will the AHA's liability under this Agreement exceed $1,000 (US$).

14. **Force Majeure:** Neither party will be in default under this Agreement, if such results, whether directly or indirectly, from fire, explosion, strike, freight embargo, vis major, or of the public enemy, war, terrorism, civil disturbance, act of any government, de jure or de facto, or agency or official thereof, labor shortage, transportation contingencies, unusually severe weather, default of manufacturer or a supplier, quarantine restrictions, epidemic, or catastrophe.

15. **Notices:** Any notice required or permitted under this Agreement, will be given in writing and will be deemed to have been duly given upon actual receipt if delivered personally or by courier with receipt obtained therefrom to the parties at their respective addresses.

16. **Miscellaneous Provisions:**

(a) This Agreement may not be assigned by ITC without the AHA's prior written consent.

(b) No amendment of this Agreement will be binding or enforceable on either party hereto unless in writing signed by both parties.

(c) Should any part, term, or provision of this Agreement be declared to be invalid, void, or unenforceable by a court of competent jurisdiction, all remaining parts, terms, and provisions hereof will remain in full force and effect, and will in no way be invalidated, impaired or affected thereby.

(d) This Agreement will be governed by the laws of the State of New York without regard to its conflict of laws provisions. Any controversy or claim arising out of or relating to this Agreement will be settled by arbitration in Dallas, Texas in accordance with the International Arbitration Rules of the American Arbitration Association. The language of the arbitration will be English. The arbitrators will have no authority to award punitive damages, and may not, in any event, make any ruling, finding, or award that does not conform to the terms and conditions of this Agreement. Judgment upon any award rendered through arbitration may be entered in any court having jurisdiction. Injunctive relief may be sought in any court of competent jurisdiction.

(e) This agreement contains the entire agreement between the parties and supersedes all prior written and oral communications. This Agreement will be written in and governed by the English language.

(f) AHA reserves the right to appoint other ITCs within the Geographic Territory.

(g) The following paragraphs and their subparagraphs will survive termination of this Agreement: 13 (Indemnification and Liability), 16(d) and 16(e)

INCHARGE
MGM SKILLS LAB
DATE: 28/01/2020

MGM Medical College & Hospital SKILLS LAB

DIRECTOR
MGM SKILLS LAB
DATE: 28/01/2020

भारतीय गैर न्यायिक

Rs. 100

ONE HUNDRED RUPEES

INDIA NON JU

महाराष्ट्र MAHARASHTRA ◑ 2023 ◑ 64AA 449850

ASHOK P. GAYKAR NOTARY MUMBAI MAHARASHTRA REGN. NO. 5873 GOVT. OF INDIA

NOTARIAL

27 JUL 2023

उप कोषागार अधिकारी पनवेल रायगड

GOVT. OF INDIA NOTARY A.P. GAYKAR Mumbai Maharashtra Regn. No. 5873

MGM MEDICAL COLLEGE & HOSPITAL, KAMOTHE, NAVI MUMBAI
DEPARTMENT OF PATHOLOGY

Memorandum of Understanding for Clinical Autopsy

MGM Medical College , Kamothe , Navi Mumbai has applied for clinical autopsy as the applicant hospital does not have adequate exposure in the areas of clinical autopsy.

Memorandum of Understanding (MOU) is executed between Government Medical college (Alibaug) and MGM Medical college & hospital (Kamothe, Navi Mumbai) as the clinical autopsy is available in Government Medical College, Alibaug, Maharashtra.

As per the MOU, the trainees of the applicant hospital shall be rotated to the above mentioned hospital under MOU as per following externship plan:

Areas wherein exposure is inadequate in the applicant hospital	Proposed hospital for externship of trainees (Specify Name & complete address)	Duration of rotational posting (in weeks/months)
Clinical Autopsy	Government medical college, Alibaug, Maharashtra, 402209	4 weeks

जोडपत्र—२ / Annexure - II

मुद्रांक विक्री नोंदवही अनु—क्रमांक –५३०६ दिनांक ०४.०८.२०२३
दस्ताचा प्रकार **MOU**
दस्त नोंदणी करणार आहेत का होय / नाही
मिळकतीचे थोडक्यात वर्णन
मुद्रांक विकत घेणाऱ्यांचे नाव व सही **MGM MEDICAL COLLEGE , KAMOTHE , NAVI MUMBAI**
हस्ते असल्यास दुस—या पक्षकाराचे नाव **BHARAT THAPA**
मुद्रांक शुल्क रक्कम १००/—

सौ. मंगला कृष्णा पगडे
स्टॅप वेंडर, कळंबोली
दुकान न ंबी ९, सेक्टर ३ई/ए, कळंबोली, जि. रायगड
परवाना क्रं ६/१९९६—९७

ज्या कारणासाठी ज्यांनी मुद्रांक खरेदी केला त्याची त्याच कारणासाठी व खरेदी केल्यापासून ६ महिन्यात वापरणे बंधनकारक आहे.

The above said externship shall be governed by following terms and conditions:

	Terms & Conditions for Externship	Hospital submission
1.	The rotation shall be Hands on experience and not mere observership.	The rotation will be hands on
2.	How does the applicant hospital propose to monitor the training of the candidates as part of the proposed MoU?	Candidates will be posted under HOD pathology (Government Medical College, Alibaug)
3.	Who shall bear the stipend of the candidate during this period of training outside the hospital in another accredited institute?	Applicant hospital will pay stipend
4.	What shall be status of theses supervision?	Thesis supervision will be done by guides
5.	How will the thesis supervisor and guide of the candidate provide teaching and mentoring support during this period?	They will report after after posting is over / during posting via emails
6.	Nature of responsibilities of the respective hospitals that shall deploy the candidate for the appropriate period of providing training.	PGs will also take microteaching and UG practical support
7.	Validity of MoU: The MOU shall be effective w.e.f. 07/08/23 and shall remain valid till 06/08/2027	

Date: 7/8/23

Place: MGM medical College, Kamothe

Signature & Stamp of Head of the Institute
(Applicant Hospital)

Dean
MGM Medical College & Hospital
Kamothe, Navi Mumbai-410209

Signature & Stamp of Head of the Institute
(Hospital under MOU)

ATTESTED BY ME

Adv. ASHOK P. GAYKAR
B.Com., LL.B., G.D.C.&A.
NOTARY GOVT. OF INDIA
Reg No. 5873.

7 AUG 2023

American Heart Association.

International Training Agreement

Company Information:

International Training Center ("ITC"):	Mahatma Gandhi Mission Medical College and Hospital
Address:	MGM Medical College and Hospital, Plot No. 01 Sector 01 Kamothe, Navi Mumbai, Maharashtra 410209, India
Form of Organization:	Not for Profit / University

This Agreement is between the American Heart Association, Inc. ("AHA"), a New York not-for-profit corporation, having its principal offices at 7272 Greenville Avenue, Dallas, Texas 75231-4596, and ITC.

IN CONSIDERATION of the mutual promises contained herein, the parties agree as follows:

1. Term: Beginning Date: January 24, 2020. Ending Date: January 24, 2023. This Agreement will be in effect for a period of Three (3) calendar years. It may be renewed for additional one (1) year periods by letter issued from AHA.

2. AHA ECC Courses to be Taught by ITC:

Basic Life Support	Advanced Cardiac Life Support
Provider Course(s)	Provider Course(s)
Instructor Course(s)	Instructor Course(s)

3. Geographic Territory: India

4. Insurance: $28,024.69 US

ITC will obtain and maintain at its expense, commencing upon the beginning date of this Agreement and during its entire term, liability insurance from a qualified insurance carrier, as set out above. This policy will specify that it may not be modified or canceled by the insurer, except after thirty (30) days prior written notice by the insurer. Upon execution of this Agreement ITC will provide the AHA with a certificate of insurance showing the required coverage.

5. Copyrights: ITC acknowledges and agrees that the AHA owns all copyrights in the ECC Materials, and ITC may not copy, or permit others to copy, distribute, perform or make derivative works based upon the ECC Materials, Course Completion Cards, or eCards.

6. Marks: ITC acknowledges the AHA's trademark rights and ownership of the name "American Heart Association", the heart-and-torch trademark and slogans (e.g., "Life is Why") (hereinafter "AHA Marks"). ITC will not use or display the AHA Marks. ITC shall not apply for any trademark registrations with respect to any AHA Marks or any marks similar to the AHA Marks.

7. Entire Agreement: This Agreement, including the terms and conditions set out on Page Two, contains the entire agreement between the parties relating to the rights granted and the obligations assumed.

EXECUTED by the parties on the date(s) set out below.

American Heart Association, Inc.	**International Training Center**
Signature:	Signature:
Name: Keith Jansen	Name: GURUNATH S NARSHETTY
Title: SVP, International	Title: DEAN
Date: January 24, 2020	Date: 18-02-2020

MGM Medical College & Hospital SKILLS LAB

INCHARGE
MGM SKILLS LAB
DATE: 25/01/2020

DIRECTOR
MGM SKILLS LAB
DATE: 25/01/2020

heartful campus
be all you can be

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (hereinafter referred to as "MOU") has been agreed upon, made, and executed on this 10th December 2021).

Between

HEARTFULNESS EDUCATION TRUST, a registered trust having its registered office at no. 40-15-9/12, Nandamuri Road, Venkateswarapuram Post Office, Vijayawada – 520 010, Andhra Pradesh, India (hereinafter referred to as "**HET**", which expression shall unless repugnant to the context and meaning thereof mean and include its successors, administrators, authorized representatives and permitted assigns);

And

MGM SCHOOL OF BIOMEDICAL SCIENCES, Navi Mumbai (MGMSBS, NM), a constituent unit of MGM Institute of Health Sciences (MGMIHS), established in the year 2008 as a is deemed university with campuses in Aurangabad and Navi Mumbai by statutory enactment to cater to the growing requirements of Higher Education of the region in general, and of Raigad district, in particular, located at Kamothe, Navi Mumbai, 410206, Raigad District (hereinafter referred to as "**MGMSBS, NM**", which expression shall unless it be repugnant to the context or meaning thereof mean and include its successors, administrators, authorized representatives and permitted assigns).

(**HET** and **MGMSBS, NM** shall hereinafter be collectively referred to as the "**Parties**" and individually referred to as "**Party**" in this MOU)

WHEREAS:

i) **HET** is a public charitable trust registered under the Indian Trust Act, 1882 *inter alia* with an objective to impart Heartfulness approach to various wellness programs including relaxation, meditation, values-based educational programs for schools, colleges, government organizations,

corporates, etc., made available to all who are willingly interested in individual development and wellbeing. HET is also engaged in conducting various Teachers' training programs in collaboration with Certain State Governments/ Education Institutions.

ii) **MGMSBS, NM** is MGM SCHOOL OF BIOMEDICAL SCIENCES (MGMSBS, NM), a constituent unit of MGM Institute of Health Sciences (MGMIHS), established in the year 2008 as a is deemed university with campuses in Aurangabad and Navi Mumbai by statutory enactment to cater to the growing requirements of Higher Education of the region in general, and of Raigad district, in particular, located at Kamothe, Navi Mumbai, 410206, Raigad District in particular. **MGMSBS, NM** desires to provide and inculcate in its students' values and inner development in order for them to perform better as students and be leaders for growth in nation-building. MGMIHS, NM has several recognized institutions under its umbrella.

iii) **HET** through its Heartfulness initiatives offers a way for balanced living through various meditation techniques. These simple and effective techniques gradually imbibe feelings of discipline, empathy, and brotherhood, leading to mental, spiritual, and psychological well-being, helping an individual to transform not only inwardly but also his/ her attitudes and dealings with society at large.

iv) **PU** intends to procure training and experiential learning services provided by HET on the terms agreed to herein, in order to stimulate and facilitate the development of programs/modules which serve to enhance the educational, social, spiritual & emotional development of students. Further, HET and MGMSBS, NM in support of their interest in the field of education are desirous of promoting mutual cooperation by organizing and conducting educational workshops for the mental, spiritual, and psychological well-being of its students, and desire to extend the basis for friendly and cooperative collaboration by way of this MOU.

NOW, THEREFORE, THE PARTIES HEREBY AGREE AS UNDER:

1. PURPOSE AND OBJECTIVES

1.1. MGMSBS, NM desires to create a precedent by offering suitable and pertinent learning and offerings to its students so as to enable them to lead their lives with purpose and be of help to the society at large. MGMSBS, NM constituent unit of MGMIHS has represented that it is a leading allied health professionals' college that offers high-quality education and its priority is to provide its students with values, and inner development enabling them to perform better in their education & be leaders in the nation building. It seeks to provide its students with basic life skills to manage challenges in their relationships, avoid intoxicating abuses, and digital dependence, and deal with the stress of modern life. It aims to enable its students and staff to de-stress, manage life's challenges in healthy ways and find joy, purpose, and fulfillment. This will directly enhance their academic and work performance and create a harmonious environment within MGMSBS, NM.

1.2. HET has agreed to be helpful in such a mission through its offerings as listed in Schedule 1 ("**Offerings**").

1.3. Both the Parties, hereby express their commitment to collaborate with each other to conduct (i) **educationa**l, (ii) Heartfulness relaxation, meditation, and (iii) other connected wellness workshops to help students, and teachers regulate their minds, moderate their tendencies, increase their concentration, sharpen the use of their will, introspect and self-analyses and accept people and situations in general. Through such workshops and Offerings of HET, they intend to help the students to improve their learning skills and behavior and inculcate humility, emotional maturity, confidence, stress management, self-awareness, and most importantly, develop a sense of purpose in life.

2. FACILITATORS

Both Parties shall nominate one or more representatives, who shall be the point of contact/ facilitator ("**Facilitators**") for the purposes of this MOU. The Facilitators of the respective Parties shall maintain regular contact with each other. Further, they shall propose and review the response received from the participants for the workshops and other activities that may be

conducted pursuant to this MOU and in furtherance to fulfilling the purpose and objectives envisioned under this MOU.

3. RESOURCES

3.1. MGMSBS, NM shall make arrangements at its agreed venue(s) with required reference and reading material as specified by HET, ban an establishing an (i) Heartfulness corner in their library, and (ii) meditation practice room, and by providing such audio-visual equipment and other facilities as shall be required for the conduct of the workshops and/programs with respect to the Offerings.

3.2. **HET** shall nominate such teachers, trainers, and support staff as it deems necessary for conducting and providing training to participants at these workshops and programs pursuant to this MOU.

3.3. **HET** shall provide support to orient PU's teachers to conduct the sessions as advised by **HET** for the students at MGMSBS, NM, and shall provide such external support as required. Through these Offerings, **HET** will make students at MGMSBS, understand values and their role in improving the quality of their life and enable them to impart spiritual training as an extended activity in its institutions as and when feasible.

3.4. The Parties agree to distribute reading materials/ promotional/ literature to the participants, through any means including but not limited to audio and/or video recordings, books, and magazines as deemed fit by **HET**. **HET** shall share the content of such reading materials, literature, video recordings, and other such material with MGMSBS, NM, before distributing the same to the participants.

3.5. The Parties further agree that at **HET's** discretion, they shall set up stalls at the program venue to distribute promotional items including but not limited to clothing, apparel, mementos, brochures, other merchandise, and/or articles and details of the program, etc.

3.6. The Offerings detailed in Schedule 1 shall be the scope of service to be rendered by **HET** which will be adhered to by **HET** during the term of this MOU.

4. OTHER OBLIGATIONS OF MGMSBS, NM

4.1. MGMSBS, NM shall extensively promote **HET** Offerings so that a greater populace of students in MGMSBS, NM shall benefit from this initiative. As previously indicated in Clause 1.1 above, being a value-based model of education, MGMSBS, NM may make all or any part of the Offerings, as applicable, a part of their curriculum for the students on a mutually agreed basis between the Parties.

4.2. MGMSBS, NM shall:

i) Take initiatives such that its students shall attend the sessions conducted by **HET** with an objective to help them develop ideal value systems to make them global citizens;

ii) Facilitate students to integrate and imbibe such values into their lives and education;

iii) Jointly conduct surveys at regular interviews to find the effectiveness of the programs conducted pursuant to this MOU;

iv) Encourage its students, faculty, staff, and administration to share written, audio, and/or video testimonials with respect to any training programs, workshops, or seminars conducted by **HET**;

5. FINANCIAL UNDERSTANDING

5.1. **HET** shall provide its services with respect to Heartfulness meditation practices on a free of charge basis at all times as agreed. However, it is hereby agreed that certain expenses relating to but not limited to training programs, workshops and faculty shall be charged in the following manner. MGMSBS, NM shall bear the expenses:

i) Relating to the Offerings in terms of material, recommended readings, library Heartfulness corner, meditation room(s) to be used by students and teachers at MGMSBS, NM shall be borne by MGMSBS, NM and the same would be set up as per the recommendations made by HET.

ii) for training programs for faculty and students organized at HET centers, wherein an appropriate per diem expense would be undertaken by MGMSBS, NM for boarding and lodging of the participants.

5.2. **Logistics:**

PU shall reimburse all expenses with respect to (i) all actual to and from travel expenses, including but not limited to train, bus, flight, and taxi, borne by all the **HET** trainers and special guests who are invited to MGMSBS, NM for conducting sessions/programs, (ii) food and (iii) other miscellaneous expenses shall be reimbursed. HET shall provide such guidelines as necessary.

6. TERM

6.1. This MOU has been executed for the purpose of organizing workshops/ seminars/ training sessions at the premises of MGMSBS, NM or such other premises as may be mutually agreed upon in writing.

6.2. This MOU shall come into effect from the Execution Date and shall remain in force for a period of one year thereafter.

6.3. This MOU shall terminate after the completion of the term of one year from the Execution Date, without any financial obligations of Parties, except for any pending reimbursements and costs as provided herein.

6.4. The Parties may execute similar agreements for similar initiatives in the future or even extend the term of this MOU for such further periods as mutually agreed to by the Parties.

6.5. Either Party may voluntarily terminate this MOU by giving a 3-month notice in writing to the other.

6.6. The provisions of this Clause 6.6 and 8 and all of its sub-clauses will survive any expiration or termination of this MOU.

7. ASSIGNMENT

This MOU is personal to the Parties and the rights and obligations established herein shall not be assignable by the Parties, except to the extent expressly permitted under this MOU or with the prior written consent of the other Party.

8. INTELLECTUAL PROPERTY

8.1. Neither Party shall exercise any rights in the trademarks, copyright, or other intellectual property of the other Party, except as expressly stipulated herein.

8.2. All intellectual property rights including all (i) copyrights and other rights associated with works of authorship throughout the world, including neighboring rights, moral rights, and mask works, (ii) trade secrets and other confidential information, (iii) patents, patent disclosures and all rights in inventions (whether patentable or not), (iv) trademarks, trade names, internet domain names, and registrations and applications for the registration thereof together with all of the goodwill associated therewith, (v) all other intellectual and industrial property rights of every kind and nature throughout the world and however designated, whether arising by operation of law, contract, license, or otherwise, and (vi) all registrations, applications, renewals, extensions, continuations, divisions, or reissues thereof now or hereafter in effect ("**IPR**") with respect to (a) "Heartfulness", (b) "Heartfulness Relaxation", (c) "Heartfulness Meditation", (d) "Heartfulness Cleaning", their techniques and/or connected procedures therein and (d) the title and content/modules or any other information shared with PU, it's staff, students and teachers, as the case may be, as part of the Offerings of HET, and (e) other trademarks belonging to **HET** or of those of its associates, (collectively referred to as "**Heartfulness IP**") as and when used by **HET** under license shall always vest with **HET** or its associates, as applicable. **HET** reserves the right to use the same internally or externally at its sole discretion.

8.3. This MOU in no way creates or conveys any ownership interests in Heartfulness IP to **PU**. MGMSBS, NM shall only use such Heartfulness IP or any part thereof, in the manner and form previously approved in writing by **HET** and in coordination with and assistance of **HET** authorized representatives.

8.4. HET reserves the right to modify, change or improve such Heartfulness IP in the manner it deems fit and implements such changed versions of Heartfulness IP or wellness techniques at any time during the term of this MOU.

8.5. The Parties agree that all ownership rights in any and all testimonials submitted in accordance with Clause 4.2 (IV) above shall vest with **HET**.

9. INDEMNITY

9.1. Except for cost reimbursements, the services provided by **HETs** with respect to the Offerings are on a mutual basis and free of cost. Only willing participants for their own wellbeing / self-development are required to participate. MGMSBS, NM may for the development of its students make the **HET** programs, modules, and/or workshops, as part of its curriculum. The Parties, therefore, agree that such services do not give rise to any kind of damage or liability to anybody who participates and therefore no damage can arise therefrom. No indemnity is therefore provided herein. The Parties agree that **HET** programs do not guarantee the success of its objectives or purposes as mentioned anywhere in this MOU.

9.2. In the event MGMSBS,NM breaches the terms of Clause 8 (intellectual property) of this MOU, HET shall be entitled to seek specific performance against the MGMSBS,NM for performance of its obligations under Clause 8 (intellectual property) of this MOU in addition to any and all other legal or equitable remedies available to it.

10. GOVERNING LAW, JURISDICTION & ARBITRATION

10.1. This MOU shall be construed, interpreted, and enforced in accordance with the laws of India. In case of any differences between the Parties, they shall make all efforts to settle the disputes amicably through mutual discussion and negotiation within [30 days], failing which, dispute(s) shall be referred to a sole arbitrator appointed by both the Parties, as per provisions of Arbitration and Conciliation Act, 1996. The language of the arbitration shall be English and the place of arbitration shall be Hyderabad.

10.2. Subject to the arbitration Clause 10.1 above, the courts of competent jurisdiction in Hyderabad shall have exclusive jurisdiction with respect to any and all matters pertaining to this MOU.

11. MISCELLANEOUS

i) This MOU together with any other documents including but not limited to the memorandum of understandings, communications exchanged between the Parties defining responsibilities, obligations of both the Parties for different programs, initiatives, etc. under this MOU, each of which shall be deemed to be an original, and all of which, taken together, shall constitute an integral part of this MOU constitute the entire agreement and supersedes any previous agreement between the Parties relating to the subject matter of this MOU.

ii) This MOU can only be amended in writing by mutual consent of both the Parties. No modification or amendment to this MOU and no waiver of any of the terms or conditions hereof shall be valid or binding unless made in writing and duly executed by or on behalf of both the Parties.

iii) This MOU may be executed in counterparts and shall be effective when each Party has executed a counterpart. Each counterpart shall constitute an original of this Agreement.

iv) If any provision of this MOU shall be invalid, illegal, or otherwise unenforceable, the validity, legality, and enforceability of the remaining provisions shall in no way be affected or impaired thereby.

v) The captions of the clauses of this MOU are for convenience of reference only and in no way define, limit or affect the scope or substance of any clause of this MOU.

vi) The arrangement contemplated herein being in nature of cooperative strategic alliance for general wellbeing, no monetary consideration is involved except as provided for herein.

vii) None of the provisions of this MOU as stated above shall be deemed to constitute a partnership between **HET** and MGMSBS, NM and neither

Party shall have any authority to bind or shall be deemed to be the agent of the other in any way. It is on a principle-to-principle basis.

viii) PU agrees that the participants in any of the HET programs shall participate voluntarily. The practices prescribed by HET are not substitutes for any medical prescription or medical advice, if any, recommended by any medical practitioner.

IN WITNESS WHEREOF the Parties hereto have executed this MOU, in duplicate, by their duly authorized representatives on the date, month, and year first written above.

For **HEARTFULNESS EDUCATION TRUST**

Nivedita

Dr Nivedita Shreyans
Coordinator Healthful Campus
Date: 10th Dec 2021.

For **MGM SCHOOL OF BIOMEDICAL SCIENCES(MGMSBS), NM**

Dr. Mansee Thakur
Director MGMSBS, NM
Date: 10th Dec 2021.

Director
MGM School of Biomedical Science
Kamothe, Navi Mumbai

Witnesses:

1) Dr. Kapil S. Thaker.

2)

Witnesses:

1) Mr. Yogesh Patil

2) Dr. Neelam Yeram

SCHEDULE- 1
Scope of Work

Heartfulness Education Trust (HET) shall offer the following programs specifically developed for the specific needs of the University:

1. **Staff Training**: **HET** shall impart a training program on "Wellness at work" to all Principals, Teachers, and Staff of the MGMSBS, NM institutions at its campus. MGMSBS, NM may at its sole discretion make it compulsory for its faculty/staff. Initially, this would be a three-day program to introduce the Heartfulness Meditation Practice and how it can be integrated into best education practices. This wellness program can also be offered at Kanha Shanti Vanam, the world headquarters of Heartfulness located near chegur village, RangaReddy district with a residential program facility on the basis of mutual agreement.

2. **In-depth Faculty Training on Heartfulness Curricula:** Following the initial introduction, interested faculty would be provided a longer duration in-depth teacher training program to further enhance and develop the Heartfulness tools and Curricula. This program would be developed suitably by Heartfulness Education Trust and made available at Kanha Shanti Vanam / Heartfulness centers or on MGMSBS, NM campus on an ongoing basis on agreed intervals during the term of this MOU.

3. **HELM (Heartfulness Enabled Leadership Mastery) curriculum for students: HET** shall choose a college on MGMSBS, NM campus to begin in-depth training for students. This would cover a [3 day] induction program and a [16-week] life-skills course which will be followed by subsequent foundational leadership programs such as 'Discover', 'Develop', 'Deepen', 'Dedicate' etc which can be included as credit courses. These are core Heartfulness programs conducted by certified Heartfulness trainers which will be experiential sessions of 60-90 minutes for each student group.

4. **Internships for students:** Faculty offering 'Heartful Electives' can design projects that aim to integrate ethical and contemplative aspects into particular student projects.

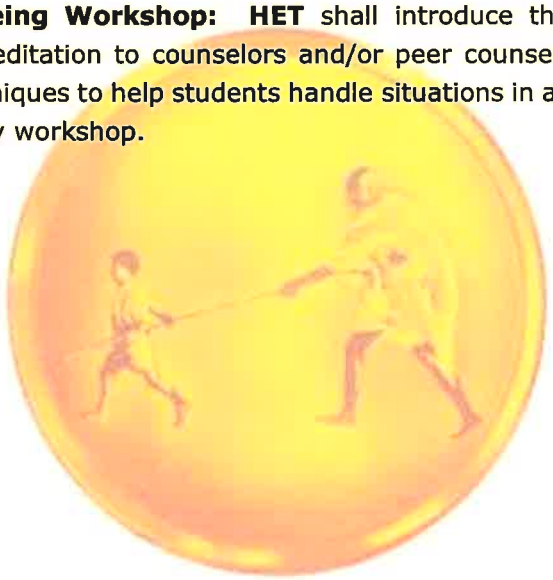
5. **Leadership Conclave/Roundtable on Heartfulness Leaderships:** HET shall conduct a 3-day workshop for the senior management of **PU,** including to limited to the vice-chancellors, registrars of MGMSBS, NM to shine some

light on the relationship between meditation and education.

6. **H.E.A.R.T: HET** shall conduct a workshop for the faculty at PU, to inspire them to teach in a reflective manner and also to help them integrate meditative aspects to their course design.

7. **Heartfulness Meditation Workshop: HET** shall introduce the experience of Heartfulness Meditation to the administration department, the ground staff, general public and parents of the students at MGMSBS, NM through a 3-day experiential workshop.

8. **Inner Well-Being Workshop: HET** shall introduce the experience of Heartfulness Meditation to counselors and/or peer counselors and provide them with techniques to help students handle situations in a calmer manner, through a 3-day workshop.



भारतीय गैर न्यायिक

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ONE HUNDRED RUPEES

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VR 323334

चा प्रकार Undertaking

न नोंदणी करणार आहेत का?

नोंदणी होणार असल्यास दु निबंधक कार्यालयाचे नाव

लिहिकर्तीचे वर्णन.....

मुद्रांक शुल्क

26 SEP 2019

दिनांक 5/10/2019

एस.टी.कार्यालय प्रयोजनासाठी सही.....

दुय्यम निबंधक/मुद्रांक विक्रेत्याची सही.....

A Memorandum of Understanding (MoU)

Between

MGM SCHOOL OF BIOMEDICAL SCIENCES
(MGM INSTITUTE OF HEALTH SCIENCES)
KAMOTHE, NAVI MUMBAI

And

PROGRESSIVE EDUCATION SOCIETY'S
MODERN COLLEGE OF ARTS, SCIENCE & COMMERCE
GANESHKHIND, PUNE

Director
MGM School of Biomedical Science
Kamothe, Navi Mumbai

Principal

MGM SCHOOL OF BIOMEDICAL SCIENCES, NAVI MUMBAI
(A constituent unit of MGM INSTITUTE OF HEALTH SCIENCES)
(Deemed University u/s 3 of UGC Act 1956)
Grade "A" Accredited by NAAC
Sector 1, Kamothe Navi Mumbai-410209, Tel.No:022-27437631, 27432890
Email. sbsnm@mgmuhs.com / Website: www.mgmsbsnm.edu.in

Under

DEPARTMENT OF MEDICAL BIOTECHNOLOGY
MGMSBS, MGMIHS
Sector 1, Kamothe Navi Mumbai-410209, Tel.No:022-27437631, 27432890
Email. sbsnm@mgmuhs.com / Website: www.mgmsbsnm.edu.in

For

PROGRESSIVE EDUCATION SOCIETY'S
MODERN COLLEGE OF ARTS, SCIENCE & COMMERCE
Pune University Circle, Pashan Road, Ganeshkhind, Pune 411 016
Email: moderncollege16@gmail.com / Website: www.moderncollegegk.org

Day 07th October 2019

Principal
Modern College of Arts, Science & Commerce, Ganeshkhind, Pune-16.

7/10/19

Director
MGM School of Biomedical Science

PREAMBLE:

The MEMORANDUM OF UNDERSTANDING (MoU) made on 7th October 2019 between the MGM Institute of Health Sciences, Navi Mumbai, a deemed to be University under section 3 of the University Grants Commission Act,1956 having its office at –MGMIHS, Kamothe, Navi Mumbai -- through its Department of Medical Biotechnology, MGM School of Biomedical Sciences, through Dr. Mansee Thakur, Director (hereinafter referred to as the party of the **"First Part/MGMSBSMBT"** which expression shall, unless repugnant to the context thereof, include its, successors and assigns.) **and Progressive Education Society's Modern College of Arts, Science and Commerce, having its office at Ganeshkhind, Pune** through Dr. Sanjay S. Kharat, its Principal (hereinafter referred to as the party of the **"Second Part/MCASCGK"** which expression shall, unless repugnant to the context thereof, include its, successors and assigns).

SCOPE AND OBJECTIVES OF MoU:

The scope and objectives of MoU are defined as:

MGMSBSMBT and MCASCGK agree to sign MoU for sharing academic, clinical training/internship, on job training, project work, student/faculty exchange and for collaborative research programmes to get the Mutual Benefits.

DURATION OF MoU:

This MoU comes into effect from the date of its signing and will remain in force for a period of **FIVE YEARS**. Its validity can be extended by mutual agreement between both the parties.

RESPONSIBILITIES OF MGMSBSMBT, KAMOTHE, NEW MUMBAI AND MCASCGK, GANESHKHIND, PUNE:

Specific Roles of MGMSBSCN:

1. Provide technical support and facility for the students under the UG/PG/PhD programs
2. The prospective students will be allowed to undergo training in the following specialty departments
    - Hydroponics
    - Zebra fish facility
    - Molecular Biology

Modern College of Arts, Science & Commerce, Ganeshkhind, Pune-16.

Principal

07/10/2019

Director

MGM School of Biomedical Science

MGM SCHOOL OF BIO-MEDICAL SCIENCES KAMOTHE NAVI MUMBAI

3. MGM will provide the academic staff and necessary infrastructure for UG/PG/PhD courses mutually for smooth conduct of the programs.
4. Exchange of information through lectures and practicals relating to their activities in field of mutual interest.
5. Provide internship to the B.Sc/M.Sc. students.
6. Provide Dissertation projects to the M.Sc students.
7. Arrange observer ship programs for the students.
8. Sharing of information periodically and regularly.

Specific roles of MCASCGK

1. Provide technical support and laboratory facility for the students under the UG/PG/PhD programs.
2. Exchange of information through lectures and practicals relating to their activities in field of mutual interest.
    - Microbiology
    - Molecular Biology
    - Plant Tissue Culture
    - Animal Sciences
    - Animal Tissue Culture

Common Activities by Both the Parties

1. Both institutions agree to supply work space, library and technical facilities as applicable.
2. The consultancy and travel expenses related to the visits for lectures/sessions will be reimbursed by the host institute on mutually agreed terms.
3. The MoU may be amended, renewed and terminated by mutual written agreement between the Heads of both the institutes.
4. Either institute shall have the right to terminate this MoU upon 60 days prior notice period to the other Institute.
5. Both the institute and industry i.e. MGMSBSBT and MCASCGK will organize conferences, workshops, seminars etc The faculty, students and staff shall be

Modern College of Arts, Science & Commerce, Ganeshkhind, Pune-16

Principal

Director
MGM School of Biomedical Sciences

encouraged to participate in such activities so as to interact with each other for their academic and professional growth; such programmes will be conducted by both the institutions with information to each other in advance, as and when required.

6. MGMSBSMBT and MCASCGK mutually agree to exchange staff / students for their projects, clinical training/internship, on job training, project work, and student/faculty exchange and for collaborative research programmes to get the Mutual Benefits and the charges will be borne by individual students as per the institutes rules and regulations.
7. MGMSBSMBT and MCASCGK mutually agree to help each other to establish and develop laboratories, research centers, etc. as and when required.
8. Faculty of MGMSBSMBT and MCASCGK depending on their qualifications and experience can act as co-guides to the students pursuing the M.Sc and Ph.D. programmes at MGMSBSMBT and MCASCGK as the case may be.
9. Areas for faculty development shall be identified and joint proposals shall be submitted to various funding agencies like ICMR, DST, DBT, BRNS, and RGSTC etc.
10. Both the institutes will participate in relevant government programs / schemes to take mutual benefits of Institute - Institute collaborations where ever possible.
11. MGMSBSMBT and MCASCGK mutually agree that Publications of the joint research carried out will be done jointly by both the Institutes incorporating the names of all the contributors
12. This document is in no way intended to create a legal or binding obligations on either party. It serves only as a record of the parties' current intentions to enhance relationship of the Institute and Institute going forward.

General Conditions:

1. The MoU will be valid for a period of 5 years to ensure smooth conduct of the activities under the MoU and to achieve the objective of the MoU. The parties may further extend/renew the MoU on terms and conditions as mutually agreed. Within the aforesaid period of 5 years, the MoU may be terminated only by mutual consent.

Modern College of Arts, Science & Commerce, Ganeshkhind Pune-53

7/10/19

Principal
Modern College of Arts, Science & Commerce, Ganeshkhind Pune-53

7/10/2019

Director
MGM School of Biomedical Sciences

MGM SCHOOL OF BIO-MEDICAL SCIENCES KAMOTHE NAVI MUMBAI

3. Once the MoU is terminated no new activity will be conducted by and between the parties. However, the parties undertake to complete the activities, programs etc which have already been commenced or are in progress pursuant/under this MoU.

2. The parties will jointly conduct quarterly meetings to ensure that the activities/programs undertaken under this MoU by and between the parties are conducted in a proper manner and as per the schedule laid down.

NOTICES

Any notices given under this Agreement will be in writing and delivered by e-mail or speed post or by hand addressed to the parties as follows:

MGMSBSMBT:-

Address: Department of Medical Biotechnology, MGMSBS, MGMIHS

Sector 1, Kamothe Navi Mumbai-410209, Tel.No:022-27437631, 2743289
Email. sbsnm@mgmuhs.com / Website: www.mgmsbsnm.edu.in

MCASCGK:-

Address: Progressive Education Society's Modern College of Arts, Science and Commerce, Ganeshkhind, Pune

MISCELLANEOUS

a. **Assignment.**

Neither party may assign this Agreement or the rights there under without the prior written consent of the other party.

b. **Survival.**

Any of the sections that include any other rights and obligations under this Agreement which by their nature should survive, shall survive the expiration or termination of this Agreement.

c. **Severability**

If any provision of this Agreement becomes or is declared illegal, invalid, or unenforceable,

Principal
Modern College of Arts, Science

Director
MGM School of Biomedical Sciences

such provision will be divisible from this Agreement and will be deemed to be deleted from this Agreement. If such deletion substantially alters the basis of this Agreement, the parties will negotiate in good faith to amend the provisions of this Agreement to give effect to the original intent/object of the parties under this MOU.

d. **Independent Entities.**

MGMSBSMBT and MCASCGK are independent parties and neither is an agent, joint venture partners, or partner of the other.

e. **Order of Precedence.**

In the event of any inconsistency between the terms of this Agreement and the documents referenced or incorporated herein or any other document, correspondence or agreement concerning this Programme between the Parties and/or their employees, the terms of this Agreement will prevail.

f. **Entirety.**

This Agreement represents the entire agreement and understanding between the parties with respect to its subject matter and supersedes any prior and/or contemporaneous discussions, representations, or agreements, whether written or oral, of the parties regarding this subject matter.

g. **Amendments.**

The Amendments or changes to this Agreement must be in writing and signed by duly authorized representatives of both the parties. No amendment or modification of this MoU shall be valid unless the same is made in writing by both the parties or their authorized representatives and specifically stating the same to be an amendment of this agreement. The modification/changes shall be effective from the date on which they are made / executed unless otherwise agreed to.

h. **Counterparts.**

This Agreement may be executed in multiple counterparts, each of which will be deemed an original, but all of which will constitute one and the same Agreement, and the signature pages from any counterpart may be appended to any other counterpart to assemble fully executed counterparts.

Principal
Modern College of Arts, Science & Commerce, Ganeshkhind Pune-16

9/10/2019
Director
MGM School of Bio-Medical Sciences, Kamothe, Navi Mumbai

i. **Dispute Resolution.**

- In event of dispute or claim between the parties concerning the interpretation of any provision of this agreement or the performance of any of the terms/obligations of/under this Agreement, such matter or matters in dispute shall be first settled amicably by mutual discussion between the **Director of MGMSBS and Principal of MCASCGK** failing which through the Arbitration process. Both the parties after due discussion shall appoint an Arbitrator for resolving the dispute arising out of this Agreement.

Now, therefore, for and in consideration of the foregoing premises the parties have signed the Memorandum of Understanding on 7th Day of October 2019.

PARTIES

Director	Principal
MGM School of Biomedical Sciences, Navi Mumbai, (A Constituent Unit Of MGM Institute Of Health Sciences), Sector 1, Kamothe Navi Mumbai-410209	**Progressive Education Society's Modern College of Arts, Science and Commerce,** Ganeshkhind, Pune 411016
07/10/2019 Director MGM School of Biomedical Science Kamothe, Navi Mumbai	7/10/19 Principal Modern College of Arts, Science & Commerce, Ganeshkhind, Pune-16.

WITNESS

1. 07/10/19 (Pune)
2. Himanshu Rajat Gupta 7/10/19

Dated

WITNESS

1. 7.10.19 C S U Todkar
2. Dr. Vinay Kumar

Dated 07/10/2019

18

MEMORANDUM OF UNDERSTANDING

BETWEEN

MGM SCHOOL OF BIOMEDICAL SCIENCES,NAVI MUMBAI
(A constituent unit of MGM INSTITUTE OF HEALTH SCIENCES)
(Deemed University u/s 3 of UGC Act 1956)
Grade "A" Accredited by NAAC
Sector 1, Kamothe Navi Mumbai-410209, Tel.No:022-27437631, 27432890
Email. sbsnm@mgmuhs.com / Website: www.mgmsbsnm.edu.in
Under

DEPARTMENT OF CLINICAL NUTRITION, MGMSBS, MGMIHS,

Sector 1, Kamothe Navi Mumbai-410209, Tel.No:022-27437631, 27432890
Email. sbsnm@mgmuhs.com / Website: www.mgmsbsnm.edu.in

For

NIRMALA NIKETAN COLLEGE OF HOME SCIENCE,
49, NEW MARINE LINES,
Mumbai- 400 020
Phone: 022-22076503 Fax: 22003217
Email: info@nirmalaniketan.com
Under

DEPARTMENT OF FOODS, NUTRITION AND DIETETICS
Nirmala Nilketan College of Home Science,
49, New Marine Lines, Mumbai- 400 020
Phone: 022-22076503 Fax: 22003217
Email: info@nirmalaniketan.com

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act 1956)
Navi Mumbai- 410 209

Thursday 4th April 2019

PREAMBLE:

The MEMORANDUM OF UNDERSTANDING (MoU) made on 4th April 2019 between the MGM Institute of Health Sciences, Navi Mumbai, a deemed to be University under section 3 of the University Grants Commission Act,1956 having its office at –MGMIHS, Kamothe, Navi Mumbai -- through its Department of Clinical Nutrition, MGM School of Biomedical Sciences, through Dr. Mansee Thakur, Director (hereinafter referred to as the party of the **"First Part/MGMSBSCN"** which expression shall, unless repugnant to the context thereof, include its, successors and assigns.) **and Nirmala Niketan College of Home Science, Mumbai, having its office at New Marine lines through Dr. Geeta Ibrahim its** Principal (hereinafter referred to as the party of the **"Second Part/NN"** which expression shall, unless repugnant to the context thereof, include its, successors and assigns.) .

SCOPE AND OBJECTIVES OF MoU:

The scope and objectives of MoU are defined as:

MGMSBSCN and NN agree to sign MoU for sharing academic, clinical training/internship, on job training, project work, student/faculty exchange and for collaborative research programmes to get the Mutual Benefits.

DURATION OF MoU:

This Mou comes into effect from the date of its signing and will remain in force for a period of **FIVE YEARS**. Its validity can be extended by mutual agreement between both the parties.

RESPONSIBILITIES OF MGMSBSCN, KAMOTHE, NEW MUMBAI AND NN, MUMBAI:

Specific Roles of MGMSBSCN:

1. Provide technical support and facility for the students under the UG & PG program
2. The prospective students will be allowed to undergo training in the following specialty departments
    - Medicine
    - Surgery
    - Pediatrics
    - Gynecology and Obstetrics
    - Geriatric

- Skin and VD
- Orthopedics

3. MGM will provide the academic staff and necessary infrastructure for UG/PG course for smooth conduct of the programs.
4. Exchange of information through lectures and practical's relating to their activities in field of mutual interest;
5. Sharing of information periodically and regularly.

Specific roles of NN:

1. Provide technical support and laboratory facility for the students under the UG and PG programs.
2. Exchange of information through lectures and practical's relating to their activities in field of mutual interest;

- **Common Activities by Both the Parties**

1. Both institutions agree to supply work space, library and technical facilities as applicable.
2. The consultancy and travel expenses related to the visits for lectures/sessions will be reimbursed by the host institute on mutually agreed terms.
3. The MoU may be amended, renewed and terminated by mutual written agreement between the Heads of both the institutes.
4. Either institute shall have the right to terminate this MoU upon 60 days prior notice period to the other Institute.
5. Both the institute and industry i.e. MGMSBSCN and NN will organize conferences, workshops, seminars etc. The faculty, students and staff shall be encouraged to participate in such activities so as to interact with each other for their academic and professional growth, such programmes will be conducted by both the institutions with information to each other in advance, as and when required.
6. MGMSBSCN and NN mutually agree to exchange staff / students for their projects, clinical training/internship, on job training, project work, student/faculty exchange and for collaborative research programmes to get the Mutual Benefits and the charges will be borne by individual students as per the institutes rules and regulations.
7. MGMSBSCN and NN mutually agree to help each other to establish and develop laboratories, research centers, etc. as and when required.
8. Faculty of MGMSBSCN and NN depending on their qualifications and experience can act as co-guides to the students pursuing the M.Sc and Ph.D. programmes at MGMSBSCN and NN as the case may be.

9. Areas for faculty development shall be indentified and joint proposals shall be submitted to various funding agencies like ICMR, DST, BRNS, and RGSTC etc.
10. Both the institutes will participate in relevant government programs / schemes to take mutual benefits of Institute - Institute collaborations where ever possible
11. MGMSBSCN and NN mutually agree that Publications of the joint research carried out will be done jointly by both the Institutes incorporating the names of all the contributors
12. This document is in no way intended to create legal or binding obligations on either party. It serves only as a record of the parties' current intentions to enhance relationship of the Institute and Institute going forward

General Conditions:

1. The MoU will be valid for a period of 5 years to ensure smooth conduct of the activities under the MoU and to achieve the objective of the MoU. The parties may further extend/renew the MOU on terms and conditions as mutually agreed. Within the aforesaid period of 5 years, the MoU may be terminated only by mutual consent. Once the MoU is terminated no new activity will be conducted by and between the parties. However, the parties undertake to complete the activities, programs etc which have already been commenced or are in progress pursuant/under this MoU.

2. The parties will jointly conduct quarterly meetings to ensure that the activities/programs undertaken under this MoU by and between the parties are conducted in a proper manner and as per the schedule laid down.

NOTICES

Any notices given under this Agreement will be in writing and delivered by e-mail or speed post or by hand addressed to the parties as follows:

MGMSBSCN :-

Address: Department of Clinical Nutrition, MGM SBS, MGMIHS
Sector 1, Kamothe Navi Mumbai-410209, Tel.No:022-27437631, 2743289
Email. sbsnm@mgmuhs.com / Website: www.mgmsbsnm.edu.in

NN :-

Address: Nirmala Niketan College of Home Science,
49, New Marine Lines,
Mumbai- 400 020 Phone: 022-22076503 Fax: 22003217
Email: info@nirmalaniketan.com

MISCELLANEOUS

a. **Assignment.**

Neither party may assign this Agreement or the rights there under without the prior written consent of the other party.

b. **Survival.**

Any of the sections that include any other rights and obligations under this Agreement which by their nature should survive, shall survive the expiration or termination of this Agreement.

c. **Severability**

If any provision of this Agreement becomes or is declared illegal, invalid, or unenforceable, such provision will be divisible from this Agreement and will be deemed to be deleted from this Agreement. If such deletion substantially alters the basis of this Agreement, the parties will negotiate in good faith to amend the provisions of this Agreement to give effect to the original intent/object of the parties under this MOU.

d. **Independent Entities.**

MGMSBSCN and NN are independent parties and neither is an agent, joint venture partners, or partner of the other.

e. **Order of Precedence.**

In the event of any inconsistency between the terms of this Agreement and the documents referenced or incorporated herein or any other document, correspondence or agreement concerning this programme between the Parties and/or their employees, the terms of this Agreement will prevail.

f. **Entirety.**

This Agreement represents the entire agreement and understanding between the parties with respect to its subject matter and supersedes any prior and/or contemporaneous discussions, representations, or agreements, whether written or oral, of the parties regarding this subject matter.

g. **Amendments.**

The Amendments or changes to this Agreement must be in writing and signed by duly authorized representatives of both the parties. No amendment or modification of this MoU shall be valid unless the same is made in writing by both the parties or their authorized representatives and specifically stating the same to be an amendment of this agreement. The modification/changes shall be effective from the date on which they are made / executed unless otherwise agreed to.

h. **Counterparts.**

This Agreement may be executed in multiple counterparts, each of which will be deemed an original, but all of which will constitute one and the same Agreement, and the signature pages from any counterpart may be appended to any other counterpart to assemble fully executed counterparts.

i. **Dispute Resolution.**

In event of dispute or claim between the parties concerning the interpretation of any provision of this agreement or the performance of any of the terms/obligations of/under this Agreement, such matter or matters in dispute shall be first settled amicably by mutual discussion between the Director of **MGMSBS and**

Principal of NN failing which through the Arbitration process. Both the parties after due discussion shall appoint an Arbitrator for resolving the dispute arising out of this Agreement.

Now, therefore, for and in consideration of the foregoing premises the parties have signed the Memorandum of Understanding on Thursday of 4th April 2019.

PARTIES

Director	Principal
MGM School Of Biomedical Sciences, Navi Mumbai, (A Constituent Unit Of MGM Institute Of Health Sciences), Sector 1, Kamothe Navi Mumbai-410209	**Nirmala Niketan College of Home Science,** 49, New Marine Lines, Mumbai- 400 020
Dr Mansee Thaker	Dr. GEETA IBRAHIM.

Director
MGM School of Biomedical Science
Kamothe, Navi Mumbai

WITNESS

1. Dr. Mini Mol P.
2. Dr. Priyanka Pa
Dated - 4/4/19.

WITNESS

1. Anuradha Mitra
2. Noella Dias
Dated 4/4/19

भारतीय गैर न्यायिक

एक सौ रुपये Rs. 100

रु. 100 ONE HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA ◐ 2019 ◐ WF 771179

15 FEB 2020

दुय्यम निबंधक
सह दुय्यम निबंधक नवी मुंबई ५
जि. रायगड.

मुद्रांक विक्रेता अधिकारी
पनवेल - रायगड

Memorandum of Understanding
Between
MGM Institute of Health Sciences Trust, Navi Mumbai (MGMIHS)
And
Apollo Specialty Hospitals Private Limited (ASH)

This **Memorandum of Understanding** (hereinafter referred to as the "MOU") is made and entered into as of the date of last signature below by and between:
MGM Institute of Health Sciences Trust, Navi Mumbai (MGMIHS, which expression shall include its subsidiary, successors and assigns) having its office at Mahatma Gandhi Mission Medical College, Sector 1, Kamothe, Kalamboli, Navi Mumbai, Maharashtra 410209 through its Authorized representative/ Director **of the First Part**

And

Apollo Specialty Hospitals Private Limited , having its registered cum corporate office at 7-1-617/A, 615 & 616, Imperial Towers, 7th Floor, Ameerpet, Hyderabad- 500038 through its **Authorized Signatory,** Anubhav Prashant, COO- Apollo Cradle and Apollo Fertility,

Apollo Specialty Hospitals Private Limited

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

hereinafter refereed as 'ASH', which expression shall include its subsidiary, successors and assigns) of the Second Part .

MGMIHS and ASH are jointly referred as the Parties or Institutions and individually referred by their name.

Whereas the Institutions intent to work together to develop a collaborative arrangement, whereby the institutions may participate in collaborative teaching, training, research and other agreed activities that further enhance the program as more
particularly stated here in below and the relationship between the institutions.

And Whereas pursuant to various meetings and discussion the parties have agreed to conduct certain programs/courses jointly. The parties represent and warrant that the parties are within their respective rights to enter into and execute the present MOU and have been authorized to execute and enter into this MOU, which authorizations are annexed hereto as Annexure A collectively.

The "MGMIHS" and "ASH" shall be collectively referred to as "Parties" and individually as "Party" and shall mean and include their respective successors-in-interest and permitted assigns.

1. **WHEREAS:**

MGM Institute of Health Sciences Trust, Navi Mumbai (MGMIHS)

The MGMIHS was established on 28th March 2006 with a futuristic vision to provide qualitative education by applying innovative and dynamic pedagogical techniques. Since inception, MGMIHS has focused on providing Health Care Services, Medical Education with utmost dedication and commitment. Service to society at the grass root level has been the basic vocation of MGMIHS along with education. MGMIHS has been instrumental in providing prompt and efficient health care services to the economical weaker sections of the society. The Teaching Hospitals and Medical Colleges underscore its commitment to human resource development and social health and welfare.

Apollo Specialty Hospitals Private Limited (ASH)

Apollo Specialty Hospitals Private Limited (ASH), is a subsidiary company of Apollo Health and Lifestyle Limited (AHLL), a company registered under the Companies Act and having its registered office at 7-1-617/A, 615 & 616, Imperial Towers, 7th Floor, Ameerpet, Hyderabad-500038. AHLL in turn is a subsidiary company of Apollo Hospital Enterprise Limited (AHEL) a company registered under the Companies Act and having its office at 19 Bishop Gardens, Raja Annamalaipuram, Chennai 600006. ASH has all valid and subsisting approvals and licenses and is eligible to execute and enter into this MOU.

Apollo Fertility, is a brand of Apollo Specialty Hospitals Pvt. Ltd. (ASH), is a leading chain in the field of ART (Assisted Reproductive Technologies). ASH has started the brand Apollo Fertility in the year 2016, which has now over a period of 3 years established itself as a thought leader in the field of infertility medicine, and currently operates 12 centers across India. Apollo Fertility offers several specialized investigative procedures for infertility in men and women giving couples their very best chance of a successful pregnancy.

Apollo Specialty Hospitals Private Limited

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

Backed by AHEL's 35-year legacy of clinical excellence and unbeatable expertise, ASH through Apollo Fertility brings to the table unparalleled commitment towards Assisted Reproductive Technologies and successful outcomes. Over the years the ASH team has been adding advanced treatments into its service offerings through the Apollo Fertility brand and has been keen in providing best possible treatments to the couples.

With world class embryology laboratory and best possible protocols and dedicated Embryologists, ASH has been able to achieve far better success rates in comparison to the industry benchmarks. ASH team includes specialists in Fertility, Reproductive Medicine, Reproductive Endocrinology, Andrology, Urology, Fertility Enhancing Laparoscopic Surgeons, Fetal Medicine and a supportive team of Clinical Counsellors, Care Managers and Dieticians. ASH through Apollo Fertility has been making significant strides in its journey by having single minded focus on service to the patients.

The parties hereto acknowledge that the Parties have the required infrastructure and facilities including faculty, libraries, laboratories which, if associated with each other will only complement each other, enhance and improve the learning experience, provide a more comprehensive and detailed practical experience and training.

NOW THEREFORE THIS MOU WITNESSETH AS FOLLOWS:

1. **Objectives of the MOU:**

The MGMIHS and Apollo Fertility agree:

- To develop managerial and academic skills in graduates to effectively administer IVF, Clinical Embryology, Gynecology departments and or units with the application of appropriate technologies and instructional strategies
- To offer certificate programs, Masters, fellowships, PG Diploma programs and short term courses to improve the employability skills;
- To conduct jointly training programmes, workshops, seminars, and other awareness activities in the area of reproductive health and medicine which are mutually agreeable.

2. Areas of Collaboration:

- Providing fellowship program in reproductive medicine to Gynecologists
- Providing certificate program in ART (Assisted Reproductive Technology).
- To cooperate in the exchange of information through lectures and practical's relating to their activities in field of mutual interest.
- To cooperate in exchange of information through lectures and practical's by Apollo's experts for 30 days MSC clinical embryology in Semester II and Semester III at both campuses.
- To provide awareness and interaction through conducting talks and workshops.

3. The Program

The Programs under this present MOU covers the following courses: -

(i) Fellowship in Reproductive Medicine (Duration -1 Year)

(ii) M.Sc Clinical Embryology (Duration 2 Year)

Hospitals Private Limited

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Registrar
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(iii) Certificate Programmes (Duration 6 month or 1 month)

The courses entail theory and practical training. The parties agree and undertake that the parties will jointly conduct the program and the courses thereunder. The courses will be conducted at the premises of both the parties as per the required and available expertise, infrastructure and facilities. The Parties agree and acknowledge that the facilities and infrastructure of the Party's compliment and support each other and thereby provides and supports a more complete, comprehensive and advanced course/program. The courses shall be run at the premises of both the Parties and the students shall be permitted to use the facilities under supervision during the term of the course.

The Parties agree that the experts of ASH shall visit the MGMIHS premises as visiting/ honorary faculty, the schedule of which shall be synchronized.
The students will be permitted to use the laboratories of ASH at Apollo Fertility as per the schedule agreed upon. Such visits will be under the supervision of the MGMIHS faculty. Apollo agrees that the said faculty visiting the laboratories shall be trained by the experts of Apollo.

4. Administration:

4.1. The Authorized Signatories of both MGMIHS and ASH shall jointly administer and supervise the program and the courses under this MOU. The parties will be responsible for developing and carrying out a joint action plan and making regular reports on the implementation of this MoU to the Head of Department of OBGY (MGM Medical College, Navi Mumbai) and Clinical Embryology(MGMSBS, Navi Mumbai), MGMIHS. The report then shall be placed before the Board of Studies/ Academic Council in its next scheduled meeting.

5. OBLIGATIONS OF PARTIES

MGMIHS and ASH through its Apollo fertility have agreed that in support of their mutual interest in the field of education & community service, both the Parties shall undertake the following obligations.

A. **Obligations of MGMIHS**:

- To provide Reproductive Medicine Fellowship Program to M.D./MS/ DGO/FCPS in Obstetrics & Gynecology in MCI approved place or D.N.B. in Obstetrics & Gynecology in NBE approved place
- In addition to fellowship Programme, MGMIHS shall design and implement short term courses / certificate courses through MGMIHS for PG students and post graduates as approved by the Board of Management.
- Enhancing coverage and reach of infertility cases through the outreach program in the villages, among students, staff & faculty.
- Provide technical support and expertise in developing courses for fellowship, short term, and certificate courses
- Exchange of information through lectures and practical's relating to their activities in field of mutual interest;

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- Exchange of information through lectures and practical by faculty or subject experts of MGMIHS for 30 days each in MSc in Clinical Embryology program for Semester II and Semester III at campuses.
- To arrange for and make available the required classroom/s for provision of training/lectures to the enrolled students as may be mutually agreed from time to time.
- To conduct assessment / examinations, evaluation and issue certificates to the trainees after completion of the training / course.
- To prepare marks memos and dispatch the diploma certificates to the candidates.

B. **Obligations of Apollo Fertility /ASH**

- Provide technical support and facilities including but not limited to laboratory facility for the students under the fellowship program
- Provide technical support and facility for the students for short term courses / certificate courses through MGMIHS for ART to UG and PG students.
- Provide technical support and training facility for the faculty visiting the laboratories along with the students for the short-term courses / certificate courses through MGMIHS for ART to UG and PG students.
- Conduct weekly or biweekly infertility OPD at MGM Kalamboli and MGM CBD.
- Provide technical support and expertise in developing courses for fellowship, short term, and certificate courses.
- Provide diagnosis at mutually agreed costs and treatment to the economically challenged people affected by infertility which is in congruent to the organizations mission.
- Exchange of information through lectures and practical's relating to their activities in field of mutual interest;
- Exchange of information through lectures and practicals by experts for 30 days each in MSc in Clinical Embryology program for Semester II and Semester III at both campuses.

C. **Joint Obligations of Apollo Fertility/ASH and MGMIHS**

- To make joint efforts and take care of promotional activities, for wide publicity of the courses being conducted under this Understanding
- Both institutions agree to supply work space, library and technical facilities to the students as per the need and requirements.
- The parties agree that the consultancy and travel expenses related to the visits for lectures/sessions, talks and workshops will be reimbursed by the host institute on mutually agreed terms.
- Both the parties agree and undertake jointly and independently to organize conferences, workshops, seminars etc. The faculty, students and staff shall be encouraged to participate in such activities so as to interact with each other for their academic and professional growth.
- Various programmes, seminars and events may be conducted by the parties with information to each other in advance, as and when required

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Registrar
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- The parties agree to make efforts to exchange staff / students for their projects and provide support, train the faculty and staff of MGMIHS with laboratory working and functioning.
- The parties agree to help each other to establish and develop laboratories, research centers, etc. as and when required including after the termination or determination of this MOU.
- The parties agree for exchange and sharing of technical and scientific data and research material, solely for the purpose of education and research.
- Faculty of MGMIHS and Apollo Fertility depending on their qualifications and experience can act as co-guides to the students pursuing the M.Ss, M. Tech, and Ph.D. programmes at MGMIHS and Apollo Fertility as the case may be.

6. For the purpose of facilitating the implementation plan of this MoU, both the parties agree to have regular communication and correspondence, all of which shall be also copied to the Head of Department of OBGY (MGM Medical College, Navi Mumbai) MGMIHS and the Head of Apollo Fertility, ASH. Only writing communications shall be considered as valid official communications.

7. This MoU shall be effective and comes into force upon signature of the authorized signatories of both the parties. It shall be subject to revision only by a written and duly executed agreement/addendum between two parties.

8. **Committee;**
The MGMIHS and Apollo Fertility shall appoint the Coordinators/Authorized representatives in their respective offices who shall be responsible for coordinating all communication, supervising and directing the implementation of the MoU. Activities like examination, admission, administrative matters will be monitored through a committee of MGMIHS.
The authorized representatives and or coordinators shall jointly supervise the program and courses, and file reports in respect thereof to the Committee. The committee shall place the reports before the Board of Management or the Board of studies or Academic Council as required.

9. **Duration:**
The MoU shall become effective from August 1, 2019 ('**Effective Date**') and this document is executed by the authorized officials of both the parties and shall remain in force for a period of **Three years** ('**Term**'). Upon the completion of this term, the MoU may further be renewed for a period of another three years or a mutually agreed period upon the assent of both the parties.

10. **Financial Provisions:**
Fees and Expenses
The parties shall in consultation jointly decide upon the fees and other charges for the courses. The parties agree that the programs are the joint responsibility of the parties and are being conducted jointly at the premises of the parties. The parties have agreed

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Registrar
MGM Institute of Health Sciences
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and undertaken to comply with their respective duties, obligations listed herein and have agreed to incur the expenses for the same. The expenses required to run the programs shall be incurred from the revenue share or form the parties own resources if the expenses exceed the revenue share. The respective duties/responsibilities of the parties program wise are listed below:-

LECTURES TAKEN BY BOTH PARTY FOR THE PROGRAMME OF FELLOWSHIP IN REPRODUCTIVE MEDICINE

MGMIHS	APOLLO
1. Infertility and IVF Procedures	**1. Infertility and IVF Procedures**
• concepts in infertility	• Intrauterine Insemination
• Aetiology of female infertility	• Assisted Conception
• Evaluation of female factor	• Uterine Receptivity
• Investigations in the female	• Oocyte donation
• Uterine Receptivity	• Embryo donation
• Endometriosis – Diagnosis & management	**2. Intracytoplasmic sperm injection (ICSI)**
• Polycystic ovarian disease – Evaluation & management	• Success rate with different treatment modalities for infertility
• Recurrent loss – Evaluation & management	• Monitoring & treatment of early pregnancy after ART treatment
	• Complications of ART & its management
	3. Andrology
	• Hands on semen analysis
	• semen washing,
	• Sperm Donation
	• sperm freezing and Thawing
	4. Tests for ovarian reserve
	• Different stimulation protocol and monitoring of controlled ovarian hyper stimulation
	• Prevention of OHSS and its management
	• Approaches to ovarian stimulation in PCO patients
	5. QC, QA and Record keeping in ART –
	• Setting up of an ART Lab

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	• Equipment required for setting an ART Lab
	• Quality Assurance & quality control in ART laboratory
	6. Ethics and regulation in ART
	• Ethical aspects of infertility management
	7. ART in endometriosis
	• Egg pick up protocol, its trouble shoots, Hands on egg pick up in oocyte pick up room
	• Hands on culture dish preparation
	• Hands on Gamete handling and IVF insemination in embryology lab
	• Hands on catheter loading of embryos and transfer using non gamete cells
	8. Luteal support
	• Cryopreservation [Vitrification] and preparation for frozen Thaw
	• Embryo transfer and its protocol
	• Discussion Demonstration about ICSI and IMSI.

LECTURES & PRACTICALS SCHEDULE FOR M.Sc. CLINICAL EMBROLOGY

MGMIHS **Lectures Theory / Practical**	**APOLLO INFERTILITY** **Lectures Theory /Practical**
Relevant Gross Anatomy	Infertility & Ovulation induction methods
Histology	Quality assessment, statistics, handling data, ethics, legislation
Genetics and Reproductive Hormone	IVF procedure
General & Systemic Embryology	Introduction to IVF lab
Research Methodology & Biostatistics	Techniques used in IVF Lab
Biochemistry including steroid metabolism	ICSI

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Navi Mumbai- 410 209

Dissertation / Project guidance	Dissertation / Project guidance

Fee Share:-
MGMIHS will collect the fee (as decided as this clause) from students and shall pay the fee share to ASH's Apollo Fertility within 30 days after the last date for receiving fees from the students. Payment shall be subject to TDS as per applicable rate.
The parties agree to share the fees as under:

Course	**Total Fee**	**Apollo Fertility Share**	**MGMIHS**
Fellowship in Reproductive Medicine	INR 5,00,000/-	50%	50%
M.Sc.Clinical Embryology	INR 1,00, 000/-	25%	75%
Certificate Programmes	Mutually agreed Fee	50%	50%

Cost of GST if any applicable shall be borne by MGMIHS.

11. AMENDMENT, DURATION AND TERMINATION OF MOU

11.1 The tenure of MoU may be extended with mutual agreement of the parties and on terms and conditions as are mutually negotiated and agreed by and between the parties.

11.2 This MoU may be amended at any time only by a written document/ amendment in writing signed by the parties and with the prior mutual consent of both the parties. The parties agree that any amendment to the MOU shall be in writing and signed by the authorized person of the parties. The amendment shall be in the form of an addendum. The parties agree that the other terms and conditions of the MOU shall remain valid, effective and binding on the parties.

11.3 This MoU may be terminated by either party by the provision of prior written notice of termination of 30 days to each other. However, both parties agree that all continuing obligations to stake holders, are met in full subsequent to the notice of termination

11.4 The termination of this MoU shall not affect the rights or obligations of either party regarding any binding offer or firm obligation approved and agreed to either party prior to the termination date.

12. MISCELLANEOUS

12.1 If any provision of this Memorandum is held by any court or other competent authority to be illegal, void or enforceable in whole or in part, this MoU shall continue to be valid as to the other provisions therefore and the remainder of the effected provision.

Apollo Specialty Hospitals Pvt. Limited

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

12.2 Nothing in this MoU constitutes or to be construed a party as the partner, agent, employee or representative of the other party. A party must not act independently of the other Party and does not have the right or power to commit the other Party on any matter or incur any obligation on behalf of or pledge the credit of the other Party without the prior written approval of the other Party.

12.3 The parties agree to comply with all laws applicable within the jurisdiction of the signatories below.

12.4 Parties shall conduct their activities following all the statutory regulations and law of the land in letter and spirit

13. Assignment.

Neither party may assign this Agreement or the rights there under without the prior written consent of the other party.

14. Order of Precedence.

In the event of any inconsistency between the terms of this Agreement and the documents referenced or incorporated herein or any other document, correspondence or agreement concerning this Programme between the Parties and/or their employees, the terms of this Agreement will prevail.

15. Entirety.

This Agreement represents the entire agreement and understanding between the parties with respect to its subject matter and supersedes any prior and/or contemporaneous discussions, representations, or agreements, whether written or oral, of the parties regarding this subject matter.

16. Counterparts.

This Agreement may be executed in multiple counterparts, each of which will be deemed an original, but all of which will constitute one and the same Agreement, and the signature pages from any counterpart may be appended to any other counterpart to assemble fully executed counterparts.

17. Dispute Resolution.

In event of dispute or claim between the parties concerning the interpretation of any provision of this agreement or the performance of any of the terms/obligations of/under this Agreement, such matter or matters in dispute shall be first settled amicably by setting up a mutually agreeable committee of faculty. The parties after due discussion shall try their level best to resolve the disputes arising out of this agreement, failing which through the Arbitration process. Both the parties after due discussion shall appoint an Arbitrator for resolving the dispute arising out of this Agreement. The venue and place for arbitration shall be Hyderabad. Proceeding of arbitration shall be in English. Decision of the arbitrator shall be final and binding upon both the Parties. Cost of arbitration shall be bear by the Parties jointly.

18. Jurisdiction:

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
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Navi Mumbai- 410 209

If the dispute cannot be settled by the above process, the courts located at Mumbai could be approached for adjudication.

IN WITNESS WHEREOF, the undersigned, being duly authorized thereto, have signed this Memorandum of Understanding in two original copies in English at the place and on the date indicated below:

PARTIES

On behalf of:
Apollo Specialty Hospitals Pvt. Ltd.

Anubhav Prashant
COO- Apollo Cradle & fertility
Date:

WITNESS

1.

2.

On behalf of:
MGMIHS

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

WITNESS

1. Dr. Mini Mol
2. Mrs. Supriya Pawar

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

MGM SCHOOL OF BIOMEDICAL SCIENCES, NAVI MUMBAI
(A constituent unit of MGM INSTITUTE OF HEALTH SCIENCES)
(Deemed University u/s 3 of UGC Act 1956)
Grade "A" Accredited by NAAC
Sector 1, Kamothe Navi Mumbai-410209, Tel.No.:022-27437631,27432890
Email. sbsnm@mgmuhs.com / Website: www.mgmsbsnm.edu.in

And

SVERI

Shri Vithal Education and Research Institute's

College of Engineering, Pandharpur

For

Institutional Academic and Research Cooperation

1st day of January 2018

PREAMBLE:

The MEMORANDUM OF UNDERSTANDING (MoU) between **MGM School of Biomedical Sciences, Kamothe, Navi Mumbai** and **Shri Vithal Education and Research Institute's College of Engineering, Pandharpur for Academic and Research Cooperation,** is signed on the 1st day of January 2018.

This MOU entered between MGM School of Biomedical Sciences, Kamothe, New Mumbai (MGMSBS) (hereafter called **MGMSBS**) and Shri Vithal Education and Research Institute's College of Engineering, Pandharpur (hereafter called **SVERI**) represented in this MoU by the Director, MGMSBS and Principal, SVERI, respectively, on behalf of Board of Governors of their institutes, which shall mean and include their successors in interest and assigns.

SCOPE AND OBJECTIVES OF MoU

The scope and objective of MoU are defined as:

MGMSBS and SVERI agree for **Academic and Research Cooperation** between all their departments for mutual benefits to the institute.

DURATION OF MoU

This MoU comes into effect from the date of its signing and will remain in force for a period of **FIVE YEARS**. Its validity can be extended by mutual agreement between both the parties.

RESPONSIBILITIES OF MGMSBS, KAMOTHE, NAVI MUMBAI AND SVERI, PANDHARPUR

- **The MGMSBS and the SVERI** mutually agrees to identify the various areas of interest and depute faculty as per requirements for conducting courses or research.
- Both the institutes i.e. **the MGMSBS and the SVERI** will organize technical competitions, conferences, workshops, seminars, quizzes, etc. The faculty and students shall be encouraged to participate in such activities so as to interact with each other for their academic and professional growth, such programmes will be

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conducted by both the institutions on regular basis with information to each other in advance.

- **The MGMSBS and the SVERI** mutually agrees to exchange students for their projects. Both the institutes will provide all the facilities concerning the academics to the students of each other.
- **MGMSBS and SVERI** mutually agree to help each other to establish and develop laboratories, research centres, etc, as and when required.
- Faculty of **MGMSBS** and **SVERI** depending on their qualifications and experience can act as co-guides to the students pursuing the M. Tech, and Ph.D. programmes at **MGMSBS and SVERI** as the case may be.
- Areas for staff development shall be indentified and joint proposals shall be submitted to various funding like MHRD, DST. BRNS, RGSTC, AICTE, etc.
- Both the institutes will help each other in placement and industrial collaborations.
- This document is in no way intended to create legal or binding obligations on either party. It serves only as a record of the parties' current intentions to enhance relationship of the Institutions going forward.

AMEDEMENTS TO THE MoU

No amendment or modification of this MoU shall be Valid unless the same is made in writing by both the parties or their authorized representatives and specifically stating the same to an amendment of this agreement. The modification/changes shall be effective from the date on which they are made / executed unless otherwise agreed to.

ARBITRATION

In the event of any dispute or difference between the parties hereto, such disputes or differences shall be resolved amicably by mutual discussion between the Director of **MGMSBS** and Principal of **SVERI**.

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Now, therefore, for and in consideration of the foregoing premises the parties have signed the Memorandum of Understanding on 1st day of January 2018.

PARTIES

Director
MGM School of Biomedical Sciences,
Navi Mumbai,
(A Constituent Unit of MGM Institute Of Health Sciences), Sector 1, Kamothe Navi Mumbai-410209

Director
MGM School of Biomedical Science
Kamothe, Navi Mumbai

Principal
Shri Vithal Education and Research Institute's College of Engineering, Pandharpur,
Gopalpur-Ranjani Road, Pandharpur-413304
For and On behalf of Board of Governors
SVERI'S College of Engineering Pandharpur

COLLEGE OF ENGINEERING PANDHARPUR

WITNESS

1. (V.K.SURI)
2. Yogesh. N. Patil.

Date

WITNESS

1. Dr. P.M. Pawar
2. Mr. S.S. Wangikar

Date

NEW MEMBER AGREEMENT

This agreement is made and entered into on this 15th day of October, 2015 between;

Indian Institute of Technology, Bombay, a research and educational institution in technology and engineering disciplines established by a special act of Parliament of Republic of India having its office at Powai, Mumbai-400 076, India, hereinafter referred to as 'IITB' and **MGM Institute of Health Sciences**, Kamothe Navi Mumbai, 410209

MGM Institute of Health Sciences, Kamothe Navi Mumbai registered under societies Act, 1860 and having its registered office address at MGM campus, sector 1, Kamothe Navi Mumbai 410209 hereinafter referred as "MGM Institute of Health Sciences".

WHEREAS A Healthcare Consortium was formed vide a Consortium Agreement dated 7th September, 2011 between Indian Institute of Technology, Tata Memorial Centre, National Institute of Research in Reproductive Health, **King** Edward Memorial Hospital and Span Diagnostics Ltd (the 'Consortium Agreement' -Annexure -A) for the objectives and modes of collaboration as contained therein.

WHEREAS in pursuance thereof a Healthcare Consortium was formed to carry out and effectuate the purposes under the said Consortium Agreement with the aforestated founding partner organizations as Members thereof. The Healthcare Consortium has undertaken and started many health care activities/projects and initiatives as envisaged under the said agreeement.

WHEREAS the MGM Institute of Health Sciences has shown its interest, intends to and is keen to join and partake in the activities of the said Healthcare Consortium vide its letter/proposal dated 10th April 2015 to the Consortium.

WHEREAS In view of the aforesaid letter/proposal reflecting the desire of MGM Institute of Health Sciences intending to become a Member of the Healthcare Consortium, the Advisory Committee has accepted/approved such a proposal of the MGM Institute of Health Sciences, to become a new Member of the Healthcare Consortium, in its Board meeting dated 10th April 2015. Further, the Advisory Committee has approved and authorized IITB to enter into an agreement with MGM Institute of Health Sciences for inducting in the Healthcare Consortium as a New Member based on the condition that such intending New Member agrees to the terms of the Consortium Agreement.

Now, therefore, the Parties hereto, agree to the following,

(1/2)

RP Mullampatan

RP Mullampatan

1. The MGM Institute of Health Sciences hereby agrees that in addition to the terms of this agreement, it shall be subject to, bound and governed by the terms and conditions of the said Consortium Agreement (Annexure 1).

2. The MGM Institute of Health Sciences, hereby agrees that, upon execution hereof, it shall be assigned/accorded the status of a Member in the Healthcare Consortium and shall duly discharge or partake in all activities of the said consortium as per the terms of the said Consortium Agreement and the guidelines issued by the Advisory Committee from time to time.

3. The said Consortium Agreement (annexed hereto as Annexure 1) and the terms thereof are incorporated in its entirety herein by reference and form an integral part of this agreement.

4. IITB is executing this agreement with the MGM Institute of Health Sciences as a confirming party for inclusion of the MGM Institute of Health Sciences as a Member of the said consortium, as authorized by the Governing Council.

IN WITNESS WHEROF, the authorized representatives of the parties hereto, have executed this New Member Agreement as set forth below;

MGM Institute of Health Sciences, Kamothe, Navi Mumbai

By: _____

Name:Lt. Gen. Dr. Shibban .K. Kaul

Title:Pro Vice Chancellor

Date: 15th October, 2015

INDIAN INSTITUTE OF TECHNOLOGY BOMBAY, FOR CONSORTIUM

By: _____ 26/10/15

Name: Prof. K. P. Kaliappan

Title: _____

Date:

For Director, IITB

By: _____

Name: Dr. Rajani Mullerpatan

Title: Prof – Director, Physiotherapy

Date: 15th October, 2015

RMullerpatan

To,
The Director
IIT Bombay

Letter of Intent

I am writing in connection with the Healthcare Research Consortium at IIT Bombay.

This is to confirm our principle interest to participate as a member of the consortium. We understand that this may involve sharing facilities, pooling expertise, participating in joint educational and training programmes and research projects for mutual benefit.

We nominate the undersigned _____, from _____, as a nodal point to represent our organization in the healthcare research consortium.

As active members of the Consortium, we agree to initiate and/or participate in conducting workshops, seminars, conferences, joint projects or any other research/ educational/ societal level ventures that will promote the Consortium as a multi-disciplinary platform for healthcare research in India.

We look forward for working together along with other consortium members to make a greater impact to healthcare in time.

Organization Representative

12th May ~~[illegible]~~ 2015

Hon'ble Vice chancellor -

Sir, following our meeting yesterday, may I request your opinion on the faculty member nominated by MGMIHS as a point of contact.

In all earlier communications & meetings I have represented MGMIHS.

Please advise. After your advice, I shall complete the LOI on MGMIHS letter head & seek your signature. Thank You.

Kind Regards.

RMullerpatan

Signatory of non-JOI
PVC Dr Kaul -
&
Dr. Rajani Mullerpatan

RMullerpatan

MGM INSTITUTE OF HEALTH SCIENCES

(Deemed University u/s 3 of UGC Act 1956)

Grade 'A' Accredited by NAAC

To,

The Director
IIT Bombay

Letter of Intent

I am writing in connection with the Healthcare Research Consortium at IIT Bombay.

This is to confirm our principle interest to participate as a member of the consortium. We understand that this may involve sharing facilities, pooling expertise, participating in joint educational and training programmes and research projects for mutual benefit.

We nominate the undersigned Lt.Gen. Dr.S.K.Kaul & Prof.Rajani.P. Mullerpatan, from MGMIHS, as nodal points to represent our organization in the healthcare research consortium.

As active members of the Consortium, we agree to initiate and/or participate in conducting workshops, seminars, conferences, joint projects or any other research/ educational/ societal level ventures that will promote the Consortium as a multi-disciplinary platform for healthcare research in India.

We look forward for working together along with other consortium members to make a greater impact to healthcare in time.

Organization Representatives

Lt.Gen. Dr. S.K.Kaul,
Pro Vice Chancellor
MGMIHS
Email: pvc@mgmuhs.com
Tel.: 022-27437602

Prof.Rajani P Mullerpatan
Prof-Director, Physiotherapy &
MGM Centre for Human Movement Science
MGMIHS, Navi Mumbai
Email: rajani.kanade@gmail.com
Mobile: 9920048476

Date: 18.05.2015

O/C

NEW MEMBER AGREEMENT

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Indian Institute of Technology, Bombay, a research and educational institution in technology and engineering disciplines established by a special act of Parliament of Republic of India having its office at Powai, Mumbai-400 076, India, hereinafter referred to as 'IITB' and **MGM Institute of Health Sciences**, Kamothe Navi Mumbai, 410209

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WHEREAS the MGM Institute of Health Sciences has shown its interest, intends to and is keen to join and partake in the activities of the said Healthcare Consortium vide its letter/proposal dated 10th April 2015 to the Consortium.

WHEREAS In view of the aforesaid letter/proposal reflecting the desire of MGM Institute of Health Sciences intending to become a Member of the Healthcare Consortium, the Advisory Committee has accepted/approved such a proposal of the MGM Institute of Health Sciences, to become a new Member of the Healthcare Consortium, in its Board meeting dated 10th April 2015. Further, the Advisory Committee has approved and authorized IITB to enter into an agreement with MGM Institute of Health Sciences for inducting in the Healthcare Consortium as a New Member based on the condition that such intending New Member agrees to the terms of the Consortium Agreement.

Now, therefore, the Parties hereto, agree to the following:

(1/2)

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1. The MGM Institute of Health Sciences hereby agrees that in addition to the terms of this agreement, it shall be subject to, bound and governed by the terms and conditions of the said Consortium Agreement (Annexure 1).

2. The MGM Institute of Health Sciences, hereby agrees that, upon execution hereof, it shall be assigned/accorded the status of a Member in the Healthcare Consortium and shall duly discharge or partake in all activities of the said consortium as per the terms of the said Consortium Agreement and the guidelines issued by the Advisory Committee from time to time.

3. The said Consortium Agreement (annexed hereto as Annexure 1) and the terms thereof are incorporated in its entirety herein by reference and form an integral part of this agreement.

4. IITB is executing this agreement with the MGM Institute of Health Sciences as a confirming party for inclusion of the MGM Institute of Health Sciences as a Member of the said consortium, as authorized by the Governing Council.

IN WITNESS WHEROF, the authorized representatives of the parties hereto, have executed this New Member Agreement as set forth below;

MGM Institute of Health Sciences, Kamothe, Navi Mumbai

By: _____

Name:Lt. Gen. Dr. Shibban .K. Kaul

Title:Pro Vice Chancellor

Date: 15th October, 2015

INDIAN INSTITUTE OF TECHNOLOGY BOMBAY, FOR CONSORTIUM

By: _____ 26/10/15

Name: Prof. K. P. Kaliappan

Title: _____

Date:

By: _____

Name: Dr. Rajani Mullerpatan

Title: Prof – Director, Physiotherapy

Date: 15th October, 2015

Economically Developing Countries (EDC) Project
Memorandum of Understanding

Please note this document contains guidelines and examples to assist you when filling in each section. The instructions (highlighted in blue italics) should be deleted when completing this application form.

Declaration by the International Society of Biomechanics (ISB):

The ISB is dedicated to supporting international initiatives that will promote research, education, and the provision of healthcare in the field of biomechanics. The objectives of the ISB, with regards to the advocacy of projects in EDC regions, include the following:

- To make the Society truly international.
- To help develop skills of, and/or opportunities for, clinicians and researchers in EDC who do not have the resources available to do so on their own.
- To provide collaborative learning opportunities for students and researchers in developed countries to help them understand the challenges faced in the developing world.
- To enable donating organizations to do something beneficial with equipment that is no longer needed by them.
- To help provide a sustainable initiative that will allow biomechanics skills and knowledge to flourish in developing regions.
- To enable clinicians and researchers in developing countries to solve biomechanics-related problems specific to their own region.

The ISB would like to ensure the long-term sustainability and overall success of all EDC projects. As such, all participants must be clear on the objectives of the EDC participating organization(s) and the supporting organization(s), in addition to the outcomes each party wishes to achieve. This Memorandum of Understanding is intended to help clarify this for all participants. It is also the framework by which the ISB will evaluate the success of the project in the short and long-term and to find out whether the expected outcomes have been achieved, thereby enabling improvement of this process for future projects.

Participants:

Please list all organizations involved in this project (include those that are supporting the EDC participant by way of equipment donations, technical or financial support, or other resources) and their primary contacts.

	Name of Organization	EDC Participant OR	Supporting Organization	Primary Contact(s)	ISB Member Number*	E-mail
1.	*MGM School of Physiotherapy*	☒	☐	*Dr. Rajani Mullerpatan*	*5043*	*rajani.kanade@gmail.com*
2.	*Indian Institute of Technology, Mumbai*	☐	☒	*Prof. B. Ravi* *Mr. Rupesh Ghyar*	*N/A* *In progress*	*b.ravi@iitb.ac.in*
3.	*Cardiff University*	☐	☒	*Prof. Robert van Deursen*	*1974*	*vandeursenR@cardiff.ac.uk*
4.	*International Society of Biomechanics (ISB)*	☐	☒	*John Challis*	*1192*	*jhc10@psu.edu*

* A minimum of one primary contact from each organization must be a member of the ISB.

Project Proposal:

To be completed by **the EDC participant:**

1. **What is the overall mission of your organization** *(e.g. to improve the independence and wellbeing of physically disabled people...)* **and how does this project help to support it?**

The overall mission of MGMIHS is to provide healthcare services, research and higher education particularly in the area of medicine, nursing, physiotherapy and health management. Within physiotherapy/rehabilitation, training and research in the area of Biomechanics is essential to help maximize functional independence of people with physical impairments resulting from a wide spectrum of conditions i.e. repetitive stress, congenital, developmental and degenerative conditions precipitated by traumatic, vascular and pathologic origin. Precise and complete kinesiological assessment of such conditions will guide clinical decision making for accurate conservative, surgical, prosthetic/orthotic and ergonomic management for maximal functional outcome.

2. **What is the primary strategic objective(s) of this project? [Please specify details about one or more of the areas listed below. In formulating your objectives, consider specific results you would like to achieve.]**

   a. **Teaching/educational programs:**

   - To design and seek approval for a postgraduate degree course in Biomechanics designed at a level of global merit (to enable qualified postgraduates to participate in projects conducted worldwide) and local value to meet specific functional needs of our population emerging from a lifestyle influenced by exclusive Indian culture far different from Western lifestyle.
   - Establish training for students from various disciplines such as Physiotherapy, Bio-engineering, Mechanical engineering, Prosthetics - Orthotics and Orthopedics at graduate, postgraduate and PhD level.
   - Enhance skills in clinical biomechanics of faculty members of MGMSOP

   b. **Research programs:**

   - Produce high end research in the area of human movement science related to clinical questions; to offer health care solutions global in nature and specific to the Indian population.

   c. **Clinical assessment – diagnosis and treatment:**

   - Provide precise and complete kinesiological assessment of congenital, developmental and degenerative conditions precipitated by traumatic, vascular and pathologic origin which will guide clinical decision making for accurate conservative, surgical, prosthetic/orthotic and ergonomic management.

   d. **Other (please specify):**

   (Include additional lines if necessary)

3. **What initiatives/actions (project design and/or management strategies) will be implemented to achieve the results outlined in Question 2?**

a) Teaching/Educational programs:

- Curriculum for postgraduate course in Biomechanics will be designed and sought approval from MGMIHS and IIT Mumbai.

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- A circular will be sent to Bio-engineering, Mechanical Engineering, Prosthetics and Orthotics and Orthopedics departments within the above mentioned Institutes to inform students from respective disciplines training schedule in biomechanics.
- Training will be imparted to faculty members in form of continuing professional development.

b) Research programs:

- Collaborative research projects between the 3 organizations will be developed to produce high end research studies encompassing fundamental and clinical biomechanics. PhD students will be appointed on appropriate research projects. Broad areas of research are-
  i. Barefoot walking and the risk of plantar ulceration (in collaboration with IIT Mumbai, Cardiff University)
  ii. Foot and knee instability and the development of OA (in collaboration with Cardiff University and the University of Sydney)
  iii. Yoga postures and their effect on the musculoskeletal system (in collaboration with IIT Mumbai and Cardiff University)

c) Clinical assessment –

- Diagnosis and treatment: Information pertaining to available clinical biomechanical evaluation tools will be circulated to various departments within and outside the hospital within Mumbai and Navi Mumbai. Referred patients will be assessed using biomechanical tools to arrive at precise measurement of impairments. Income generated through such services will be used for financial viability of the center. Expenses incurred for annual maintenance of laboratory equipment will be covered partly from the income generated by the center and partly from the funding acquired for research projects.

4. Who will benefit from this project? *(e.g. Students, patients, etc)*

- Undergraduate and postgraduate students from Physiotherapy, Bio- engineering, Mechanical Engineering, Prosthetics and Orthotics and Orthopedics department will benefit from training. Training will be imparted to students within India and across continents. Every effort will be made to enroll students from within India and countries abroad.
- Faculty members from MGMIHS will benefit from skill development in clinical biomechanics
- A Biomechanics Center with expert input from biomechanics specialists worldwide operated in India will offer global merit training at subsidized cost thereby making it affordable for students from several developing countries.
- Patients with congenital, developmental and degenerative conditions of traumatic, vascular and pathologic origin will benefit from biomechanical evaluation.

5. What are the expected benefits for each group listed in Question 4? *(e.g. Exposure to state-of-the-art methods of...)*

- Students will be exposed to globally used state-of-the-art valid and reliable methods used for biomechanical studiessuch as quantitative movement analysis and plantar pressure measurement. They will receive hands-on training and have opportunities to use various biomechanical tools to conduct research in biomechanics. Such training of global merit will be available at affordable cost to students from developing countries.
- Patients will benefit from precise and complete kinesiological assessment which will guide clinical decision making for accurate conservative, surgical, prosthetic/orthotic and ergonomic management.
- Faculty members will benefit from acquiring skills for biomechanical evaluation which will be applied in both clinical practice and student training.
- The biomechanics center will benefit from financial viability through the above mentioned expected benefits.

6. Please list proposed milestones – associated with the actions, individuals, and benefits given in Questions 3, 4, and 5, respectively – together with a timeline of events. Milestones should include specific outcomes that the collaborators wish to achieve.

Key Milestones	Time period
1. Establish Biomechanics Center: installation of equipment and pilot start	*December 2013*
2. Collaborative research projects	*Already started. Ongoing*
3. Design the curriculum for Masters degree course in Biomechanics and seek approval from the above mentioned contributing organizations	*September 2014*
4. Commence the course in clinical biomechanics	*January 2015*
5. Commencement of clinical service to patients	*March 2014 onwards*

7. What other authority/administrative body, such as government or college administration officials, must approve this initiative to ensure resources are allocated to the intended recipients? Has approval already been sought *(please provide evidence of any approvals)*?

- Administrative/competent authorities of 3 above mentioned institutes have approved development of the research activities proposed at MGM Center for Biomechanics.
- Additionally, approval will be sought for curriculum for Masters Course in Biomechanics by University Grant Commission, India and Academic Council of MGMIHS.
- The opportunity to develop and approve transnational education in association with Cardiff University will be investigated.

8. What commitments will your organization make to ensure:
   a. Recognition of contributions provided by supporting organizations? *(e.g. Website acknowledgment, progress reports)*

- Publications and patents arising out of collaborative projects with Cardiff University and IIT Bombay will be shared by all 3 above mentioned organizations.
- MGMIHS will acknowledge the support and contribution provided by IIT

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Mumbai and Cardiff University on its website.

- Technical support provided by IIT Bombay will be acknowledged in relevant presentations and publications.
- Secondly, IIT Bombay will have an opportunity to conduct clinical trials at MGM Center for Biomechanics in collaboration with host organization which will be acknowledged in related reports.
- MGMIHS will acknowledge the support and contribution provided by IIT Mumbai, Cardiff University, ISB and AMTI on its website and in relevant publications
- MGMIHS will provide agreed upon (to be decided) educational materials to ISB to further share with ISB members in support to the EDC educational program
- MGMIHS will provide a brief "Project History" for the ISB website

b. Long-term sustainability of the project (including personnel required to ensure continuation of project into the future)? *(e.g. Staff training, technical support, security and maintenance, etc)*

- The host organization i.e. MGM Center for Biomechanics will provide ongoing security and maintenance of equipment.
- Technical guidance for equipment selection and experimental data analysis will be provided by II Bombay. The equipment maintenance will be sought via annual maintenance contract from the respective vendors.
- Staff training will continue as an ongoing process which will be partially supported by MGM Center for Biomechanics.
- Any agreed joint transnational education programs would facilitate staff development.
- Income generated through clinical services will aid financial viability of MGM Center for Biomechanics. For e.g. annual maintenance of equipment and expenses incurred towards consumables.
- Income generated through tuition fees for Masters Course in Biomechanics and PhD program will partially support salary of some staff members.
- Income generated through any agreed joint initiatives would be negotiated as appropriate.
- PhD students will be recruited as research assistants on certain projects.

Supporting Organizations – Commitments and Anticipated Benefits:

What contributions will be made by the supporting organizations? Please list all support that each participant has agreed to provide *(e.g. financial, in-kind, training, etc)*, the period over which they have committed this support, estimated costs for the organization, and how they will benefit *(e.g. publicity)*.

Organization	Commitments	Duration	Estimated Costs	Objectives/Benefits
MGMIHS	*Allotted infrastructure for Biomechanics Center*	*Ongoing*	*Approx 1 million USD*	*Supports objectives outlined on pg 1.*
	Allotted one competent Professor	*Ongoing*	*Salary is paid by MGMSOP (15,000 USD)*	
	Will recruit one research assistant & one laboratory technician	*Ongoing*	*Salary will be paid by MGMIHS (6000 USD)*	
	Already purchased some equipment such as emed pressure platform, activity monitoring system, Silicon coach etc.			
	Staff training	*2 weeks*		
Cardiff University	*Send Prof. van Deursen for 4-visits*	*4 visits:* *Nov 2013* *May 2014* *Nov 2014* *May 2015*	*Covered by ISB*	*Collaborative Research projects.* *Biomechanics lab design, installation of equipment.* *Provide expertise in curriculum design related to clinical biomechanics.*
IIT Bombay	*Technical guidance and collaborative research projects*	*ongoing*		*Using the MGMIHS Biomechanics lab for purpose of clinical testing of the products which are developed by IIT Bombay.*
ISB	*Financial support to send Prof. van Deursen to MGMIHS*	*4 visits*	*7,503 USD*	*Supports objectives outlined on pg 1; acknowledgment in appropriate media; support for development of EDC educational material.*
	Coordinate donation of two second-hand, re-calibrated force platforms from AMTI with technical support for 5 years	*As soon as available*	*Approx. 30,000 USD*	*AMTI acknowledgment in appropriate.* *MGMIHS and ISB media will strengthen relationship with AMTI.*

Budget

Before any project can be endorsed by the ISB, a detailed budget for all costs involved for each participating organization must be approved by the ISB President, EDC Project Officer, and ISB Treasurer. In the budget, please consider monetary costs involved in establishing/initiating the project plus ongoing costs to ensure the project is sustainable. Please include the budget as a separate document.

Signatures of primary contact from each participating organization:

Name (please print)	Signature	Date
Dr. Rajani Mullerpatan	RPMullerpatan	25 July 2013
Prof. B. Ravi		1 August 2013
Prof. Robert van Deursen		9 August 2013
Prof. John Challis		22nd Oct. 2013.

(Include additional lines if necessary)

RPMullerpatan

MEMORANDUM OF UNDERSTANDING (MOU)
BETWEEN
MGM INSTITUTE'S UNIVERSITY DEPARTMENT OF PHYSIOTHERAPY
(MGM IUDOP)
AND
WORLD SPINE CARE (WSC)
For rendering assistance, guidance and expertise for
establishment of World Spine Care programme of MGM IUDOP at
MGM Hospital, Kamothe, Navi Mumbai

This Memorandum of Understanding is entered into on November 10, 2016 between MGM Institute's University Department of Physiotherapy, Navi Mumbai, represented by its Director **(hereinafter referred to as MGMIUDOP)** and World Spine Care, a not for profit corporation created pursuant to the laws of the State of California **(hereinafter referred to as WSC)**, and herein after jointly referred to as Participants and in the singular as Participant":

(A) And whereas the Participants acknowledge that spinal injuries and disorders are amongst the most serious and debilitating health problems with the general population and more particularly in the working class, the labour class and the underserved/economically challenged communities in and around Navi Mumbai area;

(B) And whereas the Participants acknowledge and recognize the need for general population and more particularly in the working class, the labour class and the underserved/economically challenged communities to have access to local specialist spinal healthcare resources;

(C) And whereas the Participants acknowledge and recognize the lack of access to health care on spinal disorders could lead to physical and mental distress resulting in adverse economic implications to those who depend on manual labour and manual exertion for survival;

(D) And whereas MGMIUDOP acknowledge and recognize that WSC is supported by the Decade of the Bone and Joint, currently the Global Alliance for

Musculoskeletal Health, an Initiative of the World Health Organization and numerous other professional spine societies;

(E) And whereas the WSC has noted and appreciated that MGMIUDOP is committed to providing quality health services in the area of spinal injuries and disorders at the Kamothe hospital to the general public and specially to the working class, the labour class and the underserved communities in Navi Mumbai,

(F) And whereas the WSC has agreed to assist MGMIUDOP for treating spinal injuries and disorders by providing its guidance, supervision, assistance and medical expertise's to MGMIUDOP. The Participants have decided to reduce the said understanding by way of the present Memorandum of Understanding.

PARAGRAPH 1
PURPOSE

1.1. The purpose of this Memorandum of Understanding (MOU) is to facilitate the setting up of MGMIUDOP- World Spine Care programme **(MGM-WSC)** and to record the terms and conditions under which WSC will provide its expertise's assistance and cooperation for the establishment of the MGM's-WSC clinic in the MGM Hospital , Kamothe, Navi Mumbai Department of Physiotherapy **(hereinafter referred to as "MGM's WSC")**.

1.2 The MGM-WSC is a programme under which WSC will provide its medical expertise's and guidance in the field of spinal injuries, disorders and spine care. This agreement or programme does not amount to a transfer of rights or interest in the premises or land of whatsoever nature by MGM nor does it amount to parting with possession of the premises or land in any event whatsoever by MGM. This is a programme and not a partnership and neither party holds the right to obligate the other party without its express written permission other than as set out specifically in this agreement

PARAGRAPH 2
DEFINITIONS

2.1 **Spine:** means the neuro-musculoskeletal structures that make up the vertebral column from the base of the skull to the coccyx;

2.2 **Spinal Disorders:** means disorders of the Spine that can result in pain, neurological deficits, disability and / or deformity; and

2.3 **Spinal Injuries:** means injuries to the Spine that result in pain, neurological deficits, disability or deformity.

PARAGRAPH 3
DESCRIPTION OF THE PROJECT

The Participants have identified the following as goals/objectives of the programme which are as follows to:

3.1 Identify health care resources at MGMIUDOP, which could be considered in the establishment of an evidence-based Spine care program;

3.2 Establish MGM's WSC clinic in MGMIUDOP at Kamothe Hospital, Navi Mumbai.

3.3 Train MGMIUDOP spine care specialists in the use of the WSC spine care toolkit

3.4 Ensure worldwide interaction of health professionals to share knowledge on the assessment and management of spinal problems and harmonize treatment efforts; and

3.5 Eventually expand the spine care program to other communities where there is currently no access to spine care

The Participants have identified the following as the expected outcomes of the programme:

3.6 Improved health and healthcare of people with Spinal Disorders and injuries in Kamothe and Navi Mumbai area and eventually rural communities at reasonable and economical costs

3.7 Having trained and skilled individuals in Spine care from the communities where WSC programs exist; and

3.8 Ongoing and sustainable Spine care at the Department of Physiotherapy and the establishment of similar programs in other communities.

PARAGRAPH 4
FUNDING OF THE PROJECT

4. MGM University will provide the funding to establish and maintain the MGM-WSC project within the domains of the hospital. WSC will provide medical expertise, assistance and cooperation.

PARAGRAPH 5
COMMITMENTS OF WSC

WSC undertakes to:

5.1 Train the MGMIUDOP's Clinic Supervisors in the World Spine Care evidence-based protocols, documentation, database management, and education and prevention programs (the WSC "Toolkit"). The Clinic Supervisor will have access to all current and future WSC evidence-based education and exercise programs developed by the WSC research and clinical teams;

5.2 Provide ongoing updates of the model of care, documentation and data collection according to current evidence;

5.3 Assist in the implementation of the WSC program in MGM's WSC clinic. The Clinical Director of WSC will spend two weeks in Kamothe with the MGMIUDOP's Clinic Supervisors to ensure effective implementation of the program;

5.4 Provide specialist supervision and training on an as needed basis. MGMIUDOP's Clinic Supervisor will participate in monthly meetings with other WSC Clinic Supervisors, the Clinical Director and other clinical team members;

5.5 Provide the Clinic Supervisor access to the WSC clinical and research committees. The list of these experts, including biographies and photos, can be found on the WSC website. (www.worldspinecare.org)

5.6 Help MGM-WSC and support research initiatives depending on need and interest. This support will be in the way of expertise and supervision of researchers, and seeking grants to conduct research on the burden of spinal disorders and spinal health care needs in rural and underserved communities in Navi Mumbai;

5.7 Monitor the efficacy of the MGM's WSC clinic through on-going clinical research;

5.8 Advance the level of spine care in underserved communities by assisting and collaborating in organizing advanced education programs in conjunction with the major international spine societies on the management of spinal disorders. These educational programs will include presentations by specialists and researchers who have international reputation in the field;

5.9 Assist in establishing local public health programs such as a scoliosis and spine deformity screening program and public education.

PARAGRAPH 6
COMMITMENTS OF MGMIUDOP

MGMIUDOP undertakes to:-

6.1 Use its own space and basic furniture, such as chairs and desks, basic diagnostic equipment and monthly medical supplies, such as, gloves, gowns etc. for the project

6.2 Provide support staff for the MGM-WSC to establish and operate the Project;

6.3 Provide translators to assist volunteer clinicians working at the MGM's WSC Clinic when required

6.4 Allow for direct referral by the clinicians of the MGM's WSC Clinic of their patients to medical specialists, when required, within or outside of the hospital;

6.5 Provide laboratory and x-ray reports for patients receiving care at the MGM's WSC Clinic whenever deemed necessary by the Clinic Supervisors.

6.6 Provide accommodation and local travel expenses for the WSC Clinical Director during the implementation and yearly visits for the first 3 years of the Project. These visits will be approximately two weeks in duration;

6.7 Facilitate and support the review of WSC research proposals with the goal of ensuring permission to conduct research projects on spinal disorders that are expected to be carried out through the WSC program

6.8 Use its best efforts to arrange for registration and insurance for clinical volunteers and researchers with MGMIHS as required.

PARAGRAPH 7
ESTABLISHMENT OF MGM-WSC PROJECT IMPLEMENTATION TEAM

7 The MGMIUDOP shall establish a Project Implementation Team. The functions of the Project implementation team will be to ensure the efficient and effective implementation for the Project. This team will be made up of representatives from MGMIUDOP and WSC, and will be appointed by each entity of the participants of this MOU.

PARAGRAPH 8
MANDATE OF THE MGM-WSC PROJECT IMPLEMENTATION TEAM

The functions of the MGM- WSC Project implementation team will be to:

8.1 Oversee the implementation of the whole MGM-WSC Project. Notwithstanding the foregoing, the specific functions of the Spine Care Project implementation team will be provided for in the Terms of Reference to be developed by the Participants;

8.2 Assign resources needed for MGM-WSC Project These will be developed in discussion during November 2016 Visit.

PARAGRAPH 9
REPORTING AND NOTICES

9.1 WSC will collaborate on the creation of yearly reports to MGMIUDOP on the progress of services provided through this MGM-WSC Project through the Clinic Supervisor.

9.2 Submit to the WSC Clinical Director a monthly report, all clinic databases (these have no patient names and are stored in a secure location);

9.3 The Clinical Supervisor must participate in monthly WSC Clinic Supervisor online meeting where issues related to the clinics are discussed.

9.4 All notices required or permitted under this MOU will be in writing and will be deemed duly given when delivered by registered mail or facsimile transmission, to each participant at the addresses set forth below or at the addresses the participants may designate to each other in writing

PARAGRAPH 10
WORLD SPINE CARE DESIGNATION

10. World Spine Care is an internationally recognized brand with a reputation for the highest quality, evidence-based care for spinal disorders. Any site that wishes to carry the World Spine Care designation must uphold these standards. To ensure that the quality of care and reporting is maintained, WSC requires that any WSC location must adhere to the following requirements:

10.1 The Clinical Supervisor must use the WSC clinical documentation and databases and update those when new versions are released;

10.2 Submit to the WSC Clinical Director a monthly report, all clinic databases (these have no patient names and are stored in a secure location);

10.3 The Clinical Supervisor must participate in monthly WSC clinic supervisor online meeting where issues related to the clinics are discussed

10.4 The Clinical Supervisor/s must submit, on yearly basis, a list of continuing education credits

10.5 The Clinical Supervisor/s must follow evidence-based protocols in the clinic;

10.6 The WSC Clinical Director or designated representative will visit the MGM's WSC Project once a year for at least 3 years and possibly beyond for collaboration;

10.7 The MGMIUDOP must be willing to host WSC clinical volunteer associates on a short-term basis (up to maximum of 6 months). These volunteers are responsible for all their own expenses.

10.8 The MGM-WSC will not discriminate on the basis of sex, gender, race, religion, income, sexual orientation, or age in the delivery of services.

10.9 The MGM-WSC will not discriminate in the qualifications of participating volunteers.

10.10 Volunteer clinicians, researchers and laypersons may practice according to their training and expertise but should be licensed to practice their profession in their home country. Clinicians, however, must provide evidence based care as determined by WSC protocols. WSC programs accept clinicians who are trained medical physicians, chiropractors, physical therapists, osteopathic physicians, nurses, and acupuncturists as well as other qualified clinicians who offer spine care. In addition, yoga or tai chi practitioners and traditional healers are encouraged to participate in the WSC integrated team of clinicians. Clinicians must practice within their scope of practice in their licensing country but competence in specific spine interventions and the level of responsibility of all

clinicians may be determine or limited by the WSC clinical committee in collaboration with MGM-WSC.

PARAGRAPH 11
COMMENCEMENT, DURATION AND TERMINATION

11.1 This MOU will come into effect upon the signature of the Participants hereto and will remain in force for a period of five years.

11.2 Any Participant may terminate this MOU by giving ninety days written notice to the other Party.

11.3 The Participants will consult prior to termination, to determine how any outstanding matters arising out of this MOU will be dealt with.

PARAGRAPH 12
AMENDMENTS AND REVISION

12. This MOU may be amended or revised at any time by the mutual written consent of the Participants. No amendments or revisions will have any effect unless written and signed for by the Participants.

PARAGRAPH 13
DISPUTE RESOLUTION

13. Any dispute between the Participants arising out of the interpretation application or implementation of the MOU will be resolved by amicable consultation among the Participants, and will not be referred to any national or international tribunal, arbitrator or any third party for settlement.

13.1 Both parties will advise the other in the event of any matter arising which could affect the relationship of the parties or the goodwill of either party.

PARAGRAPH 14

ATTACHMENTS TO THE MOU

14. Attached is the detailed overview of the MGM-WSC Project (Annexure-A) with the background and status of WSC and the justification and budget for the Spine Care Project that will be presented to organizations that support WSC and private foundations for funding.

PARAGRAPH 15

FINAL PROVISIONS

15. The foregoing represents the understanding reached between the participants on matters referred to in this MOU and supersedes all prior written or oral negotiations, commitments or memoranda between participants.

IN WITNESS WHEREOF, the undersigned, duly authorized have signed this MOU in duplicate in English, each Participant hereto retaining such original, both texts being equally authentic.

SIGNED AT MGM INSTITUTE OF HEALTH SCIENCES, Kamothe, Navi Mumbai this 10th DAY OF NOVEMBER 2016.

Dr. (Lt. Gen.) S.K. Kaul
Vice Chancellor
MGM Institute of Health Sciences
Kamothe, Navi Mumbai
India -410 209.
Tel: 02227432471

Prof. Margareta Nordin
President
World Spine Care Europe
Mira House, 1 Miry Lane
Thongsbridge
Holmfirth, England
HD9 7SA
Tel: +44 754 371 3107

Dr. Rajani Mullerpatan
Professor-Director
MGM Institute's
University Department of Physiotherapy
Kamothe, Navi Mumbai India -410 209

Dr. Adam Wilkey
Vice President
World Spine Care Europe

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (MOU) is made at Navi Mumbai this 19th day of November, 2018.

MGM Institute of Health Sciences, a deemed to be University having it office at Plot No 1 & 2, Sector No.1 Kamothe Navi Mumbai, 410-209 through the MGM School of Physiotherapy and MGMIHS OMICS Research Center represented by its Authorized representative Dr Rajesh Goel, Registrar (hereinafter referred to as the "**Institute** ")

AND

Kaivalyadhama S.M.Y.M.Samiti , having its office at Swami Kuvalyananda Marg, Parsi Colony, Lonavala, Maharashtra 410403 through its Authorized representative, Mr Subodh Tiwari , Chief Executive Officer (hereinafter referred to as "**Samiti**")

WHEREAS:

1. The MGM School of Physiotherapy has been established in the year 2008 and is run and administered by the MGM Institute of Health Sciences, a deemed to be University. The Institute undertakes and conducts the BPT course (a 4 1/2 year course) and MPT course (2 year course). The Institute provides good quality education to its students in the field of Physiotherapy and has all the required facilities including research facilities and advanced laboratories. The Institute also undertakes research projects and programs for its students and faculty. The Institute has already undertaken various projects, programs and research activities with World Spine Care, University of Sydney and IIT Mumbai.

2. The MGM School of Physiotherapy is desirous of providing its students/faculty with the advanced knowledge and experience of applying yogic practices, asanas, therapies in the Physiotherapy field/treatment with an objective to enhance students/faculty knowledge and providing to the society a well educated mind and experienced hands in advancing the healing process and in an attempt to ensure that the patient, his/her attendants and other persons (preventive cure) get the benefit of yogic practices and asanas with scientific evidence in conjunction with modern techniques whereby the healing recovery process would be enhanced and made more effective.

MGM INSTITUTE OF HEALTH SCIENCES Deemed University NAVI MUMBAI

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3. MGMIHS OMICS Research Center is a centre of excellence in drug discovery and molecular diagnostics. Center is accelerating the basic and applied research. Using various domains of OMICS such as genomics, proteomics and computational biology, this center is providing unique and exploratory platform for discovery research. Research and technology innovation of center is mainly revolving around the integration of advanced knowledge of protein science, enzymology, metabolic network, natural products chemistry, green synthesis etc. The thrust area of this centre i.e. biomarker discovery, rational drug discovery, nano-biotechnology, reversal of drug resistance and green technology. Presently centre is actively engaged in discovery and diagnostic research in the area of tuberculosis, malaria, obesity and diabesity. MGMIHS OMICS Research Center is an interdisciplinary synergy and it is also acting as central facility for MGMIHS research. Faculty, clinician, scientific staff and students are using this facility. Researchers of centre have been also awarded by various national and international organization/foundation.

4. The Institute has the available infrastructure, laboratories, facilities and opportunities to evaluate yoga interventions (both at molecular level and bio mechanical investigations), to evaluate the effect of the yoga asanas, practices, kriyas on patients and other healthy willing participants, to measure, test and investigate the effect of the yoga asanas, practices, kriyas on the patients and other healthy willing participants.

5. Samiti was established in the year 1924 by Rev. Swami Kuvalayananda and is a pioneer institute to carryout scientific and philosophic literary research, training and therapy in yoga. The Samiti is aided by the Ministry of HRD, Government of India and affiliated to the Pune University as a Research Institute. The Center has been recognized as a Scientific Research Institute by the Department of Scientific and Industrial Research Organization under Ministry of Science and Technology, Government of India.

6. Samiti has yoga instructors/yoga teachers and has initiated yoga awareness programs and projects patients, their attendants and other health persons (preventive cure) with various ancient effortless yoga practices and asanas, relaxation and healing techniques for the body and mind so as to help in a faster recovery and well being of the body, mind and soul.

7. Samiti has available with it and/or has the ability to design yoga interventions (methods of Yoga kriyas), the ability to participate in the delivery of the yoga interventions and to play an important role in explaining, training the participant (patient and healthy person) and students.

MGM INSTITUTE OF HEALTH SCIENCES

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8. The parties intend to work together to develop a collaborative arrangement whereby the parties agree to participate in collaborative patient care, student training, research projects and other activities like conducting workshops, awareness camps etc and also to jointly evaluate and interpret the final outcome of combining their respective expertise and resources .

9. The aim and object of working together is to enhance the use of yogic asanas, *kriyas*, practices and methods and thereby generate scientific evidence for yoga practices. The parties intend to do undertake robust research and investigations, its effect and derive archivable evidence to demonstrate the meeting of yoga and science and its combined benefits etc.

10. The parties are desirous of reducing the basic understanding and the terms and conditions in writing.

IT IS NOW AGREED BETWEEN THE PARTIES AS FOLLOWS:-

11. The parties will use their reasonable endeavors to effect with best ethical practices, within the parties limitations :-

(a) To attain the aims and objectives as stated hercin above;

(b) To use their independent expertise, knowledge, infrastructure , facilities to design, develop and enhance the use of Yoga interventions in patient care and health promotion;

(c) To study /evaluate the interventions, to measure, test and investigate the effect of the yoga interventions and develop joint devices, products, intellectual properties etc ;

(d) To participate in delivering the yoga interventions, explaining and training the participants including patients, students and faculty etc;

(e) To develop and pursue collaborative research projects, shared intellectual property;

(f) To visit the other party/deploy members of its team for the purpose of participating in patient care, student training, research programs and other agreed activities;

(g) To encourage the exchange of scientific methods, materials publications and other information between parties ;

(h) To provide assistance on research projects and scientific inputs to develop and advance the use of yoga and yogic practices in physiotherapy and for the advancement treatment provided to patients;

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Swami Kuvalyananda
Marg, Lonavla 410 403
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(i) To undertake joint discussions and interactive sessions between the faculty/teachers of the institutions so as to solve problem areas, address issues and discuss on new methods and/or combined practices to develop and better treatment and patient care;

12. The parties agree that this Memorandum of Understanding is in no way intended to create legal or binding obligations on either parties and serves only as a record of the parties current intentions to enhance relationships of the parties between them with a view and object to improve health related quality of life of people with disorders and integrate them in the society.

13. Before any of the activities set out in this MOU are undertaken or implemented, the parties agree to execute formal and binding agreements/documents between them which will detail the specific form, and contents of the activities, address the responsibilities and rights of each of the parties in relation to the activities. The parties agree to negotiate the terms of any such agreement(s) in good faith and for the purposes of enhancing the relationships of the parties and in furtherance of the aims and objectives of this Memorandum of Understanding.

For MGM Institute of Health Sciences

Authorized representative

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

Dr Rajesh Goel
Registrar

Chief Research Officers

Dr Rajani Mullerpatan
Director,
MGM School of Physiotherapy

Professor - Director
MGM School of Physiotherapy
MGMIHS, Navi Mumbai

Dr Raman P. Yadav
Technical Director,
MGMIHS OMICS Research Center

Witness:

1. _____

I/C Principal
MGM School of Physiotherapy
Navi Mumbai

MGM School of Physiotherapy NAVI MUMBAI

For Kaivalyadhama S.M.Y.M.Samiti

Authorized representative

Shri Subodh Tiwari
Chief Executive Officer

Chief Research Officer

Dr.Satish Phatak
Research Associate

Dr.Praseeda Menon
Research Officer

Witness:

1. _____

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MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding (MOU) is made and entered into as of 9th day of February 2022 by and between **Shri Vithal Education and Research Institute** having its registered office at P.B. No. 54 Gopalpur-Ranjani Road, Gopalpur, Pandharpur- 413304 (hereinafter referred to as "**SVERI**" which term unless repugnant to the context includes its successors and permitted affiliates)

AND

MGM Institute of Health Sciences, a deemed to be University, through the MGM School of Physiotherapy, a research and educational institution, having its office at MGM Educational Campus, Sector 1, Kamothe, Navi Mumbai, 410209 through its Authorized Representative, Dr. Rajesh Goel, Registrar, (here in after referred to as 'MGMIHS/MGMSOP').

SVERI and MGMIHS are individually referred to herein as a 'Party' and collectively referred to herein as the 'Parties'.

Whereas **Shri Vithal Education and Research Institute** is a registered charitable trust established in the year 1995 under the Bombay public trust act founded by a group of technocrats embarked on an ambitious project and as its first venture established college of engineering Pandharpur, rural area of Maharashtra with the approval of All India Council of Technical Education (AICTE) and Government of Maharashtra. The campus is established in 27 acres with state-of-the-art infrastructure and employee strength of 300+. The institute has been actively involved in promoting science and technology based rural development and is offering Bachelors and Masters programs in various disciplines of engineering and pharmacy and Ph.D. in engineering.

Whereas MGM Institute of Health Sciences, a deemed to be University was established in the year 2006. The MGM School of Physiotherapy (MGMSOP) is a constituent unit of MGMIHS. MGMSOP undertakes and conducts the BPT (4 ½ years'), MPT (2 years') and Ph.D. in Physiotherapy programs. MGMIHS through the MGMSOP provides good quality education to its students in the field of Physiotherapy and has the required infrastructure, facilities including research facilities and an advanced biomechanics laboratory. MGMIHS also undertakes research projects and programs for its students and faculty. MGMIHS has undertaken various projects, programs and research activities with renowned institutes and entities. MGMIHS through MGMSOP is engaged in research, development of medical technology and validation of medical devices.

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Whereas MGMIHS has an advanced biomechanics laboratory, which undertakes various kinds of testing, development of devices proposed to be used in rehabilitation of people with musculoskeletal and neurological disorders. During the said testing and development work, MGMIHS through MGMSOP carries out extensive research, testing and validation procedures. In the said process, mechanical engineers give incidental and peripheral support in respect of the mechanical aspects on the concerned issues.

Whereas the parties have realized the importance of collaborating with each other jointly leveraging each other's strengths and expertise and hence agree to establish a basis for collaboration according to the terms and conditions set out in this MOU.

Whereas the parties agree that this MOU is in no way intended to create a legal or binding obligation on either party. The MOU serves only as a record of the parties' current intentions to enhance relationships of the Institutions going forward. The parties agree that the parties shall as and when required enter into separate independent agreements for the specific collaboration /programs or projects under this MOU.

Whereas the Parties desire to record the broad terms and conditions that are mutually accepted and agreed to by and between them in this MOU as contained hereunder.

NOW THEREFORE THESE PRESENTS WITNESSETH AND IT IS AGREED BY AND BETWEEN THE PARTIES HERETO AS FOLLOWS:

1. **AREAS OF COOPERATION**

The parties shall explore collaboration in the following areas to include but not limited to:-

- Create a holistic ecosystem to support academic and research collaborations between the parties and the various departments of the said parties/institutes
- Support researchers, innovators, social & other entrepreneurs from the stapes of ideation, proto type development, product design, device development and clinical validation to commercial transfer.
- Engage in a student exchange program to facilitate interdisciplinary research.
- Faculty of both institutes can serve as co-guides for research projects carried out by undergraduate, post graduate and doctoral programs in their areas of expertise.
- Submit joint proposals for seeking external funding agencies.
- Participate in joint courses, workshops and other activities.

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2. DURATION OF THE AGREEMENT, TERMINATION AND MODIFICATION

This agreement shall remain in force for an initial period of five (5) years, from the date of the signature/execution by the duly authorized representatives of the parties and may be renewed by mutual agreement of the parties for a further period thereafter.

Either party may terminate this MOU with 90 days' notice in writing to the other party. In the event of termination, the parties will take steps to bring the activities under this MOU to a prompt and orderly conclusion. If the MOU is terminated neither party shall be liable to the other for any monetary or other losses that may result. The parties agree that the Agreements/MOU executed pursuant to this MOU shall be treated as independent and separate agreements/MOU and shall be governed by the terms of the said agreements/MOU.

The parties agree that this MOU if required may be amended with the mutual consent of the parties. All amendments shall be in writing, by way of an addendum and shall be signed by the authorized representatives of the parties.

3. INTELLECTUAL PROPERTY

No rights of any kind whatsoever in any invention, copyright, trade secret, or any other form of intellectual property (collectively defined as "IP") are granted or transferred under this MOU. Any IP exchanged pursuant to this MOU shall be governed by the terms of a separate written agreement.

4. NON-DISCLOSURE

Neither Party or its authorized personnel, students, related personnel etc will disclose or make available to any third party any information or confidential information, whether documented or not, relating to the objectives, scope, work, effort or results of work performed during the period of this MOU or any other documents and or information received under this MOU.

In this Clause "confidential information" means: (i) all information or data of a confidential nature concerning the trade secrets or business dealings, methods of business, transactions, plans or affairs of a Party or third party to whom the Party owes a duty of confidence; (ii) any document or information or data marked "Commercial in Confidence" or otherwise expressly designated as confidential and (iii) any information or data which by its nature the recipient ought reasonably to conclude was confidential information of the Party in all cases including all copies of the above on any media (including electronic media) whatsoever, but excludes the following:

a) Information actually known to the disclosing Party prior to its disclosure;

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b) Information independently developed by the Party receiving the confidential information or communicated to it in circumstances otherwise than where its disclosure imparted a duty of confidence;

c) Information that is or becomes generally and freely publicly available through no fault of the receiving Party or its servants or agents;

d) Such information which is required to be disclosed to or by any Court, tribunal or Governmental authority with competent jurisdiction.

5. NOTICES

Any notices given under this MOU will be in writing and delivered by e-mail or speed post or by hand addressed to the parties as follows:

MGM Institute of Health Sciences: Dr. R. B. Goel, Registrar

Address- MGM Institute of Health Sciences, Plot No 1 & 2 Sector No.1, Kamothe, Navi Mumbai, 410-209

SVERI:- Shri Vithal Education and Research Institute : Dr. B. P. Ronge, Secretary

Address-P.B. No. 54 Gopalpur-Ranjani Road, Gopalpur, Pandharpur-413304

6. MISCELLANEOUS

a) **Assignment.**

Neither party may assign this MOU or the rights thereunder.

b) **Survival.**

Any of the sections that include any other rights and obligations under this MOU which by their nature should survive, shall survive the expiration or termination of this MOU.

c) **Severability**

If any provision of this MOU becomes or is declared illegal, invalid, or unenforceable, such provision will be divisible from this MOU and will be deemed to be deleted from this MOU. If such deletion substantially alters the basis of this MOU, the parties will negotiate in good faith to amend the provisions of this MOU to give effect to the

B. Ronge

original intent/object of the parties under this MOU.

d) **Independent Entities.**

SVERI and MGMIHS are independent parties and neither is an agent, joint venture partners, or partner of the other.

e) **Order of Precedence.**

In the event of any inconsistency between the terms of this MOU and the documents referenced or incorporated herein or any other document, correspondence or MOU concerning this Programme between the Parties and/or their employees, the terms of this MOU will prevail.

f) **Entirety.**

This MOU represents the entire agreement and understanding between the parties with respect to its subject matter and supersedes any prior and/or contemporaneous discussions, representations, or agreements, whether written or oral, of the parties regarding this subject matter.

g) **Amendments.**

The Amendments or changes to this MOU must be in writing and signed by duly authorized representatives of both the parties.

h) **Counterparts.**

This MOU may be executed in multiple counterparts, each of which will be deemed an original, but all of which will constitute one and the same MOU, and the signature pages from any counterpart may be appended to any other counterpart to assemble fully executed counterparts.

i) **Dispute Resolution.**

In event of dispute or claim between the parties concerning the interpretation of any provision of this MOU or the performance of any of the terms/obligations of/under this MOU, such matter or matters in dispute shall be first settled amicably by setting up a mutually agreeable committee of surgeons. The parties after due discussion shall try

B. Ronge

their level best to resolve the disputes arising out of this MOU, failing which through the Arbitration process. Both the parties after due discussion shall appoint an Arbitrator for resolving the dispute arising out of this Agreement. The arbitration shall be held at Navi Mumbai.

IN WITNESS WHEREOF, these duly authorized representatives of the parties hereby execute this Agreement, including all the terms and conditions mentioned herein above.

Through its authorized representative

MGM Institute of Health Sciences,

Navi Mumbai.

Name: Dr. Rajesh Goel

Designation: Registrar

Date:

Dr. Rajesh B. Goel
Registrar
MGM Institute of Health Sciences
(Deemed University u/s 3 of UGC Act, 1956)
Navi Mumbai- 410 209

In presence of

Dr. Rajani Mullerpatan. Director,

MGM School of Physiotherapy,
MGM Institute of Health Sciences,
Navi Mumbai.

Dr. Sabita Ram
Research Director,
MGM Institute of Health Sciences,
Navi Mumbai.

Shri Vithal Education and Research Institute,

Pandharpur

Name: Dr. B. P. Ronge

Designation: Secretary

Date:

SECRETARY
Shri Vithal Education & Research Institute, Pandharpur

In presence of

Dr. R. R. Gidde

Dean, R & D
SVERI's College of Engineering.
Pandharpur

Mr. A. A. Mote
Training and Placement Officer
SVERI's College of Engineering.
Pandharpur

MAHATMA EDUCATION SOCIETY'S
PILLAI COLLEGE OF ENGINEERING
(AUTONOMOUS)
Approved by AICTE, Recognized by Government of Maharashtra, Affiliated to University of Mumbai
Accredited by NAAC with A+ Grade
Re-Accredited by NBA (Computer Engineering and Mechanical Engineering Programs)
Inst. Code: EN3207 | ME3207
Since 1970

Endorsement from the Head of the Institution

This is to certify that:

1. Institute welcomes participation of Dr. Richa Agrawal as the Co-Investigator for the project titled Re-configuration of management of osteoporosis in children and adults: a shift in paradigm from treatment to prevention using a novel biotechnology device: Swasthya for Asthi Tavasya and that in the unforeseen event of discontinuance by the Principal Investigator, the Principal Co-Investigator will assume the responsibility of the fruitful completion of the project with due information to SERB.

2. The Co-Investigator, Dr. Richa Agrawal, Associate Professor, Department of Mechanical Engineering, Pillai College of Engineering, New Panvel is a permanent or regular employee of this Institute/University/Organization and has 17 years of regular service left before superannuation

3. The project starts from the date on which the University/Institute/ Organization/College receives the grant from SCIENCE & ENGINEERING RESEARCH BOARD (SERB), New Delhi.

4. The investigator will be governed by the rules and regulations of University/ Institute/Organization/College and will be under administrative control of the University/ Institute/Organization/College for the duration of the project.

5. The grant-in-aid by the SCIENCE & ENGINEERING RESEARCH BOARD (SERB), New Delhi will be used to meet the expenditure on the project and for the period for which the project has been sanctioned as mentioned in the sanction order.

6. No administrative or other liability will be attached to SCIENCE & ENGINEERING RESEARCH BOARD (SERB), New Delhi at the end of the project.

7. The University/Institute/Organization/College will provide basic infrastructure and other required facilities to the investigator for undertaking the research project.

8. The University/ Institute/Organization/College will take into its books all assets created in the above project and its disposal would be at the discretion of SCIENCE & ENGINEERING RESEARCH BOARD (SERB), New Delhi.

9. The University/ Institute/Organization/College assumes to undertake the financial and other management responsibilities of the project.

Seal of University/Institute/Organization/College

M.E.S. PILLAI COLLEGE OF ENGINEERING AUTONOMOUS NEW PANVEL

Date: 9/5/22

Signature

Registrar of University/Head of the Institute/ Head of Organization / Principal of College

PRINCIPAL
MAHATMA EDUCATION SOCIETY'S
PILLAI COLLEGE OF ENGINEERING (AUTONOMOUS)
Dr K.M. Vasudevan Pillai Campus, Sector-16,
New Panvel-410206, Navi Mumbai, Maharashtra, INDIA

A. BUDGET ESTIMATES: SUMMARY:

Item	Budget		
	1st Year	2nd Year	Total
A. Recurring			
1. Salaries/Wages	600000.00	300000.00	900000.00
2. Consumables	100000	300000	400000.00
3. Travel	125000.00	125000.00	250000.00
Other Costs			
10% Institutional overhead	227000		227000
5% Contingency	113500		113500
B. Non- Recurring			720000.00
Grand Total (A+B)	**1890500.00 +720000.00**		**2610500.00**

BUDGET FOR SALARIES/WAGES (In Rupees)

Designation (number of persons)	Monthly Emoluments in INR	BUDGET		
		1st yr. (m.m.)	2nd yr. (m.m.)	Total in INR
Full time Junior Research Fellow (Physiotherapist)	25000.00	25000*12= 300000.00	25000*12= 300000.00	600000.00
*Junior research fellow (Engineer)	25000.00	25000*12 = 300000.00	-	300000.00
Total				**900000.00**

* Will be working at PCE, New Panvel with co-PI

PRINCIPAL
MAHATMA EDUCATION SOCIETY'S
PILLAI COLLEGE OF ENGINEERING (AUTONOMOUS
Dr K.M. Vasudevan Pillai Campus, Sector-16,
New Panvel-410206, Navi Mumbai, Maharashtra, INDIA

BUDGET FOR PERMANENT EQUIPMENT

SR NO	NAME OF EQUIPMENT	JUSTIFICATION FOR REQUIREMENT	FUNDS REQUESTED (INR)	Remarks
1	Development of device		INR 5,60,000.00	Details attached
2	Tablet computer	Real time E-communication, data	65,000.00	11th Generation Intel® Core™ i3-1115G4 Processor (6MB

		capturing and use of medical applications		Cache, up to 4.1 GHz), 8GB, 1x8GB, DDR4, 3200MHz, Windows 10 Home Single Language, English
5	Laptop computer	Data recording/analysis	95,000.00	10th Generation Intel®Core™ i5-10300H (8MB Cache, up to 4.5 GHz, 4 cores) NVIDIA® GeForce GTX® 1650 Ti 4GB GDDR6, 8GB, onboard, DDR4, 2933MHz, Windows 10 Home Single Language, English
			7,20,000.00	

(In Rupees)

Device development Budget: (Funds Required) utilised by PCE, New Panvel

SN	Generic Name	Make & Model	Qty	Cost
1	Transducers for Source and Receiver	MECO 0.5 Frequency Transducer, Din Rail Mounting, Ft	8 Nos.	30000.00
2	Amplifier	Behringer HA400 4-Channel Headphone Amplifier	4 Nos.	20000.00
3	Data Acquisition System (Digital to Analog Converter, Oscilloscope)	NI ADCs NI 779680-01 Sound and Vibration Module	1 No.	250000.00
4	Chassis for Interface Board	NI cDAQ 9174	1 No.	250000.00
5	Power Driver for Transducers		1 No.	10000.00
Total				560000.00

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PILLAI COLLEGE OF ENGINEERING (AUTONOMOUS)
Dr. K.M. Vasudevan Pillai Campus, Sector-16,
New Panvel-410206, Navi Mumbai, Maharashtra, INDIA

THE UNIVERSITY OF SYDNEY

MGM Institutes of Health Science

Memorandum of Understanding

Between

The Faculty of Health Sciences,

The University of Sydney, Australia (CRICOS Provider 00026A)
and

MGM School of Physiotherapy, MGM Institutes of Health Sciences
(Deemed University u/s 3 of UGC Act 1956) Navi Mumbai, India.

1. The Institutions intend to work together to develop a collaborative arrangement, whereby the institutions may participate in collaborative teaching, training, research and other agreed activities that further enhance the program and the relationship between the institutions.

2. The Institutions will use their reasonable endeavors to effect, within the institutions limitations:

   a) will develop and pursue collaborative research projects;
   b) visit from one institution to the other by members of their academic staff for the purpose of participating in teaching, training, research programs and other agreed activities; and
   c) encourage (on a completely voluntary basis) the exchange of scientific materials, publications and other information between the institutions.

3. This document is in no way intended to create legal or binding obligations on either party. It serves only as a record of the parties' current intentions to enhance relationship of the Institutions going forward.

4. Before any of the activities set out in the Memorandum of Understanding are implemented, the Institutions must enter into formal and binding agreement/(s) (separate from this Memorandum of Understanding) with each other which will detail the specific form and content of the activities and address the responsibilities and rights of each Institution in relation to those activities. The institutions agree to negotiate the terms of any such agreement/(s) in good faith and for the purposes of enhancing the relationship of the Institution.

RPMullangatang

On behalf of
Partner

.....

Dr. S.N. Kadam
Vice Chancellor

Date :

.....

Dr. Rajani Mullerpatan
Professor-Director, Physiotherapy

Date : 09-03-2015

On behalf of the
The University of Sydney

.....

Dr. Michael Spence
Vice-Chancellor and Principal

Date :

.....

Professor Kathryn Refshauge
Dean, Faculty of Health Sciences

Date : 10/2/15

RMullerpatan

THE UNIVERSITY OF SYDNEY

MGM Institutes of Health Science

Memorandum of Understanding

Between

The Faculty of Health Sciences,

The University of Sydney, Australia (CRICOS Provider 00026A)
and

MGM School of Physiotherapy, MGM Institutes of Health Sciences
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   a) will develop and pursue collaborative research projects;
   b) visit from one institution to the other by members of their academic staff for the purpose of participating in teaching, training, research programs and other agreed activities; and
   c) encourage (on a completely voluntary basis) the exchange of scientific materials, publications and other information between the institutions.

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4. Before any of the activities set out in the Memorandum of Understanding are implemented, the Institutions must enter into formal and binding agreement/(s) (separate from this Memorandum of Understanding) with each other which will detail the specific form and content of the activities and address the responsibilities and rights of each Institution in relation to those activities. The institutions agree to negotiate the terms of any such agreement/(s) in good faith and for the purposes of enhancing the relationship of the Institution.

On behalf of
Partner

.....

Dr. S.N. Kadam
Vice Chancellor

Date :

.....

Dr. Rajani Mullerpatan
Professor-Director, Physiotherapy

Date : 09-03-2015

On behalf of the
The University of Sydney

.....

Dr. Michael Spence
Vice-Chancellor and Principal

Date :

.....

Professor Kathryn Refshauge
Dean, Faculty of Health Sciences

Date : 10/2/15

ASSOCIATION FOR CLINICAL NEUROLOGY AND MENTAL HEALTH

International Conference

by

ASSOCIATION FOR CLINICAL NEUROLOGY AND MENTAL HEALTH

CORPORATE OFFICE:
Girija Towers,
Arumbakkam, Chennai,
Tamil Nadu -600106, India.

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ASSOCIATION FOR CLINICAL NEUROLOGY AND MENTAL HEALTH

MEMORANDUM OF UNDERSTANDING

Between

Association for Clinical Neurology and Mental Health(ACNM)

AND

MGM School of Physiotherapy, Aurangabad, A Constituent Unit of MGM Institute of Health Science, Navi Mumbai, India

Preamble

This Memorandum of Understanding (hereinafter referred to us " MOU ') is made and entered into by and between the **Association for Clinical Neurology and Mental Health (ACNM)**, with a registered address at Chennai, ACNM, India (herein referred to as "**First Party**") **and MGM School of Physiotherapy, Aurangabad, Maharashtra, India** (herein referred to as "**Second Party**").

This memorandum sets out the initial relationship between the parties as well as the respective rights and responsibilities of each party. Each Party respectively is expected to act in good faith in accordance with this Memorandum.

Purpose

The purpose of this MoU is to establish a frame work for International conference collaboration between **Association for Clinical Neurology and Mental Health (ACNM)** and **MGM School of Physiotherapy, Aurangabad** for organizing an International virtual conference under ACNM Conference Sponsor schemes and to set forth the understandings and intentions of the partners with regard to collaboration in areas of mutual concern mentioned herein.

ACNM

(Signature – ACNM)

Principal
MGM School of Physiotherapy
Aurangabad

(Signature – MGM SOP)

MGM School of Physiotherapy Aurangabad

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ASSOCIATION FOR CLINICAL NEUROLOGY AND MENTAL HEALTH

Background

The partnership is important between **ACNM** and **MGM School of Physiotherapy, Aurangabad** Since , ACNM meant for research and development in the field of Neuroscience, Neurology & Neurosurgery. ACNM is a paramount body which has brought revolution and sustainable development in the field of Neuroscience, Neurology & Neurosurgery.

ACNM is an international forum for Doctors, Medical Practitioners, Research Scholars, Scientists for sharing knowledge and innovation in the field of Neuroscience, Neurology & Neurosurgery. ACNM aims to bring together Doctors and medical practitioners to encourage intellectual development and providing opportunities for networking and collaboration. ACNM forms partnerships with colleges, universities, professional associations, societies, and organizations to operate our local chapter functions worldwide. ACNM is one of the leading publishers of research articles in its high-quality peer reviewed journals, proceedings, and research magazines. ACNM fulfil the need of professionals even for their end-to-end research and development. ACNM is a leading publisher of scientific research works in highly cited, high indexed and high standard International Journals such as SCOPUS, SCI/ESCI, Web of Science, UGC etc.

MGM School of Physiotherapy, Aurangabad is a growing institution which pledges to train globally competent Physiotherapists who can deliver state of the art services for patient care. The Institute focuses on research through graduate, post graduate and doctoral programs. The courses are designed to impart Physiotherapy knowledge along with skills underpinned by relevant biomedical and behavioral sciences.

(Signature – ACNM)

Principal
MGM School of Physiotherapy
(Signature – MGM SOP)

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ASSOCIATION FOR CLINICAL NEUROLOGY AND MENTAL HEALTH

This MoU sets forth the intentions of the parties for increased collaboration, co-operation and interaction and does not create any legally binding commitments. If the parties later agree to undertake any specific new projects, they will develop separate written agreements for such projects, setting out each party's contributions, deliverables, and budgets.

Responsibilities

The partners will continue to maintain their separate and unique missions, mandates, and accountabilities. Each partner will be fully and solely responsible for any and all expenses it incurs in relation to this memorandum.

Title of the Conference: International Multidisciplinary Rehab-E-Con 2022

Theme: A Journey Towards Inclusive Society

Date: February 26-27, 2022

Venue: Virtual

Expected Number of participants from the MGM School of Physiotherapy, Aurangabad:100

Services /Benefits to the MGM School of Physiotherapy by ACNM

Scientific Management

- Speakers & Sessions
- Scientific schedules, Agendas & Propaganda
- Scientific Content Management
- Scientific Community Management
- Article Management & Scientific Editorship
- Publication
- Accelerated Citation and Worldwide Access of Conference Contents
- Committee Establishment

ACNM

(Signature – ACNM)

Principal
MGM School of Physiotherapy
Aurangabad

(Signature – MGM SOP)

MGM School of Physiotherapy Aurangabad

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ASSOCIATION FOR CLINICAL NEUROLOGY AND
MENTAL HEALTH

- Committee Engagement
- Intra & Inter Organizational Propagation
- Engagement of Global Organization
- Oversea Profile Involvement
- Appreciations & Awards

Financial Assistance

- Conference Management
- Funding Research Proposals
- Grants for Institutional Chapters &Center of Excellence

Global Promotion & Networking

- Global Projection of Conference
- International Promotion and Branding
- International Speakers & Committee Members
- International Co -Hosts / Co-organizer and Institutional partner
- Broadcasting of conference at international forums, channels and medias
- Conference production
- Convenience: Article Management & Processing
- Editorial board for Swift review and convenient publication

Association for Clinical Neurology and Mental Health ACNM

(Signature – ACNM)

MGM School of Physiotherapy Aurangabad

Principal
MGM School of Physiotherapy
Aurangabad
(Signature – MGM SOP)

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ASSOCIATION FOR CLINICAL NEUROLOGY AND MENTAL HEALTH

- Speaker Management System
- Organizing Committee Management System
- Registration Management System
- Publication Management System

Corporate Services

- Strategic project planning , management & execution
- Round the clock customer /delegate support
- Interphase for organizers and co-organizers
- Technical support and assistance

Note :

All the accepted paper will be published in relevant International Journals & Extended version of the selected papers will be published in Scopus Indexed Journals with terms and conditions.

Conference Fee Structure: Registration fees are inclusive of 18% GST

REGISTRATION CATEGORIES	NATIONAL (INR)	INTERNATIONAL (USD)
Students	INR 1200	USD 60
Professionals/Academicians	INR 1450	USD 80

MGM School of Physiotherapy Fee Structure: Inclusive of 18% GST

REGISTRATION CATEGORIES	NATIONAL (INR)
Students	INR 1000
Professionals/Academicians	INR 1200

Registration fee for the virtual conference includes E-Conference Proceeding, E-Certificate.

(Signature – ACNM)

Principal
MGM School of Physiotherapy
Aurangabad

(Signature – MGM SOP)

MGM School of Physiotherapy Aurangabad

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ASSOCIATION FOR CLINICAL NEUROLOGY AND MENTAL HEALTH

Publication Fee

- Registration fee doesn't include the article processing fee for publication.
- Article Processing Fee will vary depending upon the journal for publication.

Publication Terms & Conditions

1. Article Processing Fee for Publication
2. Charges for selected SCOPUS Indexed Journals Only.
3. Note that plagiarism articles are strictly rejected (Must be 10% below without including references).
4. Copying of other article contents is prohibited.
5. Agreement should be confidential and to be followed accordingly.
6. Publication may delay on the basis of Journal maintenance.
7. Review reports have to be answered by the author accurately. Malpractice will not be encouraged.
8. The Publisher reserves the right to require payment before publishing.
9. Payment is due upon receipt of invoices.
10. All bank charges are payable by the author.

Awards:

- Awards will be given for the **Best Research Paper** as well as **Best Paper Presentation**.

Duration

This MOU is at-will and may be modified by mutual consent of authorized officials of **MGM School of Physiotherapy** and of **Mr. Rudra Bhanu Satpathy, CEO, ACNM, India**. This MOU shall become effective upon signature by the authorized officials from the **MGM School of Physiotherapy, Aurangabad** and of **Mr. Rudra Bhanu Satpathy, CEO, ACNM, India** and will remain in effect until modified or terminated by any one of the partners by mutual consent.

For Further details visit us at: http://ianeuro.com/

(Signature – ACNM)

Principal
MGM School of Physiotherapy
Aurangabad
(Signature – MGM SOP)

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ASSOCIATION FOR CLINICAL NEUROLOGY AND MENTAL HEALTH

Terms and Conditions

- The title and the dates of the conference have to be finalized at the time of the MoU agreement signing.
- The list of the organizing committee members from MGM School of Physiotherapy, Aurangabad and the theme to be provided with a week of the MoU by MGM School of Physiotherapy
- Press release in digital platform and newspapers has to be arranged by the MGM School of Physiotherapy, Aurangabad after the MoU has been made and signed duly.
- Photos and video of the conference will be shared to the ACNM by MGM School of Physiotherapy, Aurangabad.
- Agreement should be confidential and to be followed accordingly.
- The Publication cost & publication time of each journal like may vary depending upon the journal maintenance.

I ....Dr. Rinkle Malani..... **agree to the above Terms and Conditions.**

(Signature – ACNM)

Principal
MGM School of Physiotherapy
Aurangabad
(Signature – MGM SOP)

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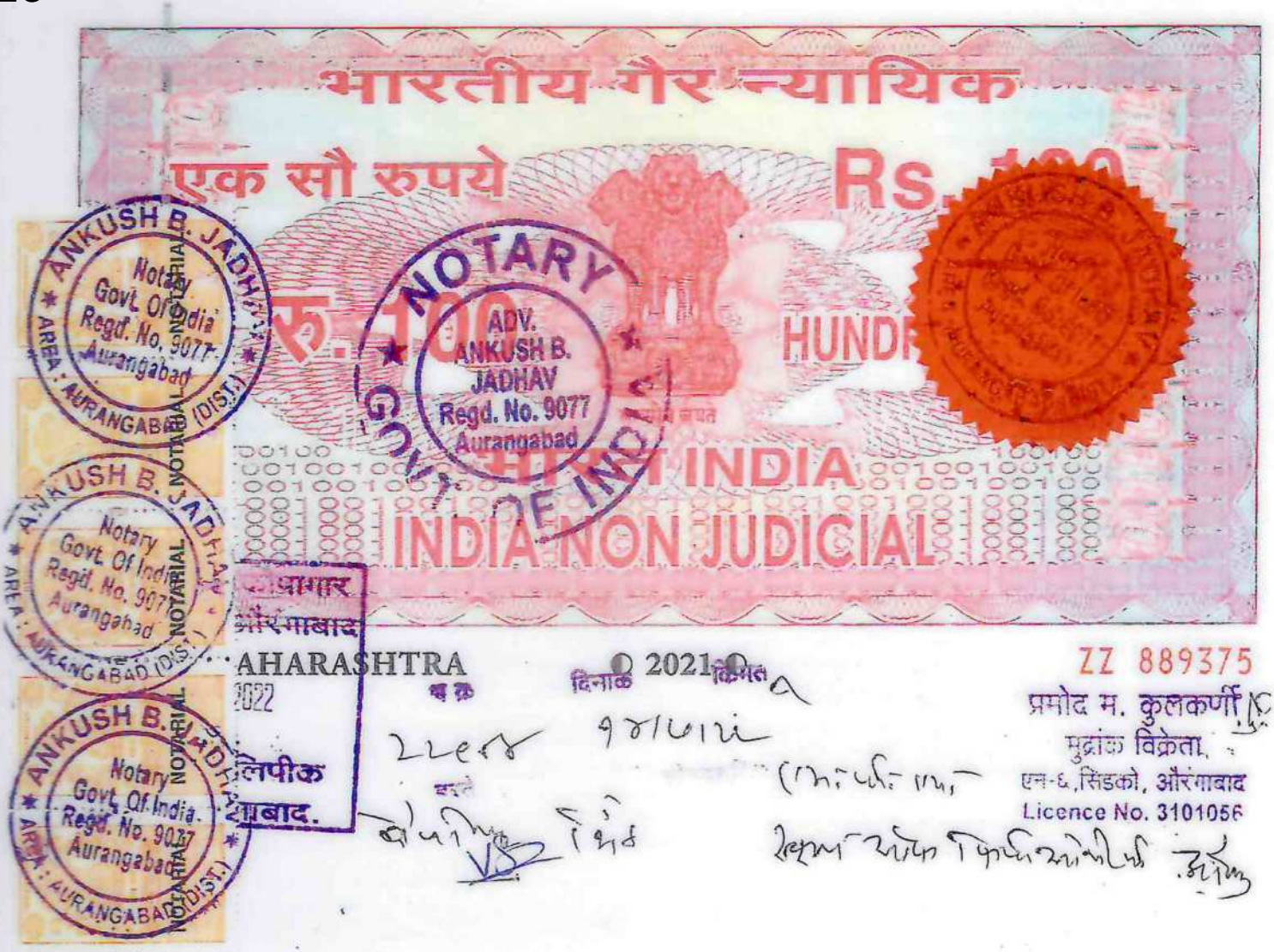

Memorandum of Understanding MOU
Between
M.G.M. School of Physiotherapy, N6, Cidco, Aurangabad and
Samagra Shiksha Abhiyan Aurangabad Municipal Corporation Aurangabad & Saksham Sambhaji Nagar.

As a part of our special clinical training for students program, **MGM School of Physiotherapy, N-6, CIDCO, Aurangabad** enters into this Memorandum of understanding with **Samagra Shiksha Abhiyan Aurangabad Municipal Corporation Aurangabad& Saksham Sambhaji Nagar,** to further our vision of optimizing our healthcare delivery and the overall health and wellbeing of disabled people as well as education and learning of clinical skills for physiotherapy students. The purpose of this MOU is to define goals and expectations for relationship between **MGM School of Physiotherapy, N-6, CIDCO, Aurangabad and Samagra Shiksha Abhiyan Aurangabad Municipal Corporation Aurangabad& Saksham Sambhaji Nagar,** so as to pertain the services for disabled people. This MOU will provide a framework for access to rehabilitation services, effective collaborations and timely communication among **MGM School of Physiotherapy and Samagra Shiksha Abhiyan Aurangabad Municipal Corporation Aurangabad& Saksham Sambhaji Nagar.**

Expectations:

Samagra Shiksha Abhiyan Aurangabad Municipal Corporation Aurangabad & Saksham Sambhaji Nagar.	MGM School of Physiotherapy, N6, Cidco, Aurangabad
Inform **Samagra Shiksha Abhiyan Aurangabad Municipal Corporation Aurangabad & Saksham Sambhaji Nagar** of the relationship with M.G.M. school of Physiotherapy,N6, Cidco, Aurangabad	Providing logistical support for transportation, materials to students for successful health care delivery in **Samagra Shiksha Abhiyan Aurangabad Municipal Corporation Aurangabad& Saksham Sambhaji Nagar.**
Allowing assistance and guidance to students of MGM School of Physiotherapy, N-6, Cidco, Aurangabad from technical and medical or paramedical staff during scheduled clinical posting program.	Scheduling clinical posting program and managing patient care and safety during Physiotherapy treatment
Provide students of MGM school of Physiotherapy, N6, Cidco, Aurangabad with any necessary medical information including diagnosis, medications and treatment needs.	Review clinical information sent by the primary care provider (PCP) and work on it practically in real world. It will also provide opportunities to carry out new researches on the patients attending the rehabilitation sessions.
Students of MGM school of Physiotherapy, N6, Cidco, Aurangabad should be treated with proper dignity and professionalism.	If any important communication related to patient safety is there, it will be communicated properly.

Other terms:

Volume or Value of Referrals
Nothing in this MOU requires, is intended to require, or provides payment or benefit of any kind (directly or indirectly) for the referral of individuals or businesses to either Party by the other Party. Neither Party shall track such referrals for purposes relating to setting the compensation of its professionals or influencing their choice.
Confidentiality
The Parties (and their directors, officers, employees, agents, and contractors) shall maintain the privacy and confidentiality of all information regarding the personal facts and circumstances of their special children in accordance with all applicable state laws and regulations. The Parties (and their directors, officers, employees, agents and contractors) shall not use or disclose special children information, other than as permitted or required by this MOU for the proper performance of duties and responsibilities here under. The Parties shall use appropriate safeguards to prevent use or disclosure of special children information, other than as provided for under this MOU.
Termination
This MOU may be terminated by either Party without penalty or cause by giving written notice to the other Party.
Notices
All notices and other communications required or permitted under this MOU, unless otherwise stated, shall be deemed duly given if in writing and delivered personally, via e-mail.
Dispute Resolution
If a dispute arises regarding this MOU, **M.G.M. school of Physiotherapy, N6, Cidco, Aurangabad** and **Samagra Shiksha Abhiyan Aurangabad Municipal Corporation Aurangabad& Saksham Sambhaji Nagar.** shall first attempt to resolve it by informal discussions between Parties, unless there are circumstances under which an extended resolution procedure may endanger the health and safety of special children.
Relationship of the Parties
The Parties are and shall remain separate and independent entities. Neither Party shall be construed to be the agent, partner, co-venture, employee or representative of the other Party.
Amendments
This MOU may be modified or amended in writing with the express written consent of both Parties.

IN WITNESS WHEREOF, the Parties here have executed this MOU as of the dates written below.

MGM School of Physiotherapy, N6, Cidco,Aurangabad	Samagra Shiksha Abhiyan Aurangabad Municipal Corporation Aurangabad& Saksham Sambhaji Nagar.
Signed: Title: Dr. Rinkle Malani (Director) Date: 11/07/2022	Signed: Title: Dr. Sandip Sisode (Psychology), Dr. Aditi Shardul Date: 11/07/2022

IDENTIFIED & DRAFTED
BY Mr.:

BEFORE ME
18/7/22
ADV. ANKUSH B. JADHAV
Notary Govt. Of India
Regd. No. 9077 Aurangabad

Abhijit S. Joshi

ANKUSH B. JADHAV Notary Govt. Of India Regd. No. 9077 Aurangabad

भारतीय गैर न्यायिक

एक सौ रुपये Rs. 100

रु. 100 ONE HUNDRED

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

NOTARIAL

महाराष्ट्र MAHARASHTRA ◐ 2018 ◐

UN 281055

15 MAY 2019

मुद्रांक प्रमुख लिपीक
ब.को.अ. औरंगाबाद.

म.क्र. 6704 दि.3 MAY 2019 किंमत 100

नोंदणीकरिता [illegible]

एस.एस. खैरे
स्टॅम्प व्हेंडर हायकोर्ट
मुद्रांक परवाना क्र.31010
औरंगाबाद

Memorandum of Understanding
Between
MGM School of Physiotherapy, Aurangabad
And
Sports Authority of India, Aurangabad.

This Memorandum of understanding is dated on 09.10.2021 and made between,

1. **MGM School of Physiotherapy, N-6, Cidco, Aurangabad.**
2. **Sports Authority of India, NCOE, Aurangabad**

1. **Objectives:-**
   1. **MGM School of Physiotherapy & Sports Authority of India, NCOE, Aurangabad** wish to build and outgrow a mutual understanding for general purpose of promoting teaching, educational, research & other collaborative activity for the mutual benefit of both the institutes.
   2. This MOU sets out below the principles by which **MGM School of Physiotherapy & Sports Authority of India, NCOE, Aurangabad** may initiate necessary arrangements.

3 MGM School of Physiotherapy graduates, post graduates will attend clinical training at **Sports Authority of India, Aurangabad**.

2 Principles:-

MGM School of Physiotherapy & Sports Authority of India, Aurangabad agrees the following.

1 To identify & develop mutually beneficial educational opportunities, progresses & wish to enter in this MOU for the development of physiotherapy students, faculties, sports scientist, coaches and athletes.

2. To explore research opportunities that may develop from the alignment of **MGM School of Physiotherapy & Sports Authority of India, NCOE, Aurangabad.**

3. Any activity carried out within the broad framework of this MOU shall be subject to mutual consent of the both parties.

4. Both the parties to emphasize upon common objectives & goals for promotion & development of sports activities & sports persons.

5. MGM School of Physiotherapy will render the services as per laid down policy of Sports Authority of India, NCOE, Aurangabad.

3 Renewal, Amendment & Termination:-

1. This MOU shall be effective for an initial period of 3 years from this date. Thereafter this MOU may be extended for a further period by mutual consent to be made in writing by both the parties.

2. The parties may amend this MOU at any time, provided it is with prior written consent of both parties.

3. Either party may terminate this MOU at any time by giving six months notice to the other party in writing.

4 Settlement of Disputes:-

1. Any dispute arising out of the interpretation or implementation of this MOU will be settled by the parties on mutual understanding.

2. This MOU records the understanding between the parties & is not intended to be legally binding document & shall not be enforceable in any court of law.

IDENTIFIED BY Shri Smt. Shivaji Kwad R/o. 29213275 Sainad

1. MGM School of Physiotherapy

Sign:-

By:- Dr. Principal MGM School of Physiotherapy

Position:- Principal

For:- MGM School of Physiotherapy, Aibad

2. Sports Authority of India, Aurangabad.

Sign:-

By:- V. P. Bhandari

Position:- Director

For:- Sports Authority of India NCOE, Aurangabad

BEFORE ME
Affidavit Sworn on Oa

Bhimrao S. Mundhe
Notary
Govt. of India
Reg.No. 4707

09 OCT 2021
NOTED & REGISTERED
AT Sr.No. 3340/21
THIS DOCUMENT CONTAIN

महाराष्ट्र MAHARASHTRA ◑ 2020 ◑ XC 790110

म.क. 3257 दि. 19 JAN 2021 किमत/-

कोणाकरिता M G M School of Physiotherapy, Aurangabad

हस्ते Chandrakant Dakhore

एस.एस. कोत्रे
मुद्रांक वेंडर लायसेन्स
दाक वरहाना क्र.3101071
औरंगाबाद

जिल्हा न्यायालय औरंगाबाद
- 5 JAN 2021
मुद्रांक प्रमुख लिपीक
व.को.अ. औरंगाबाद.

Memorandum of Understanding
MOU Between:

M.G.M. School of Physiotherapy, N6, Cidco, Aurangabad and Primary Health Care Center, Warudkazi and associate sub-centres, As part of our patient-centered clinical postings program, **M.G.M. School of Physiotherapy, N6, Cidco, Aurangabad** enters into this Memorandum of Understanding (MOU) with **Primary Health Care Center, Warudkazi and associate sub-centres,** to further our vision of optimizing health care delivery and the overall health and well being of patients as well as education and learning of clinical skills for Physiotherapy students. The purpose of this MOU is to define goals and expectations for the relationship between **M.G.M. School of Physiotherapy, N6, Cidco, Aurangabad** and **District Health Office, Z.P. Aurangabad** as it pertains to the care of patients who receive services from Physiotherapy students in **M.G.M. School of Physiotherapy, N6, Cidco, Aurangabad**. This MOU will provide a framework for access to services, effective collaboration, and timely communication among both healthcare service providers and Physiotherapy students.

Goals for M.G.M. School of Physiotherapy, N6, Cidco, Aurangabad and District Health Office, Z.P. Aurangabad:

- Provide optimal health care for patients, allowing access to Physiotherapy services. This includes care that is timely, high quality, and patient-centered.
- Improve collaboration, communication, coordination of services, and continuity of care by supporting efficient, real-time communication of patient information among those caring for the patient.
- Foster learning in Physiotherapy students by community centered health care delivery at rural and semi urban areas.
- Providing timely physical function and fitness screening at remote places for early prevention and rehabilitation services.

Expectations:

District Health Office, Z.P. Aurangabad	M.G.M. School of Physiotherapy, N6, Cidco, Aurangabad
Inform Primary Health Care Center, Warudkazi and associate sub-centres of the relationship with M.G.M. School of Physiotherapy, N6, Cidco, Aurangabad	Providing logistical support for transportation and required equipment's or necessary tools and materials to students for successful health care delivery in each respective health care center.
Allowing assistance and guidance to students of M.G.M. School of Physiotherapy, N6, Cidco, Aurangabad from technical and medical or paramedical staff during internship	Scheduling Internship program and managing patient care and safety during Physiotherapy treatment
Provide students of M.G.M. School of Physiotherapy, N6, Cidco, Aurangabad with any necessary medical information for the admission, including medications, chronic diagnosis, etc.	Review clinical information sent by the primary care provider (PCP).
Confer with students of M.G.M. School of Physiotherapy, N6, Cidco, Aurangabad to provide list of specialists who have agreed to provide services patients if indicated.	At the discretion of the attending provider, contact PCP during the hospital admission to discuss any serious complications or change in status and collaborate on recommended plan to support the patient/family, as appropriate. Also, Inform patient of diagnosis and prognosis.

Other terms:

Volume or Value of Referrals
Nothing in this MOU requires, is intended to require, or provides payment or benefit of any kind (directly or indirectly) for the referral of individuals or businesses to either Party by the other Party. Neither Party shall track such referrals for purposes relating to setting the compensation of its professionals or influencing their choice.
Confidentiality
The Parties (and their directors, officers, employees, agents, and contractors) shall maintain the privacy and confidentiality of all information regarding the personal facts and circumstances of their patients in accordance with all applicable state laws and regulations. The Parties (and their directors, officers, employees, agents and contractors) shall not use or disclose patient information, other than as permitted or required by this MOU for the proper performance of duties and responsibilities here under. The Parties shall use appropriate safeguards to prevent use or disclosure of patient information, other than as provided for under this MOU.
Duration
This MOU is signed for an initial period of 2021-2022 to 2022-2023 [2years] and may be renewed by mutual agreement between the parties
Termination
This MOU may be terminated by either Party without penalty or cause by giving written notice to the other Party.
Notices
All notices and other communications required or permitted under this MOU, unless otherwise stated, shall be deemed duly given if in writing and delivered personally, via e-mail.
Dispute Resolution
If a dispute arises regarding this MOU, **M.G.M. School of Physiotherapy, N6, Cidco, Aurangabad** and **District Health Office, Z.P. Aurangabad** shall first attempt to resolve it by informal discussions between Parties, unless there are circumstances under which an extended resolution procedure may endanger the health and safety of patients.
Relationship of the Parties
The Parties are and shall remain separate and independent entities. Neither Party shall be construed to be the agent, partner, co-venture, employee or representative of the other Party.
Amendments
This MOU may be modified or amended in writing with the express written consent of both Parties.

IN WITNESS WHEREOF, the Parties here have executed this MOU as of the dates written below.

M.G.M. School of Physiotherapy, N6, Cidco, Aurangabad	District Health Office, Z.P. Aurangabad
Signed: Principal	Signed:
Title: MGM School of Physiotherapy Aurangabad	Title: District Health Officer Zilla Parishad, Aurangabad.
Date: 05/02/21	Date:

MGM School of Physiotherapy Aurangabad

Aurangabad Health Care & Research LLP
Shop No.126, CTS No.12482/1, Chetan Trade Centre, Opp. S.F. School,
Jalna Road, Aurangabad, Maharashtra, India 431001
Email: ahrllp20@gmail.com

Memorandum of Understanding

This Agreement entered on 27th Jan 2021 at Aurangabad city, is between-

Aurangabad Health Care & Research LLP (AH&R) having registered address at, Aurangabad Health Care & Research LLP, Shop No.126, CTS No.12482/1 Chetan Trade Centre, Opp. S. F School, Jalna Road, Aurangabad, Pin 431001, MH India, represented by authorized signatories, Dr Renuka Madnurkar & Dr Ujwala Kulkarni, (Designated partners-AH&R LLP), Aurangabad Health Care & Research LLP is a registered partnership firm, bearing number AAS-0217 registered under the Limited Liability Partnership Act, 2008 registered with Registrar of Companies (ROC), here in called First party which expression may also include its representative if situations are not objectionable and acceptable to other party

And

Mahatma Gandhi Mission (MGM) Medical College & Hospital, N-6, Cidco, Aurangabad, Maharashtra 430 003 referred as a party-B **(here in after referred to as the "Institution")**

The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfill conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promise and mutual covenants herein contained and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties here to as follows

MGM Medical College & Hospital appoints Aurangabad Health Care & Research LLP as a site management organization on Exclusive basis for period of 10 years w.e.f 27th Jan 2021 to 26th Jan 2031. (Will be reviewed and updated accordingly)

Obligations of AH&R Services:

AH&R is a site management Organization based in Aurangabad providing end to end clinical research services to the Hospitals and Offers a complete range of Clinical Research in all therapeutic areas. We expertise in site Management Activities, Project Management, Monitoring, Safety Reporting, Regulatory services, Potential Site selection, Faster patient Recruitment, Quality compliance & Maintenance, and Clinical Research Expertise in India.

AH&R Services is desirous of working with Hospital for the purpose of conducting ICH-GCP complaint phase I-IV clinical trials for new drug & treatment.

AH&R Services Shall play vital role in getting clinical trials to the hospital /Hospital from the sponsors and CROs and execute them in Hospital.

AH&R Services will manage study Operations and study services as directed by study protocol for the duration of the clinical trial.

AH&R Services will appoint a Clinical Research Coordinators (CRC)/existing site coordinator who will be a point of contact with Sponsor & CRO and ensure smooth conduct of trial at the site.

AH&R will appoint project manager (PM) who will be responsible to coordinate and over-see the progress and management of CRC activities & trial, ensure data quality, resolve

screening, enrollment or general issue if any, follow up on post -monitoring action elements and study training as per needs and frequent discussion with investigator & sponsor / CRO on trial progress.

AH&R will appoint Quality check (QC Experts) who will be responsible to ensure adherence to the protocol, regulatory requirements record keeping and retention.

Study co-ordination, project management and quality management will be done by AH&R services. AH&R personnel, CRC, PM, QC Experts will assist PI and the Intuitions in all trial related activities.

AH&R will bear all the administrative cost related to the various activities undertaken by PM, CRC or any other staff placed by AH&R Services which includes telecommunication, travel cost, training cost at various centers across India or abroad.

AH&R will be exclusively conducting/managing all trial at the Hospital during the tenure of this agreement. This agreement will last for 10 (ten) years and can be renewed further on mutual agreement.

Following activities will be carried out by appointed CRCs

1. Performing all the activities in strict adherence to the ICH-GCP guidelines, Schedule Y India GCP and Regulatory requirement
2. Preparation for site selection visit and Site Initiation Visit (SIV)
3. Communication & Follow up with IRB/IEC Submission and Approval
4. Accurate and complete documentation of relevant EC documentation
5. Regulatory documents Collection
6. Patient Identification for assigned study form OPD or Hospital Database.
7. Maintenance and update of Trial Master File (TMF), site binders and relevant files
8. Preparation for site Monitoring Initiation Visit (SMV) and resolving all action items generated during Previous monitoring visits
9. Conduct Study according to International Conference of Harmonization (ICH) E6 and India Good Clinical Practice (GCP) regulation
10. Assisting Principal Investigator in administrating ICF and its procedures
11. Ensure protocol & applicable regulatory guidelines compliance and adherence
12. Patients pre- screening enrollment and recruitment
13. Preparing source notes and CRF filling
14. Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates
15. Coordinate and schedule subject's regular follow up visits and procedures, maintain regular Telephonic contact with patients to preventing lost to follow- up and missed visits.
16. Managing Clinical Trial Materials (CTM) maintenance, Accountability, distribution and logistics at site
17. Coordinate all site specific queries- medical, administrative, subject reimbursements and other study related activities.
18. Reporting and coordinating all AE/SAEs according to their timelines as per regulatory norms

19. Filling up and maintaining trial related logs likes source documentation, drug dispensing logs, subject log, visit logs, Investigational product log, temperature log, SAE and EC communication log
20. Documentation of protocol deviation as appropriate and communicate any impacting subject safety to the ethics committee
21. Coordinate with central and local lab for logistics and sample flow
22. Attend study related meeting as appropriate
23. Preparing sites for Monitoring / Auditing visits coordinate close out visit and Archival at site
24. Any other required activities during the trials.
25. Identification of potential database from different therapeutic area of PIs
26. Communication with Investigators/ Hospitals and conduct protocol specific feasibility
27. Other duties as requested by AH&R Services Management

B. Hospital permits

1. Hospital will give the space and required facilities to appointed CRC & AH&R in order to perform clinical trials activities under respected PI.
2. Hospital will allow AH&R and Sponsors of Clinical trials to access the facility to verify source documents.
3. Hospital will allow AH&R to bring Sponsors of clinical trials to meet with PI/SITE representatives at a mutually convenient time.
4. Hospital shall permit AH&R to exclusively manage all clinical trial commenced by AH&R Services

C. Term of Agreement

The term of this Agreement shall be for a period of 10 years commencing on the effective date 27th Jan 2021. However, this Agreement shall be reviewed annually by both parties if needed.

D. Relationship of the parties

1. Hospital and AH&R are independent parties. Both parties agree that their relationship is that of an Independent contractor and not employer and employee.
2. Neither party shall have express or implied rights nor did authority to assume or create any obligation or responsibility on behalf of or in the name of the other party by reason of this Agreement, except as provide in this Agreement.

E. GCP, ICH and CFR compliance

Hospital agrees to comply with International Conference of Harmonization & Good Clinical Practices (ICH-GCP) and all India regulations, CDSCO requirement and circulars there under.

F. Confidentiality

1. The parties here recognize and agree that due to the complex and competitive nature of the business, the confidential of information concerning both parties is of critical importance. Either party shall not, either during or after the term of this Agreement, disclose to any third party any confidential information and all Information or information relative to the work or the business of either party without the written consent of either party AH&R agrees that it shall not during, or at any time after the termination of this Agreement, directly or indirectly disclose or use any information for any reason whatever, without the prior written consent of SITE.
2. Hospital shall not disclose to any third party any and information about new studies received from AH&R.

G. Indemnification

Hospital shall indemnify and hold harmless AH&R against any losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by SITE, its agents, directors or employees, AH&R shall indemnify and hold harmless hospital against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of act or commission by AH&R, its agents, directors, or employees. In no event will either party be required to indemnify or hold harmless the other's negligence or gross negligence.

H. Compensation and Agreement

1. The Hospital, principle Investigator, AH&R and Sponsor and/or CRO will enter into a quadripartite clinical trial agreement before/at the time of placement of each trial at the Hospital.
2. All feasibilities and payments shall be routed through AH&R and pricing while bidding for the trial shall be discussed mutually and final correspondence with the Sponsor/CRO also would be handled by AH&R Services for smooth and hassle-free finalization of Clinical Trial Agreements.
3. Getting payment from sponsor and giving to Hospital and /or Investigator is the responsibility of AH&R Services.
4. AH&R will be payee name for all trial related payment.
5. All payment shall be due and payable to the hospital on actual work i.e. number of subject randomized or visits completed.
6. The payment of remuneration shall be after deduction of all taxes under applicable laws.
7. All invoices will be requested from the hospital for study payment and all study related payment will be done to MGM Medical College & Hospital, in a period of 15 working days after receiving the payment from the sponsor/CRO.
8. The details of study budget sharing in INR is as follow:
   - **100%** study payment will be paid to AH&R from Sponsor/ CRO for each study.
   - **65%** study payment will be paid to Hospital /Principal Investigator from AH&R.
   - **35%** study payment fees will be paid to AH&R.

- **100%** CRC fees will be paid to AH&R from sponsor /CRO.
- Additional **30%** Institutional overhead will be paid from AH&R received from sponsor /CRO.
- AH&R will pay Lab Cost, subject Hospitalization, SAE Medical Management charges at actual basis to Hospital /Principal Investigator received from sponsor /CRO.

(**Note**: Hospital/Principal Investigator should provide dedicated working printer, stationary, Electricity, Working place, Internet connection facility to our study team.)

I. Termination of Agreement

1. This Agreement shall be terminated by mutual agreement by giving sixty (60) days prior written notice by either party after the completion of any ongoing trials.

J. Permission to use personal Information or Statement

For good consideration, the undersigned authorizes AH&R and its assigns to use, publish or reprint in whole or part any basic information about my identity, practice, and participation in clinical research including any specific details of my clinical research that do not conflict with a previously contacted privacy agreement.

The two parties shall consult with each other and medicate any disputes which may arise about the contact. If all attempts fail the two parties can appeal to the organization of arbitration in judicial court of the state of Aurangabad, Maharashtra India.

Accepted & Signed on behalf of MGM Hospital, Aurangabad

Authorized Signature: Signature & Date: Name: Dr.Rajendra Bohra Title: Dean Hospital Name:Mahatma Gandhi Mission (MGM) Medical College& Hospital	 Signature & Date: 5.2.2021 Name: Dr.Deepak Bhosle Title: Professor & Head Dept.of Pharmacology Hospital Name: Mahatma Gandhi Mission (MGM) Medical College & Hospital

Accepted & Signed on behalf of AH&R LLP, Aurangabad

Authorized Signature: Signature & Date: 5/02/2021 Name: Dr Ujwala Kulkarni Designated Partner, Aurangabad Health Care & Research LLP, Chetan Trade Centre, Opp.S.F School, Jalna Road, Aurangabad, Pin 431001, MH, India	 Signature & Date: 05/Feb/2021 Name: Dr Renuka Madnurkar Designated Partner, Aurangabad Health Care & Research LLP, Chetan Trade Centre, Opp.S.F School, Jalna Road, Aurangabad, Pin 431001, MH, India

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital

N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS

Office: Dr. Deepak Bhosle, Prof & Head, Dept. of Clinical Pharmacology & Therapeutics, MGM Medical College & Hospital
N-6,CIDCO,Aurangabad – 431003. Ph. No: 0240-6601423, 0240-6601174, Email: pharmacology@mgmmcha.org

Memorandum of Understanding

This Agreement is made on 01st Jan 2020, by and between "**Biosphere Clinical Research Pvt Ltd** having its Office at **SB-02,03,04, 2nd Floor, Highland Corporate Center, Kapurbawdi Junction, Thane West - 400607**" referred as a party- A **(here in after referred to as the CRO)**

And

Mahatma Gandhi Mission (MGM) Medical College & Hospital, N-6, Cidco, Aurangabad, Maharashtra 431 003 referred as a party-B **(here in after referred to as the "Institution")**

The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfill conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promise and mutual covenants herein contained and for Other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties here to as follows

MGM Medical College & Hospital appoints **Biosphere Clinical Research Pvt Ltd** as a Clinical Research Organization **for period of 10 years w. e. f 1st Jan 2020 to 31st Dec 2029. (Will be reviewed and updated accordingly)**

A. Hospital permits

1. Hospital will give the space and required facilities to Biosphere Clinical Research in order to perform clinical trials activities under respected PI.
2. Hospital will allow Biosphere Clinical Research and Sponsors of Clinical trials to access the facility to verify source documents.
3. Hospital will allow Biosphere Clinical Research to bring Sponsors of clinical trials to meet with PI/SITE representatives at a mutually convenient time.

B. Term of Agreement

The term of this Agreement shall be for a period of 10 years commencing on the effective date 01st Jan 2020. However, this Agreement shall be reviewed annually by both parties if needed.

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital

N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS

Office: Dr. Deepak Bhosle, Prof & Head, Dept. of Clinical Pharmacology & Therapeutics, MGM Medical College & Hospital
N-6,CIDCO,Aurangabad – 431003. Ph. No: 0240-6601423, 0240-6601174, Email: pharmacology@mgmmcha.org

C. Relationship of the parties

1. Hospital and Biosphere Clinical Research are independent parties. Both parties agree that their relationship is that of an Independent contractor and not employer and employee.
2. Neither party shall have express or implied rights nor authority to assume or create any obligation or responsibility on behalf of or in the name of the other party by reason of this Agreement, except as provided in this Agreement.

D. GCP, ICH and CFR compliance

Hospital agrees to comply with International Conference of Harmonization & Good Clinical Practices (ICH-GCP) and all India regulations, CDSCO requirement and circulars there under.

E. Confidentiality

1. The parties here recognize and agree that due to the complex and competitive nature of the business, the confidential of information concerning both parties is of critical importance. Either party shall not, either during or after the term of this Agreement, disclose to any third party any confidential information and all information or information relative to the work or the business of either party without the written consent of either party. Biosphere Clinical Research agrees that it shall not during, or at any time after the termination of this Agreement, directly or indirectly disclose or use any information for any reason whatever, without the prior written consent of SITE.

2. Hospital shall not disclose to any third party any and information about new studies received from Biosphere Clinical Research.

G. Compensation and Agreement

1. The Hospital, principle Investigator, Biosphere Clinical Research will enter into a tripartite clinical trial agreement before/at the time of placement of each trial at the Hospital.
2. Getting payment from sponsor and giving to Hospital and /or Investigator is the responsibility of Biosphere Clinical Research.
3. All payment shall be due and payable to the hospital /or Investigator on actual work i.e. number of subject randomized or visits completed, as per the Clinical Trial Agreement.
4. The payment of remuneration shall be after deduction of all taxes under applicable laws.

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital

N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS

Office: Dr. Deepak Bhosle, Prof & Head, Dept. of Clinical Pharmacology & Therapeutics, MGM Medical College & Hospital
N-6,CIDCO,Aurangabad – 431003. Ph. No: 0240-6601423, 0240-6601174, Email: pharmacology@mgmmcha.org

5. All invoices will be requested from the hospital for study payment and all study related payment will be done to MGM Medical College & Hospital.

(**Note**: Hospital/Principal Investigator should provide dedicated working printer, stationary, Electricity, Working place, Internet connection facility to study team.)

Authorized Signature:	Witness Signature:
.....	.....
Name: Dr. Rajendra Bohra	Witness Name: Dr. Deepak Bhosle
Title: Dean	Title: Professor and Head Department of Pharmacology
Date: 24/01/2020	Date: 23 Jan 2020
Hospital Name: **Mahatma Gandhi Mission (MGM) Medical College & Hospital**	Hospital Name: **Mahatma Gandhi Mission (MGM) Medical College & Hospital**

M. G. M. Hospital Aurangabad.

1) Authorized Signature:

.....

Name: Dr. Neeta Nargundkar

Title: Managing Director

Date: 15 JAN 2020

BIOSPHERE CLINICAL RESEARCH PVT. LTD. MUMBAI

Biosphere Clinical Research, Thane, Maharashtra

CANVASS
CLINICAL RESEARCH
SERVICES PRIVATE LTD.
"Research Provides you Quality with Integrity"

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info@ccrsindia.com www.ccrsindia.com

Memorandum of Understanding

This Agreement is made on **04th Aug 2022** by and between "**CANVASS CLINICAL RESEARCH SERVICES PVT.LTD"** having its Office **B Wing, 303, Keshav Imperial, Sitabuldi, Nagpur 440012, Maharashtra, India** at referred as a party- A **(here in after referred to as the SMO"")**

And

Mahatma Gandhi Mission (MGM) Medical College & Hospital, N-6, Cidco, Aurangabad, Maharashtra 430 003 referred as a party-B **(here in after referred to as the "Institution")**

The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfill conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promise and mutual covenants herein contained and for Other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties here to as follows

MGM Medical College& Hospital appoints SMO **CANVASS CLINICAL RESEARCH SERVICES PVT.LTD**As a site management organization on **Exclusive basis for period of 10 years w.e.f 04thAug 2022 to 03rd Aug 2029. (Will be reviewed and updated accordingly)**

Obligations of SMO NAME Services:

CANVASS CLINICAL RESEARCH SERVICES PVT.LTD is a site management Organization based in Hyderabad providing end to end clinical research services to the Hospitals and Offers a complete range of Clinical Research in all therapeutic areas. We expertise in site Management Activities, Project Management, Medical Writing, Monitoring, Safety Reporting, Regulatory services, Potential Site selection, Faster patient Recruitment, Quality compliance & Maintenance, and Clinical Research Expertise in India.

CANVASS CLINICAL RESEARCH SERVICES PVT.LTD Services is desirous of working with Hospital for the purpose of conducting ICH-GCP complaint phase I-IV clinical trials for new drug & treatment.

CANVASS CLINICAL RESEARCH SERVICES PVT.LTD Services shall play vital role in getting clinical trials to the hospital /Hospital from the sponsors and CROs and execute them in Hospital.

CANVASS CLINICAL RESEARCH SERVICES PVT.LTD Services will manage study Operations and study services as directed by study protocol for the duration of the clinical trial.

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CANVASS CLINICAL RESEARCH SERVICES PVT.LTD Services will appoint a Clinical Research Coordinators (CRC)/existing site coordinator who will be a point of contact with Sponsor & CRO and ensure smooth conduct of trial at the site.

CANVASS CLINICAL RESEARCH SERVICES PVT.LTD will appoint project manager (PM) who will be responsible to coordinate and over-see the progress and management of CRC activities & trial, ensure data quality, resolve screening, enrollment or general issue if any, follow up on post -monitoring action elements and study training as per needs and frequent discussion with investigator & sponsor / CRO on trial progress.

CANVASS CLINICAL RESEARCH SERVICES PVT.LTD will appoint Quality check (QC Experts) who will be responsible to ensure adherence to the protocol, regulatory requirements record keeping and retention.

Study co-ordination, project management and quality management will be done by SMO **CANVASS CLINICAL RESEARCH SERVICES PVT.LTD**.SMO **CANVASS CLINICAL RESEARCH SERVICES PVT.LTD** personnel, CRC, PM, QC Experts will assist PI and the Intuitions in all trial related activities.

SMO **CANVASS CLINICAL RESEARCH SERVICES PVT.LTD** will bear all the administrative cost related to the various activities undertaken by PM, CRC or any other staff placed by SMO **CANVASS CLINICAL RESEARCH SERVICES PVT.LTD** which includes telecommunication, travel cost, training cost at various centers across India or abroad.

SMO **CANVASS CLINICAL RESEARCH SERVICES PVT.LTD** will be exclusively conducting/managing all trial at the Hospital during the tenure of this agreement. This agreement will last for 10 (ten) years and can be renewed further on mutual agreement.

Following activities will be carried out by appointed CRCs

1. Performing all the activities in strict adherence to the ICH-GCP guidelines, Schedule Y India GCP and Regulatory requirement
2. Preparation for site selection visit and Site Initiation Visit (SIV)
3. Communication & Follow up with IRB/IEC Submission and Approval
4. Accurate and complete documentation of relevant EC documentation
5. Regulatory documents Collection
6. Patient Identification for assigned study form OPD or Hospital Database.
7. Maintenance and update of Trial Master File (TMF), site binders and relevant files

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8. Preparation for site Monitoring Initiation Visit (SMV) and resolving all action items generated during Previous monitoring visits
9. Conduct Study according to International Conference of Harmonization (ICH) E6 and India Good Clinical Practice (GCP) regulation
10. Assisting Principal Investigator in administrating ICF and its procedures
11. Ensure protocol & applicable regulatory guidelines compliance and adherence
12. Patients pre- screening enrollment and recruitment
13. Preparing source notes and CRF filling
14. Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates
15. Coordinate and schedule subject's regular follow up visits and procedures, maintain regular Telephonic contact with patients to preventing lost to follow- up and missed visits.
16. Managing Clinical Trial Materials (CTM) maintenance, Accountability, distribution and logistics at site
17. Coordinate all site-specific queries- medical, administrative, subject reimbursements and other study related activities.
18. Reporting and coordinating all AE/SAEs according to their timelines as per regulatory norms
19. Filling up and maintaining trial related logs likes source documentation, drug dispensing logs, subject log, visit logs, Investigational product log, temperature log, SAE and EC communication log
20. Documentation of protocol deviation as appropriate and communicate any impacting subject safety to the ethics committee
21. Coordinate with central and local lab for logistics and sample flow
22. Attend study related meeting as appropriate
23. Preparing sites for Monitoring / Auditing visits coordinate close out visit and Archival at site
24. Any other required activities during the trials.
25. Identification of potential database from different therapeutic area of PIs

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26. Communication with Investigators/ Hospitals and conduct protocol specific feasibility

27. Other duties as requested by SMO **CANVASS CLINICAL RESEARCH SERVICES PVT.LTD**

B. Hospital permits

1. Hospital will give the space and required facilities to appointed CRC & SMO **CANVASS CLINICAL RESEARCH SERVICES PVT.LTD** in order to perform clinical trials activities under respected PI.
2. Hospital will allow SMO **CANVASS CLINICAL RESEARCH SERVICES PVT.LTD** and Sponsors of Clinical trials to access the facility to verify source documents.
3. Hospital will allow SMO **CANVASS CLINICAL RESEARCH SERVICES PVT.LTD** to bring Sponsors of clinical trials to meet with PI/SITE representatives at a mutually convenient time.
4. Hospital shall permit SMO **CANVASS CLINICAL RESEARCH SERVICES PVT.LTD** to exclusively manage all clinical trial commenced by SMO **CANVASS CLINICAL RESEARCH SERVICES PVT.LTD**

C. Term of Agreement

The term of this Agreement shall be for a period of 10 years commencing on the effective date 04th Aug 2022. However, this Agreement shall be reviewed annually by both parties if needed.

D. Relationship of the parties

1. Hospital and SMO **CANVASS CLINICAL RESEARCH SERVICES PVT.LTD** are independent parties. Both parties agree that their relationship is that of an independent contractor and not employer and employee.
2. Neither party shall have express or implied rights nor authority to assume or create any obligation or responsibility on behalf of or in the name of the other party by reason of this Agreement, except as provided in this Agreement.

E. GCP, ICH and CFR compliance

Hospital agrees to comply with International Conference of Harmonization & Good Clinical Practices (ICH-GCP) and all India regulations, CDSCO requirement and circulars there under.

F. Confidentiality

1. The parties here recognize and agree that due to the complex and competitive nature of the business, the confidential of information concerning both parties Is of critical importance. Either party shall not, either during or after the term of this Agreement, disclose to any third party any confidential information and all Information or information relative to the work or the business of either party without the written consent of either party SMO **CANVASS CLINICAL RESEARCH SERVICES PVT.LTD** agrees that it shall not

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during, or at any time after the termination of this Agreement, directly or indirectly disclose or use any information for any reason whatever, without the prior written consent of SITE.

2. Hospital shall not disclose to any third party any and information about new studies received from SMO **CANVASS CLINICAL RESEARCH SERVICES PVT.LTD**.

G. Indemnification

Hospital shall indemnify and hold harmless SMO **CANVASS CLINICAL RESEARCH SERVICES PVT.LTD** against any losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by SITE, its agents, directors or employees, SMO **CANVASS CLINICAL RESEARCH SERVICES PVT.LTD** shall indemnify and hold harmless hospital against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of act or commission by SMO **CANVASS CLINICAL RESEARCH SERVICES PVT.LTD**, its agents, directors, or employees. In no event will either party be required to indemnify or hold harmless the other's negligence or gross negligence.

H. Compensation and Agreement

1. The Hospital, principal Investigator, SMO **CANVASS CLINICAL RESEARCH SERVICES PVT.LTD** Services and Sponsor and/or CRO will enter into a quadripartite clinical trial agreement before/at the time of placement of each trial at the Hospital.
2. All feasibilities and payments shall be routed through SMO **CANVASS CLINICAL RESEARCH SERVICES PVT.LTD** and pricing while bidding for the trial shall be discussed mutually and final correspondence with the Sponsor/CRO also would be handled by SMO NAME Services for smooth and hassle-free finalization of Clinical Trial Agreements.
3. Getting payment from sponsor and giving to Hospital and /or Investigator is the responsibility of SMO NAME Services.
4. SMO NAME will be payee name for all trial related payment.
5. All payment shall be due and payable to the hospital on actual work i.e. number of subject randomized or visits completed.
6. The payment of remuneration shall be after deduction of all taxes under applicable laws.
7. All invoices will be requested from the hospital for study payment and all study related payment will be done to MGM Medical College & Hospital, in a period of 15 working days after receiving the payment from the sponsor/CRO.

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info@ccrsindia.com www.ccrsindia.com

8. The details of study budget sharing in INR is as follow:

- **100%** study payment will be paid to **CANVASS CLINICAL RESEARCH Services Pvt. Ltd** from Sponsor/ CRO for each study.
- **65%** study payment will be paid to Hospital /Principal Investigator from **CANVASS CLINICAL RESEARCH Services Pvt. Ltd**
- **35%** study payment fees will be paid to **CANVASS CLINICAL RESEARCH Services Pvt. Ltd**
- **100%** CRC fees will be paid to **CANVASS CLINICAL RESEARCH Services Pvt. Ltd** from sponsor /CRO.
- Subject Travel reimbursement amount will be paid to Hospital from **CANVASS CLINICAL RESEARCH Services Pvt. Ltd**
- Additional **30%** Institutional overhead will be paid from **CANVASS CLINICAL RESEARCH Services Pvt. Ltd** received from sponsor /CRO.
- **CANVASS CLINICAL RESEARCH Services Pvt. Ltd** will pay Lab Cost, subject Hospitalization, SAE Medical Management charges at actual basis to Hospital /Principal Investigator received from sponsor /CRO.

(**Note**: Hospital/Principal Investigator should provide dedicated working printer, stationary, Electricity, Working place, Internet connection facility to our study team.)

I. Termination of Agreement

1. This Agreement shall be terminated by mutual agreement by giving sixty (60) days prior written notice by either party after the completion of any ongoing trials.

J. Permission to use personal Information or Statement

For good consideration, the undersigned authorizes SMO and its assigns to use, publish or reprint in whole or part any basic information about my identity, practice, and participation in clinical research including any specific details of my clinical research that do not conflict with a previously contacted privacy agreement.

The two parties shall consult with each other and medicate any disputes which may arise about the contact. If all attempts fail the two parties can appeal to the organization of arbitration in judicial court of the state of Maharashtra India.

+91 8208 448 630 / +91 7028 699 360
info@ccrsindia.com www.ccrsindia.com

Authorized Signature: ..... Name: Dr.Rajendra Bohra Title: Dean Date: Hospital Name: **Mahatma Gandhi Mission (MGM) Medical College& Hospital** **Stamp:** 18 Aug 2022 DEAN MGM'S MEDICAL COLLEGE AURANGABAD	Professor & Head Dept.of Pharmacology ..... Name: Dr.Deepak Bhosle Title: Professor & Head Dept.of Pharmacology (Clinical Trial Center) Date: Hospital Name: **Mahatma Gandhi Mission (MGM) Medical College & Hospital** **Stamp:** 18 AUG 2022 Professor & H.O.D. Department of Pharmacology MGM's Medical College Aurangabad.

SMO NAME **2) Authorized Signature:** ..... Name: Vijaya Bhakte Title: Director, CCRSPL Date: 04-Aug-2022 Address: Nagpur **Stamp:** Vijaya Bhakte B.pharm, PGDCR Director of CCRSPL	**SMO NAME** **1) Authorized Signature:** ..... Name: Mahendra Yadav Title: Business Head, CCRSPL Date: 4 Aug, 2022 Address: Nagpur **Stamp:** Clinical Research Services Pvt. Ltd.

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BEED BYPASS, AURANGABAD, MH-431007

+91 9870965482/ 9673869944
info@dphsindia.com
www.dphsindia.com

GSTIN: **27BEIPA1204B1ZC**

Memorandum of Understanding

This Agreement is made on 01st DEC 2020, by and between "**DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**" having its Office atRH2, Hari Krishna Nagar, Gut No-95, Beed Bypass Aurangabad, Maharashtra. 431007 referred as a party- A **(here in after referred to as the"SMO")**

And

Mahatma Gandhi Mission (MGM) Medical College & Hospital, N-6, CIDCO, Aurangabad, Maharashtra 431 001 referred as a party-B **(here in after referred to as the "Institution")**

The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfill conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promise and mutual covenants herein contained and for Other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties here to as follows

MGM Medical College& Hospital appoints **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**As a site management organization on **Exclusive basis for period of 10 years w.e.f 1st DEC 2020 to 30th NOV 2030. (will be reviewed and updated accordingly)**

Obligations of DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS:

DESTINATION PHARMAGENS HEALTHCARE SOLUTIONSis a site management Organization based in Aurangabad, Maharashtra providing end to end clinical research services to the Hospitals and Offers a complete range of Clinical Research in all therapeutic areas. We expertise in site Management Activities, Project Management, Monitoring, Safety Reporting, Regulatory services, Potential Site selection, Faster patient Recruitment, Quality compliance & Maintenance, and Clinical Research Expertisein India.

DESTINATION PHARMAGENS HEALTHCARE SOLUTIONSare desirous of working with Institution for the purpose of conducting ICH-GCP complaint phase I-IV clinical trials for new drug & treatment.

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DESTINATION PHARMAGENS HEALTHCARE SOLUTIONSshall play vital role in getting clinical trials to the hospital /Hospital from the sponsors and CROs and execute them in Hospital.In case of conflict of a same study among the multiple SMO's, the institution shall be the arbitrator and award the study to the deserving SMO.

DESTINATION PHARMAGENS HEALTHCARE SOLUTIONSwill manage study Operations and study services as directed by study protocol for the duration of the clinical trial.

DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS will appoint a Clinical Research Coordinators (CRC's) who will be a pointof contact with Sponsor & CRO and ensure smooth conduct of trial at the site.

DESTINATION PHARMAGENS HEALTHCARE SOLUTIONSwill appointproject manager (PM) who will be responsible to coordinate and over-see the progress and management of CRC activities & trial, ensure data quality, resolve screening, enrollment or general issue if any, follow up on post -monitoring action elements and study training as per needs and frequent discussion with investigator & sponsor / CRO on trial progress.

DESTINATION PHARMAGENS HEALTHCARE SOLUTIONSwill appoint Quality check (QC Experts) who will be responsible to ensure adherence to the protocol, regulatory requirements record keeping and retention.

Study co-ordination, project management and qualitymanagement will be done by **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS.**

DESTINATION PHARMAGENS HEALTHCARE SOLUTIONSpersonnel, CRC, PM, QC Experts will assist PI and the Intuitions in all trial related activities.

DESTINATION PHARMAGENS HEALTHCARE SOLUTIONSwill bear all the administrative cost related to the various activities undertaken by PM, CRC or any other staff placed by **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**Serviceswhich includes telecommunication, travel cost, training cost at various centers across India or abroad.

Hospital and the Principal Investigator shall be responsible for the recruitment of the subjects to the study in the given timely manner.

DESTINATION PHARMAGENS HEALTHCARE SOLUTIONSwill be exclusively conducting/managing all trial at the Hospital during the tenure of this agreement. This agreement will last for 10 (ten) years and can be renewed further on mutual agreement.

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GSTIN: **27BEIPA1204B1ZG**

Following activities will be carried out by appointed CRCs

1. Performing all the activities in strict adherence to the ICH-GCP guidelines, Schedule Y India GCP andRegulatory requirement
2. Preparation for site selection visit and Site Initiation Visit (SIV)
3. Communication & Follow up with IRB/IEC Submission and Approval
4. Accurate and complete documentation of relevant EC documentation
5. Regulatory documents Collection
6. Patient Identification for assigned study form OPD or Hospital Database.
7. Maintenance and update of Trial Master File (TMF), site binders and relevant files
8. Preparation for Site Monitoring Visit (SMV) and resolving all action items generated during
9. Previous monitoring visits
10. Conduct Study according to International Conference of Harmonization (ICH) E6 and India GoodClinical Practice(GCP) regulation
11. Assisting Principal Investigator in administrating ICF and its procedures
12. Ensure protocol & applicable regulatory guidelines compliance and adherence
13. Patients pre-screening enrollment and recruitment
14. Preparing source notes and CRF filling
15. Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates
16. Coordinate and schedule subject's regular follow up visits and procedures, maintain regularTelephoniccontact with patients to preventing lost to follow- up and missed visits.
17. Managing Clinical Trial Materials (CTM) maintenance, Accountability, distribution and logistics at site
18. Coordinate all site-specific queries.Medical, administrative, subject reimbursements and other study
19. related activities.
20. Reporting and coordinating all AE/SAEs according to their timelines as per regulatory norms
21. Filling up and maintaining trial related logs likes source documentation, drug dispensing logs, subject
22. log, visit logs, Investigational product log, temperature log, SAE and EC communication log
23. Documentation of protocol deviation as appropriate and communicate any impacting subject safety

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GSTIN: **27BEIPA1204B1ZG**

24. to the ethics committee
25. Coordinate with central and local lab for logistics and sample flow
26. Attend study related meeting as appropriate
27. Preparing sites for Monitoring / Auditing visits coordinate close out visit and Archival at site
28. Any other required activities during the trials.
29. Identification of potential database from different therapeutic area of PIs.
30. Communication with Investigators/ Hospitals and conduct protocol specific feasibility
31. Other duties as requested by **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**Management

B. Hospital permits

1. Hospital will give the space and required facilities to appointed CRC &**DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**in order to performclinical trials activities under respected PI.
2. Hospital will allow **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**and Sponsors of Clinical trials to access the facility to verify source documents.
3. Hospital will allow **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**to bring Sponsors of clinical trials to meet with PI/SITE representatives at a mutually convenient time.
4. Hospital shall permit **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS** to exclusively manage all clinical trial commenced by **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**

C. Term of Agreement

The term of this Agreement shall be for a period of 10 years commencing on the effective date 01stOCT 2020. However, this Agreement shall be reviewed annually by both parties if needed.

D. Relationship of the parties

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www.dphsindia.com

GSTIN: 27BEIPA1204B1ZG

1. Hospital and **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**are independent parties. Both parties agree that their relationship is that of anIndependent contractor and not employer and employee.
2. Neither party shall have express or implied rights nor authority to assume or create any obligation or responsibility on behalf of or in the name of the other party by reason of this Agreement,except as provided in this Agreement.

E. GCP, ICH and CFR compliance

Hospital agrees to comply with International Conference of Harmonization & Good Clinical Practices (ICH-GCP) and all India regulations, CDSCO requirement and circulars there under.

F. Confidentiality

1. The parties here recognize and agree that due to the complex and competitive nature of the business, the confidential of information concerning both parties Is of critical importance. Either partyshall not, either during or after the term of this Agreement, disclose to any third party any confidential information and all Information or information relative to the work or the business of either party without the written consent of either party **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**agrees that it shall not during, or at any time after the termination of this Agreement, directly or indirectly disclose or use any information for any reason whatever, without the prior written consent of SITE.

2. Hospital shall not disclose to any third party any and information about new studies received from **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**.

G. Indemnification

Hospital shall indemnify and hold harmless **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**against any losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by SITE, its agents, directors or employees, **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**shall indemnify and hold harmless hospital against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of act or commission by

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DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS, its agents, directors, or employees. In no event will either party be required to indemnify or hold harmless the other's negligence or gross negligence.

H. Compensation and Agreement

1. The Hospital, Principal Investigator, **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**and Sponsor and/or CRO will enter into a quadripartite clinical trial agreement before/at the time of placement of each trial at the Hospital.
2. All feasibilities and payments shall be routed through **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**and pricing while bidding for the trial shall be discussed mutually and final correspondence with the Sponsor/CRO also would be handled by **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**for smooth and hassle-free finalization of Clinical Trial Agreements.
3. Getting payment from sponsor and giving to Hospital and /or Investigator is the responsibility of **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS.**
4. **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**will be payee name for all trial related payment.
5. All payment shall be due and payable to the hospital on actual work i.e. number of subject randomized or visits completed.
6. The payment of remuneration shall be after deduction of all taxes under applicable laws.
7. All invoices will be requested from the hospital for study payment and all study related payment will be done to MGM Medical College & Hospital, in a period of 15 working days after receiving the payment from the sponsor/CRO.
8. The details of study budget sharing in INR is as follow:
   - **100%** study payment will be paid to **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**from Sponsor/ CRO for each study.
   - **65%** study payment will be paid to Hospital /Principal Investigator from **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS.**
   - **35%** study payment fees will be paid to **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS.**
   - **100%** CRC fees will be paid to **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**from sponsor /CRO.

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- Additional **30%** Institutional overhead will be paid from**DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**received from sponsor /CRO.
- **DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS**will pay Lab Cost, subject Hospitalization, SAE Medical Management charges at actual basis to Hospital /Principal Investigator received from sponsor /CRO.

(**Note**: Hospital/Principal Investigator should provide dedicated working Computer/ Laptop, printer, stationary, Electricity, Working place, Internet connection facility to our study team.)

I. Termination of Agreement

1. This Agreement shall be terminated by mutual agreement by giving sixty (60) days prior written notice by either party after the completion of any ongoing trials.

J. Permission to use personal Information or Statement

For good consideration, the undersigned authorizes SMO and its assigns to use, publish or reprint in whole or part any basic information about my identity, practice, and participation in clinical research including any specific details of my clinical research that do not conflict with a previously contacted privacy agreement.

The two parties shall consult with each other and medicate any disputes which may arise about the contact. If all attempts fail the two parties can appeal to the organization of arbitration in judicial court of the state of Aurangabad, Maharashtra, India.

Authorized Signature: ..... Name: Dr. Rajendra Bohra Title: Dean Date: Hospital Name:**Mahatma Gandhi Mission (MGM) Medical College& Hospital**	Professor & Head, Dept.of Pharmacology ..... Name: Dr.Deepak Bhosle Title: Professor & Head Dept.of Pharmacology Date: Hospital Name: **Mahatma Gandhi Mission (MGM) Medical College & Hospital**

Professor & H.O.D.
Department of Pharmacology
MGM's Medical College
Aurangabad.

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www.dphsindia.com

GSTIN: **27BEIPA1204B1ZG**

DESTINATION PHARMAGENS HEALTHCARE SOLUTIONS

1) Authorized Signature:

.....

Name: Dr. Krutikesh R Age

Title: Head- Development &Clinical Operations

Date: 01/12/2020

SMO:**Destination Pharmagens Healthcare Solutions** (DPHS)

Address:RH2, HariKrishna Nagar, Gut No-95, Beed Bypass Aurangabad, Maharashtra. 431007.

भारतीय गैर न्यायिक

एक सौ रुपये Rs. 100

रु. 100 ONE HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA ◑ 2019 ◑ VD 386448

फक्त प्रतिज्ञापत्रासाठी

अनु.क्र. ५२५३ दि. 14 JUN 2019 रक्कम 200/-

मुद्रांक विक्रत घेणाऱ्याचे नांव ग्रेपसिटी रिसर्च सोल्युशन्स LLP

पत्ता प्रकाश हौ.सोसा. पेरगांव पुणे ४१

हस्तेचे नांव अदनान अग्रवाल वय्या पुणे ४५

सौ. शोभा म. डोळे

परवाना क्र २२०१९४९

मुद्रांक विक्रत घेणाऱ्याची सही बाजीप्रभु चौक, मेन रोड, कात्रवाडी, पुणे १४

सासदय कार्यालयासमोर/न्यायालयासमोर प्रतिज्ञापत्र सादर करण्याकरिता

करिता जमादाची आवश्यकता नाही (शासन आदेश दि. २/१२/२००५ नुसार

वरिष्ठ कोषागार अधिकारी पुणे

11 JUN 2019

प्रथम मुद्रांक लिपीक कोषागार पुणे करिता

ज्या कारणासाठी ज्यानी मुद्रांक खरेदी केला त्यांना त्याच कारणासाठी

मुद्रांक खरेदी केल्या पासुन 6 महिन्यात वापरणे बंधनकारक आहे

Memorandum of Understanding

This Agreement is made on ~~1st May~~ 14th Jun 2019, by and between **"GRAPECITY RESEARCH SOLUTIONS LLP"** a company registered under company act 1956 having its office at Shree Prasad, Block No. D-2, Prakash Housing Society ,Kalewadi Phata,Thergaon, Pune 411033, Maharashtra, India referred as a party- A **(herein after referred to as the "GRAPECITY RESEARCH")**

And

MAHATMA GANDHI MISSION's, MEDICAL COLLEGE & HOSPITAL (MGM HOSPITAL), N-6 CIDCO, Aurangabad-431003, Maharashtra, India referred as a party – B **(herein after referred to as the "Institution")**

The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfill conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties hereto as follows

MGM College & Hospital Aurangabad appoints "GRAPECITY RESEARCH SOLUTIONS LLP" as a Site management organization **for period of 05 years w.e.f** 14th Jun 2019 to 14th Jun 2024.

Obligations of "GRAPECITY RESEARCH SOLUTIONS LLP Clinical Research Services:

"GRAPECITY RESEARCH SOLUTIONS LLP" is a Clinical Research Organizations and Site Management Organization based in Pune providing end to end clinical research services to the Sponsors, Pharmaceutical and Biopharmaceutical industry, Institutions and Offers a complete range of Clinical Research in all therapeutic areas. We expertise in Site Management Activities, Project Management, Medical Writing, Monitoring, Safety Reporting, Regulatory services, Potential Site Selection, Faster Patient Recruitment, Quality compliance& Maintenance, and Clinical Research Expertise in India.

"GRAPECITY RESEARCH" is desirous of working with Institution for the purpose of conducting ICH-GCP complaint Phase I-IV clinical trials for new drug & treatment.

"GRAPECITY RESEARCH" shall play vital role in getting clinical trials to the hospital / institution from the sponsors and CROs and execute them in institution.

"GRAPECITY RESEARCH" will manage Study Operations and Study services as directed by Study protocol for the duration of the clinical trial.

GRAPECITY RESEARCH" will appoint a Clinical Research Coordinator (CRC) who will be a point of contact with Sponsor & CRO and ensure smooth conduct of trial at the site.

"GRAPECITY RESEARCH" will appoint Project Manager (PM) who will be responsible to co-ordinate and over-see the progress and management of CRC activities & trial ensure data quality, resolve screening, enrollment or general issue if any, follow up on post –monitoring action elements and study training as per needs and frequent discussion with investigator & Sponsor/CRO on trial progress.

"GRAPECITY RESEARCH" will appoint Quality Check Experts (QC Experts) who will be responsible to ensure adherence to the protocol, regulatory requirements record keeping and retention. Study co-ordination, project management and quality management will be done by "GRAPECITY RESEARCH". Study personnel, CRC, PM, QC Experts will assist PI and the Intuitions in all trial related activities.

"GRAPECITY RESEARCH" will bear all the administrative cost related to the various activities undertaken by PM, CRC or any other staff placed by "GRAPECITY RESEARCH" which includes telecommunication, travel cost, training cost at various centers across India or abroad.

"GRAPECITY RESEARCH" will be conducting /managing all trial (Trials come from "GRAPECITY RESEARCH SOLUTIONS LLP) at the Institution during the tenure of this agreement. This agreement will last for 05 (Five) years and can be renewed further on mutual agreement.

Following activities will be carried out by appointed CRCs

1. Performing all the activities in strict adherence to the ICH-GCP guidelines, Schedule Y Indian GCP and regulatory requirement.
2. Preparation for Site selection visit and Site Initiation Visit (SIV)
3. Communication & Follow up with IRB/IEC Submission and Approval
4. Accurate and complete documentation of relevant EC documentation
5. Regulatory Documents Collection
6. Patient Identification for assigned study from OPD or Hospital Database.
7. Maintenance and update of Trial Master File (TMF), site binders and relevant files
8. Preparation for Site Monitoring Initiation Visit (SMV) and resolving all action items generated during previous
9. Conduct study according to International Conference of Harmonization (ICH) E6 and Indian Good Clinical Practice (GCP) regulation
10. Assisting Principal Investigator in administrating ICF and its procedures

11. Ensure protocol &applicable regulatory guidelines compliance and adherence
12. Patients pre-screening, screening enrollment and recruitment
13. Preparing source notes and CRF filling
14. Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates
15. Coordinate and schedule subject's regular follow up visits and procedures, maintain regular telephonic contact with patients to preventing lost to follow-up and missed visits.
16. Managing clinical trial materials(CTM) maintenance, Accountability, distribution and logistics at site
17. Coordinate all site specific queries-medical, administrative, subject reimbursements and other
18. Reporting and coordinating all AE/SAEs according to their timelines as per regulatory norms
19. Filling up and maintaining trial related logs likes source documentation, drug dispensing logs, subject log, visit logs, Investigational product log, temperature log, logistics log, SAE and EC communication log
20. Documentation of protocol deviation as appropriate and communicate any impacting subject safety to the ethics committee
21. Coordinate with central and local lab for logistics and sample flow
22. Attend study related meeting as appropriate
23. Preparing sites for Monitoring / Auditing visits coordinate close out visit and Archival at site
24. Any other required activities during the trials.
25. Identification of potential database from different therapeutic area of PIs.

26. Communication with Investigators/ Hospitals and conduct protocol specific feasibility
27. Other duties as requested by "GRAPECITY RESEARCH" Management.

B. Institution Permits

1. Institution will give the space and required facilities to appointed CRC & "GRAPECITY RESEARCH" in order to perform clinical trials activities under respected PI.
2. Institution will allow "GRAPECITY RESEARCH" and Sponsors of clinical trials to access the facility to verify source documents.
3. Institution will allow "GRAPECITY RESEARCH" to bring Sponsors of clinical trials to meet with SITE representatives at a mutually convenient time.
4. Institution permit all Clinical Trials (The trial which comes for "GRAPECITY RESEARCH") will exclusively manage by "GRAPECITY RESEARCH" only.

C. Term of Agreement

The term of this Agreement shall be for a period of 05 year commencing on the effective date 14th Jun 2019. However, this Agreement shall be reviewed annually by both parties.

D. Relationship of the Parties

1. Hospital and "GRAPECITY RESEARCH SOLUTIONS LLP" are independent parties. Both parties agree that their relationship is that of an independent contractor and not employer and employee.
2. Neither party shall have express or implied rights nor authority to assume or create any obligation or responsibility on behalf of or in the name of the other party by reason of this Agreement, except as provided in this Agreement.

E. GCP, ICH and CFR Compliance

Institution agrees to comply with all requirements of Good Clinical Practices (GCP), International Conference of Harmonization (ICH) and Code of Federal Regulations (CFR) and any and all future regulations, requirements and writing promulgated there under.

F. Confidentiality

1. The parties hereto recognize and agree that due to the complex and competitive nature of the business, the confidentiality of information concerning both parties is of critical importance. Either party shall not, either during or after the term of this Agreement, disclose to any third party any confidential information and all information or information relative to the work or the business of either party without the written consent of either party. "GRAPECITY RESEARCH SOLUTIONS LLP" agrees that it shall not during, or at any time after the termination of this Agreement, directly or indirectly disclose or use any information for any reason whatsoever, without the prior written consent of SITE

2. Institution shall not disclose to any third party any and all information about new studies received from "GRAPECITY RESEARCH SOLUTIONS LLP"

G. Indemnification

Institution shall indemnify and hold harmless "GRAPECITY RESEARCH SOLUTIONS LLP" against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by SITE, its agents, directors or employees. "GRAPECITY RESEARCH SOLUTIONS LLP" shall indemnify and hold harmless hospital against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by "GRAPECITY RESEARCH SOLUTIONS LLP", its agents, directors, or employees. In no event will either party be required to indemnify or hold harmless the other for the other's negligence or gross negligence.

H. Compensation and Agreement

1. The Institution, Principal Investigator, "GRAPECITY RESEARCH" and Sponsor and/or CRO will enter into a quadripartite clinical trial agreement before/at the time of placement of each trial at the Institution.
2. All feasibilities and payments shall be routed through "GRAPECITY RESEARCH SOLUTIONS LLP" and pricing while bidding for the trial/ trials shall be discussed mutually and final correspondence with the Sponsor/CRO also would be handled by "GRAPECITY RESEARCH SOLUTIONS LLP for Smooth and hassle-free finalization of Clinical Trial Agreements.
3. Getting payment from sponsor and giving to Institution and /or Investigator is the responsibility of "GRAPECITY RESEARCH SOLUTIONS LLP.
4. All payment will come to "GRAPECITY RESEARCH" by the sponsors/CRO and "GRAPECITY RESEARCH SOLUTIONS LLP Clinical Research Services will be payee for all trial related payment for each trial
5. All payment shall be due and payable to the Institution on the basis of funds received from the sponsor/CRO on actual work i.e. number of subject randomized or visits completed.
6. The payment of remuneration shall be after deduction of all taxes under applicable laws.
7. An invoice will be requested from the hospital for study payment and all Study related payments will be done to MGM Medical College & Hospital Aurangabad, in a period of 15 working days after receiving the payment from the sponsor/CRO

8. The details of study budget sharing in INR is as follows:
   - Payment per patient from Sponsor/CRO to "GRAPECITY RESEARCH SOLUTIONS LLP": 100%
   - Payment to Institute/Principal Investigator from "GRAPECITY RESEARCH SOLUTIONS LLP": 65%
   - Payment to "GRAPECITY RESEARCH SOLUTIONS LLP Clinical Research Services: 35%
   - Patient travel reimbursement will be borne by "GRAPECITY RESEARCH SOLUTIONS LLP" and will be reimbursed by sponsor/CRO to "GRAPECITY RESEARCH SOLUTIONS LLP"
   - If sponsor provides, 20% Institutional Overhead Charges (Of the investigator grant) shall be paid to the Hospital/Institute.
   - If sponsor provides some instrument or pay cheque for instrument purchase for clinical research use, then it should be maintained/ returned back to the sponsor after project completion. OR If Grapecity Research Purchases any instruments for clinical trial use, that will be maintained & remained with Grapecity Research only.
   - Archival of the study documents is responsibility of Hospital/ Institute & should maintain for specific period as per Sponsors policy.
   - If coordinator charges are borne by sponsor in such cases grant will go to "GRAPECITY RESEARCH SOLUTIONS LLP" as the payment to coordinators is already the responsibility of "GRAPECITY RESEARCH SOLUTIONS LLP"

(Note: study budget sharing will be revised after one year mutually agreed by both party)

I. Termination of Agreement

1. This Agreement shall be terminated by mutual agreement by giving Sixty (60) days prior written notice by either party after the completion of any ongoing trials.

J. Permission to use Personal Information or Statement

For good consideration, the undersigned authorizes SMO and it's assigns to use, publish or reprint in whole or part any basic information about my identity, practice, and participation in clinical research including any specific details of my clinical research that do not conflict with a previously contracted privacy agreement.

The two parties shall consult with each other and mediate any disputes which may arise about the contract. If all attempts fail, the two parties can appeal to the organization of arbitration in judicial court of Aurangabad, MH, India.

MGM Medical College &Hospital Aurangabad

1) Signature: _____

DEAN
MGM'S MEDICAL COLLEGE
AURANGABAD

Name:-Dr. Rajendra Bohra
Title: - Dean
MGM Medical College and Hospital,
N-6 CIDCO, Aurangabad-431003,Maharashtra,India
Date: - 18 Jun 2019

2) Signature: _____

Dr. Pravin Suryawanshi
Professor & Head
Department of Surgery
MGM Medical College & Hospital,
Aurangabad
Reg. No. 071613

Name:-Dr. Pravin R. Suryawanshi
Title: - Dy. Dean
MGM Medical College and Hospital,
N-6 CIDCO, Aurangabad-431003,Maharashtra,India
Date: - 18 Jun 2019

3) Signature: _____

Professor & H.O.D.
Department of Pharmacology
MGM's Medical College
Aurangabad.

Name:-Dr. Deepak Bhosle
Title:- Professor & Head Department of Pharmacology
MGM Medical College and Hospital,
N-6 CIDCO, Aurangabad-431003,Maharashtra,India
Date: - 18 Jun 2019

GRAPECITY RESEARCH SOLUTIONS LLP

For Grapecity Research Solutions LLP

Signature: _____

Designates Partners / Partner

Name: - Dr. Sushil Chaudhary
Title: - Founder & Director,
GRAPECITY RESEARCH SOLUTIONS LLP
Shree Prasad, Block No. D-2, Prakash Housing Society ,
Kalewadi Phata,Thergaon, Pune 411033, Maharashtra, India.

Date: - 14th Jun 2019

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Memorandum of Understanding

This Agreement is made on 12thJuly 2022, by and between "**Med Tricare clinical research solution**" having its Office at plot no 21, PrabhatNagar Bhausingpura Aurangabad 431001 referred as a party- A **(here in after referred to as the"SMO")**

And

Mahatma Gandhi Mission's (MGM) Medical College & Hospital, N-6, Cidco, Aurangabad, Maharashtra 431003 referred as a party-B **(here in after referred to as the "Institution")**

The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfill conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promise and mutual covenants herein contained and for Other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties here to as follows

MGM Medical College& Hospital appoints Med Tricare clinical Research solution ServicesAs a site management organization on **Exclusive basis for period of 10 years w.e.f12th July 2022 to 12th July 2032. (Will be reviewed and updated accordingly)**

Obligations of Med Tricare clinical research solution Services:

Med Tricare clinical research solution is a site management Organization based in Aurangabad providing end to end clinical research services to the Hospitals and Offers a complete range of Clinical Research in all therapeutic areas. We expertise in site Management Activities, Project Management, Medical Writing, Monitoring, Safety Reporting, Regulatory services, Potential Site selection, Faster patient Recruitment, Quality compliance & Maintenance, and Clinical Research Expertisein India.

Med Tricare clinical research solution Servicesis desirous of working with Hospital for the purpose of conducting ICH-GCP complaint phase I-IV clinical trials for new drug & treatment.

Med Tricare clinical research solution Servicesshall play vital role in getting clinical trials to the hospital /Hospital from the sponsors and CROs and execute them in Hospital.

Med Tricare clinical research solution Serviceswill manage study Operations and study services as directed by study protocol for the duration of the clinical trial.

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Med Tricare clinical research solution Services will appoint a Clinical Research Coordinators (CRC)/existing site coordinator who will be a pointof contact with Sponsor & CRO and ensure smooth conduct of trial at the site.

Med Tricare clinical research solution will appoint project manager (PM) who will be responsible to coordinate and over-see the progress and management of CRC activities & trial, ensure data quality, resolve screening, enrollment or general issue if any, follow up on post -monitoring action elements and study training as per needs and frequent discussion with investigator & sponsor / CRO on trial progress.

Med Tricare clinical Research solutionwill appoint Quality check (QC Experts) who will be responsible to ensure adherence to the protocol, regulatory requirements record keeping and retention.

Study co-ordination, project management and qualitymanagement will be done by Med Tricare clinical Research solution services. Med Tricare clinical Research solution personnel, CRC, PM, QC Experts will assist PI and the Intuitions in all trial related activities.

Med Tricare clinical Research solutionwill bear all the administrative cost related to the various activities undertaken by PM, CRC or any other staff placed by Med Tricare clinical Research solution Serviceswhich includes telecommunication, travel cost, training cost at various centers across India or abroad.

Med Tricare clinical Research solutionwill be exclusively conducting/managing all trial at the Hospital during the tenure of this agreement. This agreement will last for 10 (ten) years and can be renewed further on mutual agreement.

Following activities will be carried out by appointed CRCs

1. Performing all the activities in strict adherence to the ICH-GCP guidelines, Schedule Y India GCP and Regulatory requirement
2. Preparation for site selection visit and Site Initiation Visit (SIV)
3. Communication & Follow up with IRB/IEC Submission and Approval
4. Accurate and complete documentation of relevant EC documentation
5. Regulatory documents Collection

Memorandum of Understanding

6. Patient Identification for assigned study form OPD or Hospital Database.
7. Maintenance and update of Trial Master File (TMF), site binders and relevant files
8. Preparation for site Monitoring Initiation Visit (SMV) and resolving all action items generated during Previous monitoring visits
9. Conduct Study according to International Conference of Harmonization (ICH) E6 and India Good Clinical Practice (GCP) regulation
10. Assisting Principal Investigator in administrating ICF and its procedures
11. Ensure protocol & applicable regulatory guidelines compliance and adherence
12. Patients pre- screening enrollment and recruitment
13. Preparing source notes and CRF filling
14. Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates
15. Coordinate and schedule subject's regular follow up visits and procedures, maintain regular Telephoniccontact with patients to preventing lost to follow- up and missed visits.
16. Managing Clinical Trial Materials (CTM) maintenance, Accountability, distribution and logistics at site
17. Coordinate all site specific queries- medical, administrative, subject reimbursements and other study Related activities.
18. Reporting and coordinating all AE/SAEs according to their timelines as per regulatory norms
19. Filling up and maintaining trial related logs likes source documentation, drug dispensing logs, subject Log, visit logs, Investigational product log, temperature log, SAE and EC communication log
20. Documentation of protocol deviation as appropriate and communicate any impacting subject safety To the ethics committee

Memorandum of Understanding

21. Coordinate with central and local lab for logistics and sample flow
22. Attend study related meeting as appropriate
23. Preparing sites for Monitoring / Auditing visits coordinate close out visit and Archival at site
24. Any other required activities during the trials.
25. Identification of potential database from different therapeutic area of PIs
26. Communication with Investigators/ Hospitals and conduct protocol specific feasibility
27. Other duties as requested by Med Tricare clinical Research solution ServicesManagement

B. Hospital permits

1. Hospital will give the space and required facilities to appointed CRC & Med Tricare clinical Research solutionin order to performclinical trials activities under respected PI.
2. Hospital will allow Med Tricare clinical Research solution and Sponsors of Clinical trials to access the facility to verify source documents.
3. Hospital will allow Med Tricare clinical Research solution to bring Sponsors of clinical trials to meet with PI/SITE representatives at a mutually convenient time.
4. Hospital shall permit Med Tricare clinical Research solution to exclusively manage all clinical trial commenced by Med Tricare clinical Research solution Services

C. Term of Agreement

The term of this Agreement shall be for a period of 10 years commencing on the effective date12th July 2022. However, this Agreement shall be reviewed annually by both parties if needed.

D. Relationship of the parties

1. Hospital and Med Tricare clinical Research solution are independent parties. Both parties agree that their relationship is that of an Independent contractor and not employer and employee.
2. Neither party shall have express or implied rights nor authority to assume or create any obligation or responsibility on behalf of or in the name of the other party by reason of this Agreement,except as provided in this Agreement.

Memorandum of Understanding

E. GCP, ICH and CFR compliance

Hospital agrees to comply with International Conference of Harmonization & Good Clinical Practices (ICH-GCP) and all India regulations, CDSCO requirement and circulars there under.

F. Confidentiality

1. The parties here recognize and agree that due to the complex and competitive nature of the business, the confidential of information concerning both parties Is of critical importance. Either partyshall not, either during or after the term of this Agreement, disclose to any third party any confidential information and all Information or information relative to the work or the business of either party without the written consent of either party Med Tricare clinical Research solutionagrees that it shall not during, or at any time after the termination of this Agreement, directly or indirectly disclose or use any information for any reason whatever, without the prior written consent of SITE.

2. Hospital shall not disclose to any third party any and information about new studies received from Med Tricare clinical Research solution

G. Indemnification

Hospital shall indemnify and hold harmless Med Tricare clinical Research solutionagainst any losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by SITE, its agents, directors or employees, Med Tricare clinical Research solutionshall indemnify and hold harmless hospital against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of act or commission by Med Tricare clinical Research solution, its agents, directors, or employees. In no event will either party be required to indemnify or hold harmless the other's negligence or gross negligence.

H. Compensation and Agreement

1. The Hospital, principal Investigator, Med Tricare clinical Research solution Servicesand Sponsor and/or CRO will enter into a quadripartite clinical trial agreement before/at the time of placement of each trial at the Hospital.

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2. All feasibilities and payments shall be routed through Med Tricare clinical Research solution and pricing while bidding for the trial shall be discussed mutually and final correspondence with the Sponsor/CRO also would be handled by Med Tricare clinical Research solution Servicesfor smooth and hassle-free finalization of Clinical Trial Agreements.
3. Getting payment from sponsor and giving to Hospital and /or Investigator is the responsibility of Med Tricare clinical Research solutionServices.
4. Med Tricare clinical Research solution will be payee name for all trial related payment.
5. All payment shall be due and payable to the hospital on actual work i.e., number of subject randomized or visits completed.
6. The payment of remuneration shall be after deduction of all taxes under applicable laws.
7. All invoices will be requested from the hospital for study payment and all study related payment will be done to MGM Medical College & Hospital, in a period of 15 working days after receiving the payment from the sponsor/CRO.
8. The details of study budget sharing in INR is as follow:
    - **100%** study payment will be paid to Med Tricare clinical Research solutionfrom Sponsor/ CRO for each study.
    - **65%** study payment will be paid to Hospital /Principal Investigator from Med Tricare clinical Research solution
    - **35%** study payment fees will be paid to Med Tricare clinical Research solution
    - **100%** CRC fees will be paid to Med Tricare clinical Research solutionfrom sponsor /CRO.
    - Additional **30%** Institutional overhead will be paid from**Med Tricare clinical research solution** received from sponsor/CRO.

Memorandum of Understanding

- **Med Tricare clinical research solution** will pay Lab Cost, subject Hospitalization, SAE Medical Management charges at actual basis to Hospital /Principal Investigator received from sponsor /CRO.

(**Note**: Hospital/Principal Investigator should provide dedicated working printer, stationary, Electricity, Working place, Internet connection facility to our study team.)

I. Termination of Agreement

1. This Agreement shall be terminated by mutual agreement by giving sixty (60) days prior written notice by either party after the completion of any ongoing trials.

J. Permission to use personal Information or Statement

For good consideration, the undersigned authorizes SMO and its assigns to use, publish or reprint in whole or part any basic information about my identity, practice, and participation in clinical research including any specific details of my clinical research that do not conflict with a previously contacted privacy agreement.

The two parties shall consult with each other and medicate any disputes which may arise about the contact. If all attempts fail the two parties can appeal to the organization of arbitration in judicial court of the states India.

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Memorandum of Understanding

Authorized Signature: .....29/7/22 Name:Dr.Rajendra Bohra Title: Dean Date: 29 JUL 2022 Hospital Name:**Mahatma Gandhi Mission's (MGM) Medical College& Hospital** DEAN MGM'S MEDICAL COLLEGE AURANGABAD	Professor & Head Dept.of Pharmacology .....12/7/22 Name: Dr.Deepak Bhosle Title: Professor & Head Department of Pharmacology (Clinical Trial Center) Date: 12 JUL 2022 Hospital Name: **Mahatma Gandhi Mission's (MGM) Medical College & Hospital** Professor & H.O.D. Department of Pharmacology MGM's Medical College Aurangabad.

MEDTRICARE CLINICAL RESEARCH SOLUTION.

1) **Authorized Signature:**
.....12/7/22
Name: Manish Kamalakar Wankhede
Title: Director
Date: 12/07/2022
SMO: Med Tricare clinical research solution
Address: Plot no 21, Prabhatnagarbhausingpura Aurangabad

Med Tricare Clinical Research Solutions Aurangabad

2) **Authorized Signature:**
.....12/7/22
Name:DrDhanajay Satpute
Title: Head of the clinical Operation
Date:12/07/2022
SMO: : Med Tricare clinical research solution
Address: Plot no 21, Prabhatnagarbhausingpura Aurangabad

Med Tricare Clinical Research Solutions Aurangabad

Memorandum of Understanding

This Agreement is made on **24 JAN 2022**, by and between "**METICULOUS HEALTHCARE AND RESEARCH SERVICES LLP"** having its Office at H NO 9-1-143, Lane No 6, Sharif Colony Kat KAT GATE Aurangabad referred as a party- A **(here in after referred to as the"SMO")**

And

Mahatma Gandhi Mission (MGM) Medical College & Hospital, N-6, Cidco, Aurangabad, Maharashtra 430 003 referred as a party-B **(here in after referred to as the "Institution")**

The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfill conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promise and mutual covenants herein contained and for Other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties here to as follows

MGM Medical College & Hospital appoints "**METICULOUS HEALTHCARE AND RESEARCH SERVICES LLP"** Services as a site management organization on **Exclusive basis for period of 10 years w.e.f 24 Jan 2022 to 23 JAN 2032. (Will be reviewed and updated accordingly)**

Obligations of MH & RS SMO:

MH & RS is a site management Organization based in Aurangabad, providing end to end clinical research services to the Hospitals and Offers a complete range of Clinical Research in all therapeutic areas. We expertise in site Management Activities, Project Management, Medical Writing, Monitoring, Safety Reporting, Regulatory services, Potential Site selection, Faster patient Recruitment, Quality compliance & Maintenance, and Clinical Research Expertise in India.

MH & RS is desirous of working with Hospital for the purpose of conducting ICH-GCP complaint phase I-IV clinical trials for new drug & treatment.

MH & RS shall play vital role in getting clinical trials to the hospital /institute from the sponsors and CROs and execute them in hospital /institute.

MGM's Medical College Aurangabad

METICULOUS HEALTHCARE & RESEARCH SERVICES LLP AURANGABAD

MH & RS will manage study Operations and study services as directed by study protocol for the duration of the clinical trial.

MH & RS will appoint a Clinical Research Coordinators (CRC)/existing site coordinator who will be a point of contact with Sponsor & CRO and ensure smooth conduct of trial at the site.

MH & RS will appoint project manager (PM) who will be responsible to coordinate and over-see the progress and management of CRC activities & trial, ensure data quality, resolve screening, enrollment or general issue if any, follow up on post -monitoring action elements and study training as per needs and frequent discussion with investigator & sponsor / CRO on trial progress.

MH & RS will appoint Quality check (QC Experts) who will be responsible to ensure adherence to the protocol, regulatory requirements record keeping and retention.

Study co-ordination, project management and quality management will be done by **METICULOUS HEALTHCARE AND RESEARCH SERVICES LLP**.

MH & RS personnel, CRC, PM, QC Experts will assist PI and the Intuitions in all trial related activities.

MH & RS will bear all the administrative cost related to the various activities undertaken by PM, CRC or any other staff placed by **MH & RS** which includes telecommunication, travel cost, training cost at various centers across India or abroad.

MH & RS will be exclusively conducting/managing all trial at the Hospital during the tenure of this agreement. This agreement will last for 10 (ten) years and can be renewed further on mutual agreement.

Following activities will be carried out by appointed CRCs

1. Performing all the activities in strict adherence to the ICH-GCP guidelines, India GCP and Regulatory requirement
2. Preparation for site selection visit and Site Initiation Visit (SIV)
3. Communication & Follow up with IRB/IEC Submission and Approval
4. Accurate and complete documentation of relevant EC documentation
5. Regulatory documents Collection
6. Patient Identification for assigned study form OPD or Hospital Database.
7. Maintenance and update of Trial Master File (TMF), site binders and relevant files
8. Preparation for site Monitoring Initiation Visit (SMV) and resolving all action items generated during

Previous monitoring visits

9. Conduct Study according to International Conference of Harmonization (ICH) E6 and India Good Clinical Practice (GCP) regulation
10. Assisting Principal Investigator in administrating ICF and its procedures
11. Ensure protocol & applicable regulatory guidelines compliance and adherence
12. Patients pre- screening enrollment and recruitment
13. Preparing source notes and CRF filling
14. Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates
15. Coordinate and schedule subject's regular follow up visits and procedures, maintain regular Telephonic contact with patients to preventing lost to follow- up and missed visits.
16. Managing Clinical Trial Materials (CTM) maintenance, Accountability, distribution and logistics at site
17. Coordinate all site specific queries- medical, administrative, subject reimbursements and other study related activities.
18. Reporting and coordinating all AE/SAEs according to their timelines as per regulatory norms
19. Filling up and maintaining trial related logs likes source documentation, drug dispensing logs, subject Log, visit logs, Investigational product log, temperature log, SAE and EC communication log
20. Documentation of protocol deviation as appropriate and communicate any impacting subject safety To the ethics committee
21. Coordinate with central and local lab for logistics and sample flow
22. Attend study related meeting as appropriate
23. Preparing sites for Monitoring / Auditing visits coordinate close out visit and Archival at site
24. Any other required activities during the trials.
25. Identification of potential database from different therapeutic area of PIs
26. Communication with Investigators/ Hospitals and conduct protocol specific feasibility
27. Other duties as requested by **MH & RS** Management.

MGM's Medical College Aurangabad

METICULOUS HEALTHCARE & RESEARCH SERVICES LLP AURANGABAD

B. Hospital permits

1. Hospital will give the space and required facilities to appointed CRC & **MH & RS** in order to perform clinical trials activities under respected PI.
2. Hospital will allow **MH & RS** and Sponsors of Clinical trials to access the facility to verify source documents.
3. Hospital will allow **MH & RS** to bring Sponsors of clinical trials to meet with PI/SITE representatives at a mutually convenient time.
4. Hospital shall permit **MH & RS** to exclusively manage all clinical trial commenced by SMO services.

C. Term of Agreement

The term of this Agreement shall be for a period of 10 years commencing on the effective date 14th Jan 2022. However, this Agreement shall be reviewed annually by both parties if needed.

D. Relationship of the parties

1. Hospital and **MH & RS** are independent parties. Both parties agree that their relationship is that of an Independent contractor and not employer and employee.
2. Neither party shall have express or implied rights nor authority to assume or create any obligation or responsibility on behalf of or in the name of the other party by reason of this Agreement, except as provide in this Agreement.

E. GCP, ICH and CFR compliance

Hospital agrees to comply with International Conference of Harmonization & Good Clinical Practices (ICH-GCP) and all India regulations, CDSCO requirement and circulars there under.

F. Confidentiality

1. The parties here recognize and agree that due to the complex and competitive nature of the business, the confidential of information concerning both parties is of critical importance. Either party shall not, either during or after the term of this Agreement, disclose to any third party any confidential information and all Information or information relative to the work or the business of either party without the written consent of either party **MH & RS** agrees that it shall not during, or at any time after the termination of this Agreement, directly or indirectly disclose or use any information for any reason whatever, without the prior written consent of SITE.

meticulous.smo@gmail.com 9766885171
House No. 9-1-143, Sharif Colony, Lane No. 6, Near Rashion Shop No.132, Kat Kat Gate, Aurangabad, 431001, Maharashtra, India

2. Hospital shall not disclose to any third party any and information about new studies received from **METICULOUS HEALTHCARE AND RESEARCH SERVICES LLP**.

G. Indemnification

Hospital shall indemnify and hold harmless **MH & RS** against any losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by SITE, its agents, directors or employees, **MH & RS** shall indemnify and hold harmless hospital against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of act or commission by **MH & RS**, its agents, directors, or employees. In no event will either party be required to indemnify or hold harmless the other's negligence or gross negligence.

H. Compensation and Agreement

1. The Hospital, principle Investigator, **METICULOUS HEALTHCARE AND RESEARCH SERVICES LLP** and Sponsor and/or CRO will enter into a quadripartite clinical trial agreement before/at the time of placement of each trial at the Hospital.
2. All feasibilities and payments shall be routed through **METICULOUS HEALTHCARE AND RESEARCH SERVICES LLP** and pricing while bidding for the trial shall be discussed mutually and final correspondence with the Sponsor/CRO also would be handled by **METICULOUS HEALTHCARE AND RESEARCH SERVICES LLP** for smooth and hassle-free finalization of Clinical Trial Agreements.
3. Getting payment from sponsor and giving to Hospital and /or Investigator is the responsibility of **METICULOUS HEALTHCARE AND RESEARCH SERVICES LLP**.
4. **METICULOUS HEALTHCARE AND RESEARCH SERVICES LLP** will be payee name for all trial related payment.
5. All payment shall be due and payable to the hospital on actual work i.e. number of subject randomized or visits completed.
6. The payment of remuneration shall be after deduction of all taxes under applicable laws.
7. All invoices will be requested from the hospital for study payment and all study related payment will be done to MGM Medical College & Hospital, in a period of 15 working days after receiving the payment from the sponsor/CRO.
8. The details of study budget sharing in INR is as follow:

MGM's Medical College Aurangabad

METICULOUS HEALTHCARE & RESEARCH SERVICES LLP AURANGABAD

meticulous.smo@gmail.com 9766885171
House No. 9-1-143, Sharif Colony, Lane No. 6, Near Rashion Shop No.132, Kat Kat Gate, Aurangabad, 431001, Maharashtra, India

- **100%** study payment will be paid to **METICULOUS HEALTHCARE AND RESEARCH SERVICES LLP** from Sponsor/ CRO for each study.
- **65%** study payment will be paid to Hospital /Principal Investigator from **METICULOUS HEALTHCARE AND RESEARCH SERVICES LLP**.
- **35%** study payment fees will be paid to **METICULOUS HEALTHCARE AND RESEARCH SERVICES LLP**.
- **100%** CRC fees will be paid to **METICULOUS HEALTHCARE AND RESEARCH SERVICES LLP** from sponsor /CRO.
- Subject Travel reimbursement amount will be paid to Hospital from **METICULOUS HEALTHCARE AND RESEARCH SERVICES LLP**.
- Additional **30%** Institutional overhead will be paid from **METICULOUS HEALTHCARE AND RESEARCH SERVICES LLP** received from sponsor /CRO.
- **METICULOUS HEALTHCARE AND RESEARCH SERVICES LLP** will pay Lab Cost, subject Hospitalization, SAE Medical Management charges at actual basis to Hospital /Principal Investigator received from sponsor /CRO.

(**Note**: Hospital/Principal Investigator should provide dedicated working printer, stationary, Electricity, Working place, Internet connection facility to our study team.)

I. Termination of Agreement

1. This Agreement shall be terminated by mutual agreement by giving sixty (60) days prior written notice by either party after the completion of any ongoing trials.

J. Permission to use personal Information or Statement

For good consideration, the undersigned authorizes SMO and its assigns to use, publish or reprint in whole or part any basic information about my identity, practice, and participation in clinical research including any specific details of my clinical research that do not conflict with a previously contacted privacy agreement.

The two parties shall consult with each other and medicate any disputes which may arise about the contact. If all attempts fail the two parties can appeal to the organization of arbitration in judicial court of the state of Maharashtra India.

MGM's Medical College Aurangabad

METICULOUS HEALTHCARE & RESEARCH SERVICES LLP AURANGABAD

meticulous.smo@gmail.com 9766885171
House No. 9-1-143, Sharif Colony, Lane No. 6, Near Rashion Shop No.132, Kat Kat Gate, Aurangabad, 431001. Maharashtra, India

Authorized Signature: ..... Name: Dr.Rajendra Bohra Title: Dean Hospital Name:**Mahatma Gandhi Mission (MGM) Medical College& Hospital** Date: 24 Jan 2022 **Stamp:** DEAN MGM'S MEDICAL COLLEGE AURANGABAD	**Authorized Signature:** ..... Name: Dr.Deepak Bhosle Title: Professor & Head Dept.of Pharmacology Hospital Name: **Mahatma Gandhi Mission (MGM) Medical College & Hospital** Date: 24 Jan 2022 **Stamp:** Professor & H.O.D. Department of Pharmacology MGM's Medical College Aurangabad.
Authorized Signature: ..... Name: Shaikh Yahiya Ali Title: Founder & Director, SMO: Meticulous Healthcare and Research Services LLP Date: 24 Jan 2022 Address: Sharif Colony A'bad. **Stamp:**	**Authorized Signature:** ..... Name: Shaikh Anam Fatema Title: Partner SMO: Meticulous Healthcare and Research Services LLP Date: 24 Jan 2022 Address: Sharif Colony A'bad. **Stamp:**

METICULOUS HEALTHCARE & RESEARCH SERVICES LLP ★ AURANGABAD

meticulous.smo@gmail.com 9766885171
House No. 9-1-143, Sharif Colony, Lane No. 6, Near Rashion Shop No 132, Kat Kat Gate, Aurangabad, 431001, Maharashtra, India

Cliniinfinity
Clinical Research Solutions

Memorandum of Understanding

This Agreement is made on 12 Dec 2020, by and between **"CliniInfinity Clinical Research Solutions LLP"** having its Office atFlat No. 11 , Bus Stop, Sai Corner Building, N-7 Cidco, Aurangabad – 431001, Maharashtra, India referred as a party- A **(here in after referred to as the"")**

And

Mahatma Gandhi Mission (MGM) Medical College & Hospital, N-6, Cidco, Aurangabad, Maharashtra 430 003 referred as a party-B **(here in after referred to as the "Institution")**

The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfill conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promise and mutual covenants herein contained and for Other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties here to as follows

MGM Medical College& Hospital appoints **CliniInfinity Clinical Research Solutions LLP**ServicesAs a site management organization on **Exclusive basis for period of 10 years w.e.f 12thDec 2020 to 13thDec 2029. (will be reviewed and updated accordingly)**

Obligations of CliniInfinity Clinical Research Solutions LLPServices:

CliniInfinity Clinical Research Solutions LLPis a site management Organization based in Hyderabad providing end to end clinical research services to the Hospitals and Offers a complete range of Clinical Research in all therapeutic areas. We expertise in site Management Activities, Project Management, Medical Writing, Monitoring, Safety Reporting, Regulatory services, Potential Site selection, Faster patient Recruitment, Quality compliance & Maintenance, and Clinical Research Expertisein India.

CliniInfinity Clinical Research Solutions LLP Servicesis desirous of working with Hospital for the purpose of conducting ICH-GCP complaint phase I-IV clinical trials for new drug & treatment.

CliniInfinity Clinical Research Solutions LLP ServicesShall play vital role in getting clinical trials to the hospital /Hospital from the sponsors and CROs and execute them in Hospital.

CliniInfinity Clinical Research Solutions LLP Serviceswill manage study Operations and study services as directed by study protocol for the duration of the clinical trial.

CliniInfinity Clinical Research Solutions LLP Services will appoint a Clinical Research Coordinators (CRC)/existing site coordinator who will be a pointof contact with Sponsor & CRO and ensure smooth conduct of trial at the site.

CliniInfinity Clinical Research Solutions LLPwill appoint project manager (PM) who will be responsible to coordinate and over-see the progress and management of CRC activities & trial, ensure data quality, resolve screening, enrollment or general issue if any, follow up on post -monitoring action elements and study training as per needs and frequent discussion with investigator & sponsor / CRO on trial progress.

Cliniinfinity
Clinical Research Solutions

Memorandum of Understanding

This Agreement is made on 12 Dec 2020, by and between **"CliniInfinity Clinical Research Solutions LLP"** having its Office atFlat No. 11 , Bus Stop, Sai Corner Building, N-7 Cidco, Aurangabad – 431001, Maharashtra, India referred as a party- A **(here in after referred to as the"")**

And

Mahatma Gandhi Mission (MGM) Medical College & Hospital, N-6, Cidco, Aurangabad, Maharashtra 430 003 referred as a party-B **(here in after referred to as the "Institution")**

The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfill conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promise and mutual covenants herein contained and for Other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties here to as follows

MGM Medical College& Hospital appoints **CliniInfinity Clinical Research Solutions LLP**ServicesAs a site management organization on **Exclusive basis for period of 10 years w.e.f 12thDec 2020 to 13thDec 2029. (will be reviewed and updated accordingly)**

Obligations of CliniInfinity Clinical Research Solutions LLPServices:

CliniInfinity Clinical Research Solutions LLPis a site management Organization based in Hyderabad providing end to end clinical research services to the Hospitals and Offers a complete range of Clinical Research in all therapeutic areas. We expertise in site Management Activities, Project Management, Medical Writing, Monitoring, Safety Reporting, Regulatory services, Potential Site selection, Faster patient Recruitment, Quality compliance & Maintenance, and Clinical Research Expertisein India.

CliniInfinity Clinical Research Solutions LLP Servicesis desirous of working with Hospital for the purpose of conducting ICH-GCP complaint phase I-IV clinical trials for new drug & treatment.

CliniInfinity Clinical Research Solutions LLP ServicesShall play vital role in getting clinical trials to the hospital /Hospital from the sponsors and CROs and execute them in Hospital.

CliniInfinity Clinical Research Solutions LLP Serviceswill manage study Operations and study services as directed by study protocol for the duration of the clinical trial.

CliniInfinity Clinical Research Solutions LLP Services will appoint a Clinical Research Coordinators (CRC)/existing site coordinator who will be a pointof contact with Sponsor & CRO and ensure smooth conduct of trial at the site.

CliniInfinity Clinical Research Solutions LLPwill appoint project manager (PM) who will be responsible to coordinate and over-see the progress and management of CRC activities & trial, ensure data quality, resolve screening, enrollment or general issue if any, follow up on post -monitoring action elements and study training as per needs and frequent discussion with investigator & sponsor / CRO on trial progress.

CliniInfinity Clinical Research Solutions LLPwill appoint Quality check (QC Experts) who will be responsible to ensure adherence to the protocol, regulatory requirements record keeping and retention.

Study co-ordination, project management and qualitymanagement will be done by **CliniInfinity Clinical Research Solutions LLP**services. **CliniInfinity Clinical Research Solutions LLP**personnel, CRC, PM, QC Experts will assist PI and the Intuitions in all trial related activities.

CliniInfinity Clinical Research Solutions LLPwill bear all the administrative cost related to the various activities undertaken by PM, CRC or any other staff placed by **CliniInfinity Clinical Research Solutions LLP**Serviceswhich includes telecommunication, travel cost, training cost at various centers across India or abroad.

CliniInfinity Clinical Research Solutions LLPwill be exclusively conducting/managing all trial at the Hospital during the tenure of this agreement. This agreement will last for 10 (ten) years and can be renewed further on mutual agreement.

Following activities will be carried out by appointed CRCs

1. Performing all the activities in strict adherence to the ICH-GCP guidelines, Schedule Y India GCP and Regulatory requirement
2. Preparation for site selection visit and Site Initiation Visit (SIV)
3. Communication & Follow up with IRB/IEC Submission and Approval
4. Accurate and complete documentation of relevant EC documentation
5. Regulatory documents Collection
6. Patient Identification for assigned study form OPD or Hospital Database.
7. Maintenance and update of Trial Master File (TMF), site binders and relevant files
8. Preparation for site Monitoring Initiation Visit (SMV) and resolving all action items generated during Previous monitoring visits
9. Conduct Study according to International Conference of Harmonization (ICH) E6 and India Good Clinical Practice(GCP) regulation
10. Assisting Principal Investigator in administrating ICF and its procedures
11. Ensure protocol & applicable regulatory guidelines compliance and adherence
12. Patients pre- screening enrollment and recruitment
13. Preparing source notes and CRF filling
14. Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates
15. Coordinate and schedule subject's regular follow up visits and procedures, maintain regular Telephoniccontact with patients to preventing lost to follow- up and missed visits.

CliniInfinity Clinical Research Solutions LLPwill appoint Quality check (QC Experts) who will be responsible to ensure adherence to the protocol, regulatory requirements record keeping and retention.

Study co-ordination, project management and qualitymanagement will be done by **CliniInfinity Clinical Research Solutions LLP**services. **CliniInfinity Clinical Research Solutions LLP**personnel, CRC, PM, QC Experts will assist PI and the Intuitions in all trial related activities.

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10. Assisting Principal Investigator in administrating ICF and its procedures
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12. Patients pre- screening enrollment and recruitment
13. Preparing source notes and CRF filling
14. Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates
15. Coordinate and schedule subject's regular follow up visits and procedures, maintain regular Telephoniccontact with patients to preventing lost to follow- up and missed visits.

5. All payment shall be due and payable to the hospital on actual work i.e. number of subject randomized or visits completed.
6. The payment of remuneration shall be after deduction of all taxes under applicable laws.
7. All invoices will be requested from the hospital for study payment and all study related payment will be done to MGM Medical College & Hospital, in a period of 15 working days after receiving the payment from the sponsor/CRO.
8. The details of study budget sharing in INR is as follow:
   - **100%** study payment will be paid to **CliniInfinity Clinical Research Solutions LLP**from Sponsor/ CRO for each study.
   - **65%** study payment will be paid to Hospital /Principal Investigator from **CliniInfinity Clinical Research Solutions LLP.**
   - **35%** study payment fees will be paid to **CliniInfinity Clinical Research Solutions LLP.**
   - **100%** CRC fees will be paid to **CliniInfinity Clinical Research Solutions LLP**from sponsor /CRO.
   - Additional **25%** Institutional overhead will be paid from**CliniInfinity Clinical Research Solutions LLP**received from sponsor /CRO.
   - **CliniInfinity Clinical Research Solutions LLP**will pay Lab Cost, subject Hospitalization, SAE Medical Management charges at actual basis to Hospital /Principal Investigator received from sponsor /CRO.

(**Note:** Hospital/Principal Investigator should provide dedicated working printer, stationary, Electricity, Working place, Internet connection facility to our study team.)

I. Termination of Agreement

1. This Agreement shall be terminated by mutual agreement by giving sixty (60) days prior written notice by either party after the completion of any ongoing trials.

J. Permission to use personal Information or Statement

For good consideration, the undersigned authorizes SMO and its assigns to use, publish or reprint in whole or part any basic information about my identity, practice, and participation in clinical research including any specific details of my clinical research that do not conflict with a previously contacted privacy agreement.

The two parties shall consult with each other and medicate any disputes which may arise about the contact. If all attempts fail the two parties can appeal to the organization of arbitration in judicial court of the state of Aurangabad, Maharashtra, India.

Authorized Signature: ..... Name:Dr.Rajendra Bohra DEAN Title: Dean MGM'S MEDICAL COLLEGE AURANGABAD Date: Hospital Name:Mahatma Gandhi Mission (MGM) Medical College& Hospital	Professor & Head Dept.of Pharmacology Professor & H.O.D. Department of Pharmacology MGM's Medical College Aurangabad. ..... Name: Dr.Deepak Bhosle Title: Professor & Head Dept.of Pharmacology Date: Hospital Name: Mahatma Gandhi Mission (MGM) Medical College & Hospital

1) CliniInfinity Clinical Research Solutions LLP
Authorized Signature:
.....
CLINIINFINITY Clinicial Research Solutions LLP
Partner
Name: Dr. Vinayak Ghayal
Title: Director and CEO
Date:
SMO:CliniInfinity Clinical Research Solutions LLP
Address:Flat No. 11 , Bus Stop, Sai Corner Building, N-7 Cidco, Aurangabad – 431001, Maharashtra

2) Authorized Signature:
.....
CLINIINFINITY Clinicial Research Solutions LLP
Partner
Name: Mr. Mahesh Chudavekar
Title: Director
SMO:CliniInfinity Clinical Research Solutions LLP
Address: Flat No. 11 , Bus Stop, Sai Corner Building, N-7 Cidco, Aurangabad – 431001, Maharashtra

METTA CLINICAL RESEARCH

Memorandum of Understanding

This Agreement is made on 10th Feb 2021, by and between "**Metta Clinical Research Pvt. Ltd.** " having its Office at H.No. 3232,Plot No.42,Vasant Nagar,Nagpur,440027 Maharashtra referred as a party- A **(here in after referred to as the"METTA")**

And

Mahatma Gandhi Mission (MGM) Medical College & Hospital, N-6, Cidco, Aurangabad, Maharashtra 430 003 referred as a party-B **(here in after referred to as the "Institution")**

The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfill conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promise and mutual covenants herein contained and for Other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties here to as follows

MGM Medical College& Hospital appoints **Metta Clinical Research** as a site management organization on **Exclusive basis for period of 10 years w.e.f 10st Feb 2021 to 09t Feb 2031. (will be reviewed and updated accordingly)**

Obligations of Metta Clinical Research:

Metta Clinical Research is a site management Organization based in Nagpur providing end to end clinical research services to the Hospitals and Offers a complete range of Clinical Research in all therapeutic areas. We expertise in site Management Activities, Project Management, Medical Writing, Monitoring, Safety Reporting, Regulatory services, Potential Site selection, Faster patient Recruitment, Quality compliance & Maintenance, and Clinical Research Expertise in India.

Metta Clinical Research is desirous of working with Hospital for the purpose of conducting ICH-GCP complaint phase I-IV clinical trials for new drug & treatment.

Metta Clinical Research Shall play vital role in getting clinical trials to the hospital /Hospital from the sponsors and CROs and execute them in Hospital.

METTA CLINICAL RESEARCH

Metta Clinical Research will manage study Operations and study services as directed by study protocol for the duration of the clinical trial.

Metta Clinical Research will appoint a Clinical Research Coordinators (CRC)/existing site coordinator who will be a point of contact with Sponsor & CRO and ensure smooth conduct of trial at the site.

Metta Clinical Research will appoint project manager (PM) who will be responsible to coordinate and over-see the progress and management of CRC activities & trial, ensure data quality, resolve screening, enrollment or general issue if any, follow up on post -monitoring action elements and study training as per needs and frequent discussion with investigator & sponsor / CRO on trial progress.

Metta Clinical Research will appoint Quality check (QC Experts) who will be responsible to ensure adherence to the protocol, regulatory requirements record keeping and retention.

Study co-ordination, project management and quality management will be done by **Metta Clinical Research**. **Metta Clinical Research** personnel, CRC, PM, QC Experts will assist PI and the Intuitions in all trial related activities.

Metta Clinical Research will bear all the administrative cost related to the various activities undertaken by PM, CRC or any other staff placed by **Metta Clinical Research** which includes telecommunication, travel cost, training cost at various centers across India or abroad.

Metta Clinical Research will be exclusively conducting/managing all trial at the Hospital during the tenure of this agreement. This agreement will last for 10 (ten) years and can be renewed further on mutual agreement.

Following activities will be carried out by appointed CRCs

1. Performing all the activities in strict adherence to the ICH-GCP guidelines, Schedule Y India GCP and Regulatory requirement
2. Preparation for site selection visit and Site Initiation Visit (SIV)
3. Communication & Follow up with IRB/IEC Submission and Approval
4. Accurate and complete documentation of relevant EC documentation
5. Regulatory documents Collection
6. Patient Identification for assigned study form OPD or Hospital Database.
7. Maintenance and update of Trial Master File (TMF), site binders and relevant files

METTA CLINICAL RESEARCH Pvt. Ltd
H.No. 3232,42, Vasant Nagar, Nagpur- MH.- 440027, Cell: 09545526358, 9822222459
Web: www.mettaclinical.com, email: info@mettaclinical.com

8. Preparation for site Monitoring Initiation Visit (SMV) and resolving all action items generated during Previous monitoring visits
9. Conduct Study according to International Conference of Harmonization (ICH) E6 and India Good Clinical Practice (GCP) regulation
10. Assisting Principal Investigator in administrating ICF and its procedures
11. Ensure protocol & applicable regulatory guidelines compliance and adherence
12. Patients pre- screening enrollment and recruitment
13. Preparing source notes and CRF filling
14. Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates
15. Coordinate and schedule subject's regular follow up visits and procedures, maintain regular Telephonic contact with patients to preventing lost to follow- up and missed visits.
16. Managing Clinical Trial Materials (CTM) maintenance, Accountability, distribution and logistics at site
17. Coordinate all site specific queries- medical, administrative, subject reimbursements and other study related activities.
18. Reporting and coordinating all AE/SAEs according to their timelines as per regulatory norms
19. Filling up and maintaining trial related logs likes source documentation, drug dispensing logs, subject log, visit logs, Investigational product log, temperature log, SAE and EC communication log
20. Documentation of protocol deviation as appropriate and communicate any impacting subject safety to the ethics committee
21. Coordinate with central and local lab for logistics and sample flow
22. Attend study related meeting as appropriate
23. Preparing sites for Monitoring / Auditing visits coordinate close out visit and Archival at site
24. Any other required activities during the trials.

25. Identification of potential database from different therapeutic area of PIs
26. Communication with Investigators/ Hospitals and conduct protocol specific feasibility
27. Other duties as requested by **Metta Clinical Research**

B. Hospital permits

1. Hospital will give the space and required facilities to appointed CRC & **Metta Clinical Research** in order to perform clinical trials activities under respected PI.
2. Hospital will allow **Metta Clinical Research** and Sponsors of Clinical trials to access the facility to verify source documents.
3. Hospital will allow **Metta Clinical Research** to bring Sponsors of clinical trials to meet with PI/SITE representatives at a mutually convenient time.
4. Hospital shall permit **Metta Clinical Research** to exclusively manage all clinical trial commenced by **Metta Clinical Research**

C. Term of Agreement

The term of this Agreement shall be for a period of 10 years commencing on the effective date 10 th Feb 2021. However, this Agreement shall be reviewed annually by both parties if needed.

D. Relationship of the parties

1. Hospital and **Metta Clinical Research** are independent parties. Both parties agree that their relationship is that of an Independent contractor and not employer and employee.
2. Neither party shall have express or implied rights nor authority to assume or create any obligation or responsibility on behalf of or in the name of the other party by reason of this Agreement, except as provided in this Agreement.

E. GCP, ICH and CFR compliance

Hospital agrees to comply with International Conference of Harmonization & Good Clinical Practices (ICH-GCP) and all India regulations, CDSCO requirement and circulars there under.

F. Confidentiality

1. the parties here recognize and agree that due to the complex and competitive nature of the business, the confidential of information concerning both parties Is of critical importance. Either party shall not, either during or after the term of this Agreement, disclose to any third party any confidential information and all Information or information relative to the work or the business of either party without the written consent of either party **Metta Clinical Research** agrees that it shall not during, or at any time after the termination of this Agreement, directly or indirectly disclose or use any information for any reason whatever, without the prior written consent of SITE.

2. Hospital shall not disclose to any third party any and information about new studies received from **Metta Clinical Research**.

G. Indemnification

Hospital shall indemnify and hold harmless **Metta Clinical Research** against any losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by SITE, its agents, directors or employees, **Metta Clinical Research** shall indemnify and hold harmless hospital against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of act or commission by **Metta Clinical Research**, its agents, directors, or employees. In no event will either party be required to indemnify or hold harmless the other's negligence or gross negligence.

H. Compensation and Agreement

1. The Hospital, Principle Investigator, **Metta Clinical Research** and Sponsor and/or CRO will enter into a quadripartite clinical trial agreement before/at the time of placement of each trial at the Hospital.
2. All feasibilities and payments shall be routed through **Metta Clinical Research** and pricing while bidding for the trial shall be discussed mutually and final correspondence with the Sponsor/CRO also would be handled by **Metta Clinical Research** for smooth and hassle-free finalization of Clinical Trial Agreements.
3. Getting payment from sponsor and giving to Hospital and is the responsibility of **Metta Clinical Research**.
4. **Metta Clinical Research** will be payee name for all trial related payment.
5. All payment shall be due and payable to the hospital on actual work i.e. number of subject randomized or visits completed.

6. The payment of remuneration shall be after deduction of all taxes under applicable laws.
7. All invoices will be raised by Metta Clinical Research (SMO) after the discussion with Dr. Deepak Bhosle Prof. and Head, Dept of Pharmacology and In charge Clinical Research Unit.
8. All invoices will be shared with Dr Deepak Bhosle to maintain the transparency. SMO will transfer the respected amount to MGM Medical college, Aurangabad, in period of 15 working days after receiving the payment from the Sponsor/CRO.
9. The details of study budget sharing in INR is as follow:
   - **100%** study payment will be paid to **Metta Clinical Research** from Sponsor/ CRO for each study.
   - **65%** study payment will be paid to Hospital from **Metta Clinical Research**.
   - **35%** study payment fees will be paid to **Metta Clinical Research**.
   - **100%** CRC fees will be paid to **Metta Clinical Research** from sponsor /CRO.
   - Additional **30%** Institutional overhead will be paid from **Metta Clinical Research** received from sponsor /CRO.
   - **Metta Clinical Research** will pay Lab Cost, subject Hospitalization, SAE Medical Management charges at actual basis to Hospital /Principal Investigator received from sponsor /CRO.

(**Note**: Hospital/Principal Investigator should provide dedicated working printer, stationary, Electricity, Working place, Internet connection facility to our study team.)

I. Termination of Agreement

1. This Agreement shall be terminated by mutual agreement by giving sixty (60) days prior written notice by either party after the completion of any ongoing trials.

J. Permission to use personal Information or Statement

For good consideration, the undersigned authorizes SMO and its assigns to use, publish or reprint in whole or part any basic information about my identity, practice, and participation in clinical research including any specific details of my clinical research that do not conflict with a previously contacted privacy agreement.

The two parties shall consult with each other and medicate any disputes which may arise about the contact. If all attempts fail the two parties can appeal to the organization of arbitration in judicial court of the state-S, India.

METTA CLINICAL RESEARCH

Authorized Signature: ..... Name: Dr.Rajendra Bohra Title: Dean Date: Hospital Name:**Mahatma Gandhi Mission (MGM) Medical College& Hospital**	Professor & Head Dept.of Pharmacology ..... Name: Dr.Deepak Bhosle Title: Professor & Head Dept.of Pharmacology Date: Hospital Name: **Mahatma Gandhi Mission (MGM) Medical College & Hospital**

DEAN
MGM'S MEDICAL COLLEGE
AURANGABAD

Professor & H.O.D.
Department of Pharmacology
MGM's Medical College
Aurangabad.

Metta Clinical Research Pvt. Ltd.

1) **Authorized Signature:**

METTA CLINICAL RESEARCH PVT. LTD.
H. NO. 3232, PLOT NO.42,
VASANT NAGAR, NAGPUR-27.
MAHARASHTRA INDIA

.....

Name: Dr Jayesh Dhawale

Title: Director of SMO

Date: 10 Feb 2021

SMO: **Metta Clinical Research Pvt. Ltd**

Address: **H.No 3232,42, Vasant nagar,Nagpur-MH,-440027**

METTA CLINICAL RESEARCH

2) Authorized Signature:

METTA CLINICAL RESEARCH PVT. LTD.
H. NO. 3232, PLOT NO.42,
VASANT NAGAR, NAGPUR-27.
MAHARASHTRA INDIA

10/Feb/2024

Name: Rajshri Dambhare

Title: Business Process Lead

Date:

SMO: **Metta Clinical Research Pvt. Ltd**

Address: **H.No 3232,42, Vasant nagar,Nagpur-MH,-440027**

Oxygen

Clinical Research and Service
Saiyankar Apartment, Sawangi Meghe,
Wardha-442004, Maharashtra, India
Contact No. 9284417019

Memorandum of Understanding

This Agreement is made on 27th April 2022, by and between **"Oxygen Clinical Research and Services"** having its Office at referred as a party- A **(here in after referred to as the "SMO")**

And

Mahatma Gandhi Mission (MGM) Medical College & Hospital, N-6, Cidco, Aurangabad, Maharashtra 430 003 referred as a party-B **(here in after referred to as the "Institution")**

The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfill conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promise and mutual covenants herein contained and for Other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties here to as follows

MGM Medical College& Hospital appoints Oxygen Clinical Research and Services As a site management organization on **Exclusive basis for period of 10 years w.e.f 27th Apr 2022 to 27th Apr 2032. (Will be reviewed and updated accordingly)**

Obligations of Oxygen Clinical Research and Services:

Oxygen Clinical Research and Services is a site management Organization based in Wardha, Maharashtra providing end to end clinical research services to the Hospitals and Offers a complete range of Clinical Research in all therapeutic areas. We expertise in site Management Activities, Project Management, Medical Writing, Monitoring, Safety Reporting, Regulatory services, Potential Site selection, Faster patient Recruitment, Quality compliance & Maintenance, and Clinical Research Expertise in India.

Oxygen Clinical Research and Services is desirous of working with Hospital for the purpose of conducting ICH-GCP complaint phase I-IV clinical trials for new drug & treatment.

Oxygen Clinical Research and Services Shall play vital role in getting clinical trials to the hospital /Hospital from the sponsors and CROs and execute them in Hospital.

Oxygen Clinical Research and Services will manage study Operations and study services as directed by study protocol for the duration of the clinical trial.

Oxygen Clinical Research and Services will appoint a Clinical Research Coordinators (CRC)/existing site coordinator who will be a point of contact with Sponsor & CRO and ensure smooth conduct of trial at the site.

Oxygen Clinical Research and Services appoint project manager (PM) who will be responsible to coordinate and over-see the progress and management of CRC activities & trial, ensure data quality, resolve screening, enrollment or general issue if any, follow up on post -monitoring action elements and study training as per needs and frequent discussion with investigator & sponsor / CRO on trial progress.

Oxygen Clinical Research and Services will appoint Quality check (QC Experts) who will be responsible to ensure adherence to the protocol, regulatory requirements record keeping and retention.

Study co-ordination, project management and quality management will be done by Oxygen Clinical Research and Services. Oxygen Clinical Research and Services personnel, CRC, PM, QC Experts will assist PI and the Intuitions in all trial related activities.

Oxygen Clinical Research and Services will bear all the administrative cost related to the various activities undertaken by PM, CRC or any other staff placed by Oxygen Clinical Research and Services which includes telecommunication, travel cost, training cost at various centers across India or abroad.

Oxygen Clinical Research and Services will be exclusively conducting/managing all trial at the Hospital during the tenure of this agreement. This agreement will last for 10 (ten) years and can be renewed further on mutual agreement.

Following activities will be carried out by appointed CRCs

1. Performing all the activities in strict adherence to the ICH-GCP guidelines, Schedule Y India GCP and Regulatory requirement
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4. Accurate and complete documentation of relevant EC documentation
5. Regulatory documents Collection
6. Patient Identification for assigned study form OPD or Hospital Database.
7. Maintenance and update of Trial Master File (TMF), site binders and relevant files
8. Preparation for site Monitoring Initiation Visit (SMV) and resolving all action items generated during Previous monitoring visits
9. Conduct Study according to International Conference of Harmonization (ICH) E6 and India Good Clinical Practice (GCP) regulation
10. Assisting Principal Investigator in administrating ICF and its procedures
11. Ensure protocol & applicable regulatory guidelines compliance and adherence
12. Patient's pre- screening enrollment and recruitment
13. Preparing source notes and CRF filling
14. Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates
15. Coordinate and schedule subject's regular follow up visits and procedures, maintain regular Telephonic contact with patients to preventing lost to follow- up and missed visits.

16. Managing Clinical Trial Materials (CTM) maintenance, Accountability, distribution and logistics at site
17. Coordinate all site-specific queries- medical, administrative, subject reimbursements and other study related activities.
18. Reporting and coordinating all AE/SAEs according to their timelines as per regulatory norms
19. Filling up and maintaining trial related logs likes source documentation, drug dispensing logs, subject log, visit logs, Investigational product log, temperature log, SAE and EC communication log
20. Documentation of protocol deviation as appropriate and communicate any impacting subject safety to the ethics committee
21. Coordinate with central and local lab for logistics and sample flow
22. Attend study related meeting as appropriate
23. Preparing sites for Monitoring / Auditing visits coordinate close out visit and Archival at site
24. Any other required activities during the trials.
25. Identification of potential database from different therapeutic area of PIs
26. Communication with Investigators/ Hospitals and conduct protocol specific feasibility
27. Other duties as requested by Oxygen Clinical Research and Services Management

B. Hospital permits

1. Hospital will give the space and required facilities to appointed CRC & Oxygen Clinical Research and Services in order to perform clinical trials activities under respected PI.
2. Hospital will allow Oxygen Clinical Research and Services and Sponsors of Clinical trials to access the facility to verify source documents.
3. Hospital will allow Oxygen Clinical Research and Services to bring Sponsors of clinical trials to meet with PI/SITE representatives at a mutually convenient time.
4. Hospital shall permit Oxygen Clinical Research and Services to exclusively manage all clinical trial commenced by Oxygen Clinical Research and Services

C. Term of Agreement

The term of this Agreement shall be for a period of 10 years commencing on the effective date 27th April 2022. However, this Agreement shall be reviewed annually by both parties if needed.

D. Relationship of the parties

1. Hospital and Oxygen Clinical Research and Services are independent parties. Both parties agree that their relationship is that of an independent contractor and not employer and employee.

2. Neither party shall have express or implied rights nor authority to assume or create any obligation or responsibility on behalf of or in the name of the other party by reason of this Agreement, except as provided in this Agreement.

E. GCP, ICH and CFR compliance

Hospital agrees to comply with International Conference of Harmonization & Good Clinical Practices (ICH-GCP) and all India regulations, CDSCO requirement and circulars there under.

F. Confidentiality

1. the parties here recognize and agree that due to the complex and competitive nature of the business, the confidential of information concerning both parties Is of critical importance. Either party shall not, either during or after the term of this Agreement, disclose to any third party any confidential information and all Information or information relative to the work or the business of either party without the written consent of either party Oxygen Clinical Research and Services agrees that it shall not during, or at any time after the termination of this Agreement, directly or indirectly disclose or use any information for any reason whatever, without the prior written consent of SITE.

2. Hospital shall not disclose to any third party any and information about new studies received from Oxygen Clinical Research and Services.

G. Indemnification

Hospital shall indemnify and hold harmless Oxygen Clinical Research and Services against any losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by SITE, its agents, directors or employees, Oxygen Clinical Research and Services shall indemnify and hold harmless hospital against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of act or commission by **Oxygen Clinical Research and Services**, its agents, directors, or employees. In no event will either party be required to indemnify or hold harmless the other's negligence or gross negligence.

H. Compensation and Agreement

1. The Hospital, principal Investigator, Oxygen Clinical Research and Services and Sponsor and/or CRO will enter into a quadripartite clinical trial agreement before/at the time of placement of each trial at the Hospital.
2. All feasibilities and payments shall be routed through Oxygen Clinical Research and Services and pricing while bidding for the trial shall be discussed mutually and final correspondence with the Sponsor/CRO also would be handled by Oxygen Clinical Research and Services for smooth and hassle-free finalization of Clinical Trial Agreements.
3. Getting payment from sponsor and giving to Hospital and /or Investigator is the responsibility of Oxygen Clinical Research and Services.
4. Oxygen Clinical Research and Services will be payee name for all trial related payment.

5. All payment shall be due and payable to the hospital on actual work i.e. number of subject randomized or visits completed.
6. The payment of remuneration shall be after deduction of all taxes under applicable laws.
7. All invoices will be requested from the hospital for study payment and all study related payment will be done to MGM Medical College & Hospital, in a period of 45 working days after receiving the payment from the sponsor/CRO.
8. The details of study budget sharing in INR are as follow:
    - **100 %** study payment will be paid to Oxygen Clinical Research and Services from Sponsor/ CRO for each study.
    - **65 %** study payment will be paid to Hospital /Principal Investigator from Oxygen Clinical Research and Services.
    - **35 %** study payment fees will be paid to Oxygen Clinical Research and Services.
    - **100%** CRC fees will be paid to Oxygen Clinical Research and Services from sponsor /CRO.
    - Subject Travel reimbursement amount will be paid to Hospital from Oxygen Clinical Research and Services.
    - Additional **30%** Institutional overhead will be paid from Oxygen Clinical Research and Services received from sponsor /CRO.
    - Oxygen Clinical Research and Services will pay Lab Cost, subject Hospitalization, SAE Medical Management charges at actual basis to Hospital /Principal Investigator received from sponsor /CRO.

(**Note:** Hospital/Principal Investigator should provide dedicated working printer, stationary, Electricity, Working place, Internet connection facility to our study team.)

I. Termination of Agreement

1. This Agreement shall be terminated by mutual agreement by giving sixty (60) days prior written notice by either party after the completion of any ongoing trials.

J. Permission to use personal Information or Statement

For good consideration, the undersigned authorizes SMO and its assigns to use, publish or reprint in whole or part any basic information about my identity, practice, and participation in clinical research including any specific details of my clinical research that do not conflict with a previously contacted privacy agreement.

The two parties shall consult with each other and medicate any disputes which may arise about the contact. If all attempts fail the two parties can appeal to the organization of arbitration in judicial court of the state of Maharashtra India.

Authorized Signature: ..... Name: Dr.Rajendra Bohra Title: Dean Date: Hospital Name: **Mahatma Gandhi Mission (MGM) Medical College& Hospital** **Stamp:** DEAN MGM'S MEDICAL COLLEGE AURANGABAD	Professor & Head Dept.of Pharmacology ..... Name: Dr.Deepak Bhosle Title: Professor & Head Dept.of Pharmacology Date: 10.05.2022 Hospital Name: **Mahatma Gandhi Mission (MGM) Medical College & Hospital** **Stamp:** Professor & H.O.D. Department of Pharmacology MGM's Medical College Aurangabad.

Oxygen Clinical Research and Services **1) Authorized Signature:** ..... Name: Miss. Gauri Sadhankar Title: Project Manager Date: 27 Apr 2022 Address: Saiyankar Apartment, Sawangi Meghe Wardha- 442004, Maharashtra, INDIA **Stamp:** OXYGEN CLINICAL RESEARCH & SERVICES Oxygen	**Oxygen Clinical Research and Services** **2) Authorized Signature:** ..... Name: Mr. Govind Pawar Title: Director Date: 27 Apr 2022 Address: Saiyankar Apartment, Sawangi Meghe Wardha- 442004, Maharashtra, INDIA **Stamp:** OXYGEN CLINICAL RESEARCH & SERVICES Oxygen

తెలంగాణ తెలంగాన TELANGANA

X 938377

Date 07/01/20 Serial No. 80 Rs.....

Sri/Smt NMC Services
S/o D/o W/o F/o Praveen Kumar
For whom.....

Qamar Jahan
License No.16-02-079 of 2012
SV renewal License 16-02-060 of 2018
H.No.1-1-1/18/1, Ranga Reddy Complex
Beside BSNL office, RTC X ROADS
Hyderabad- TS. 5000 20. Ph.7075692061.

Memorandum of Understanding

This Agreement is made on 01st Jan 2020, by and between **"NMC Services (Narlagiri Mogili Chandramma)"** having its Office at **KAKATIYA hospitals, # 12 -52, road no. 2, P&T colony, Medipally, Hyderabad -500039, India** referred as a party- A **(here in after referred to as the"NMC")**

And

Mahatma Gandhi Mission (MGM) Medical College & Hospital, N-6, Cidco, Aurangabad, Maharashtra 431 003 referred as a party-B **(here in after referred to as the "Institution")**

The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfill conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promise and mutual covenants herein contained and for Other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties here to as follows

MGM Medical College& Hospital appoints NMC Servicesas a site management organization on **Exclusive basis for period of 10 years w.e.f 1st Jan 2020 to 31st Dec 2029. (will be reviewed and updated accordingly)**

Obligations of NMC Services:

NMC Services(NMC) is a site management Organization based in Hyderabad providing end to end clinical research services to the Hospitals and Offers a complete range of Clinical Research in all therapeutic areas. We expertise in site Management Activities, Project Management, Medical Writing, Monitoring, Safety Reporting, Regulatory services, Potential Site selection, Faster patient Recruitment, Quality compliance & Maintenance, and Clinical Research Expertisein India.

NMC Servicesis desirous of working with Hospital for the purpose of conducting ICH-GCP complaint phase I-IV clinical trials for new drug & treatment.

NMC Servicesshall play vital role in getting clinical trials to the hospital /Hospital from the sponsors and CROs and execute them in Hospital.

NMC Serviceswill manage study Operations and study services as directed by study protocol for the duration of the clinical trial.

NMC Serviceswill appoint a Clinical Research Coordinators (CRC)/existing site coordinator who will be a pointof contact with Sponsor & CRO and ensure smooth conduct of trial at the site.

NMC Serviceswill appoint project manager (PM) who will be responsible to coordinate and over-see the progress and management of CRC activities & trial, ensure data quality, resolve screening, enrollment or general issue if any, follow up on post -monitoring action elements and study training as per needs and frequent discussion with investigator & sponsor / CRO on trial progress.

NMC Serviceswill appoint Quality check (QC Experts) who will be responsible to ensure adherence to the protocol, regulatory requirements record keeping and retention.

Study co-ordination, project management and qualitymanagement will be done by NMC services. NMC personnel, CRC, PM, QC Experts will assist PI and the Intuitions in all trial related activities.

NMC Serviceswill bear all the administrative cost related to the various activities undertaken by PM, CRC or any other staff placed by NMC Serviceswhich includes telecommunication, travel cost, training cost at various centers across India or abroad.

NMC Serviceswill be exclusively conducting/managing all trial at the Hospital during the tenure of this agreement. This agreement will last for 10 (ten) years and can be renewed further on mutual agreement.

Following activities will be carried out by appointed CRCs

1. Performing all the activities in strict adherence to the ICH-GCP guidelines, Schedule Y India GCP and Regulatory requirement
2. Preparation for site selection visit and Site Initiation Visit (SIV)
3. Communication & Follow up with IRB/IEC Submission and Approval
4. Accurate and complete documentation of relevant EC documentation
5. Regulatory documents Collection
6. Patient Identification for assigned study form OPD or Hospital Database.
7. Maintenance and update of Trial Master File (TMF), site binders and relevant files
8. Preparation for site Monitoring Initiation Visit (SMV) and resolving all action items generated during Previous monitoring visits
9. Conduct Study according to International Conference of Harmonization (ICH) E6 and India Good Clinical Practice(GCP) regulation

10. Assisting Principal Investigator in administrating ICF and its procedures
11. Ensure protocol & applicable regulatory guidelines compliance and adherence
12. Patients pre- screening enrollment and recruitment
13. Preparing source notes and CRF filling
14. Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates
15. Coordinate and schedule subject's regular follow up visits and procedures, maintain regular telephoniccontact with patients to preventing lost to follow- up and missed visits.
16. Managing Clinical Trial Materials (CTM) maintenance, Accountability, distribution and logistics at site
17. Coordinate all site specific queries- medical, administrative, subject reimbursements and other study related activities.
18. Reporting and coordinating all AE/SAEs according to their timelines as per regulatory norms
19. Filling up and maintaining trial related logs likes source documentation, drug dispensing logs, subject log, visit logs, Investigational product log, temperature log, SAE and EC communication log
20. Documentation of protocol deviation as appropriate and communicate any impacting subject safety to the ethics committee
21. Coordinate with central and local lab for logistics and sample flow
22. Attend study related meeting as appropriate
23. Preparing sites for Monitoring / Auditing visits coordinate close out visit and Archival at site
24. Any other required activities during the trials.
25. Identification of potential database from different therapeutic area of PIs
26. Communication with Investigators/ Hospitals and conduct protocol specific feasibility
27. Other duties as requested by NMC ServicesManagement

B. Hospital permits

1. Hospital will give the space and required facilities to appointed CRC &NMC in order to performclinical trials activities under respected PI.
2. Hospital will allow NMC and Sponsors of Clinical trials to access the facility to verify source documents.
3. Hospital will allow NMC to bring Sponsors of clinical trials to meet with PI/SITE representatives at a mutually convenient time.
4. Hospital shall permit NMC to exclusively manage all clinical trial commenced by NMC Services

C. Term of Agreement

The term of this Agreement shall be for a period of 10 years commencing on the effective date 01st Jan 2020. However, this Agreement shall be reviewed annually by both parties if needed.

D. Relationship of the parties

1. Hospital and NMC are independent parties. Both parties agree that their relationship is that of an Independent contractor and not employer and employee.
2. Neither party shall have express or implied rights nor authority to assume or create any obligation or responsibility on behalf of or in the name of the other party by reason of this Agreement,except as provided in this Agreement.

E. GCP, ICH and CFR compliance

Hospital agrees to comply with International Conference of Harmonization & Good Clinical Practices (ICH-GCP) and all India regulations, CDSCO requirement and circulars there under.

F. Confidentiality

1. the parties here recognize and agree that due to the complex and competitive nature of the business, the confidential of information concerning both parties Is of critical importance. Either partyshall not, either during or after the term of this Agreement, disclose to any third party any confidential information and all Information or information relative to the work or the business of either party without the written consent of either party NMC agrees that it shall not during, or at any time after the termination of this Agreement, directly or indirectly disclose or use any information for any reason whatever, without the prior written consent of SITE.

2. Hospital shall not disclose to any third party any and information about new studies received from NMC.

G. Indemnification

Hospital shall indemnify and hold harmless NMC against any losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by SITE, its agents, directors or employees, NMC shall indemnify and hold harmless hospital against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of act or commission by NMC, its agents, directors, or employees. In no event will either party be required to indemnify or hold harmless the other's negligence or gross negligence.

H. Compensation and Agreement

1. The Hospital, principle Investigator, NMC Servicesand Sponsor and/or CRO will enter into a quadripartite clinical trial agreement before/at the time of placement of each trial at the Hospital.
2. All feasibilities and payments shall be routed through NMC and pricing while bidding for the trial shall be discussed mutually and final correspondence with the Sponsor/CRO also would be handled by NMC Servicesfor smooth and hassle-free finalization of Clinical Trial Agreements.
3. Getting payment from sponsor and giving to Hospital and /or Investigator is the responsibility of NMC Services.
4. NMC Serviceswill be payee name for all trial related payment.
5. All payment shall be due and payable to the hospital on actual work i.e. number of subject randomized or visits completed.
6. The payment of remuneration shall be after deduction of all taxes under applicable laws.
7. All invoices will be requested from the hospital for study payment and all study related payment will be done to MGM Medical College & Hospital, in a period of 15 working days after receiving the payment from the sponsor/CRO.
8. The details of study budget sharing in INR is as follow:
    - **100%** study payment will be paid to NMC from Sponsor/ CRO for each study.
    - **65%** study payment will be paid to Hospital /Principal Investigator from NMC.
    - **35%** study payment fees will be paid to NMC.
    - **100%** CRC fees will be paid to NMCfrom sponsor /CRO.
    - Additional **20%** Institutional overhead will be paid from NMC received from sponsor /CRO.
    - NMC will pay Lab Cost, subject Hospitalization, SAE Medical Management charges at actual basis to Hospital /Principal Investigator received from sponsor /CRO.

(**Note**: Hospital/Principal Investigator should provide dedicated working printer, stationary, Electricity, Working place, Internet connection facility to our study team.)

I. Termination of Agreement

1. This Agreement shall be terminated by mutual agreement by giving sixty (60) days prior written notice by either party after the completion of any ongoing trials.

J. Permission to use personal Information or Statement

For good consideration, the undersigned authorizes SMO and its assigns to use, publish or reprint in whole or part any basic information about my identity, practice, and participation in clinical research including any specific details of my clinical research that do not conflict with a previously contacted privacy agreement.

The two parties shall consult with each other and medicate any disputes which may arise about the contact. If all attempts fail the two parties can appeal to the organization of arbitration in judicial court of the state of Telangana/ state of Maharashtra, India.

Authorized Signature:	Witness Signature:
.....	.....
Name: DR. RAJENDRA - BOHRA	Witness Name: Dr Deepak Bhosle
Title: DEAN	Title: Prof & HOD
Date: 21/01/2020	Date: 20/01/2020.
Hospital Name:**Mahatma Gandhi Mission (MGM) Medical College& Hospital**	Hospital Name: **Mahatma Gandhi Mission (MGM) Medical College & Hospital**

Dean
MGM Medical College,
Aurangabad.

Professor & H.O.D.
Department of Pharmacology
MGM's Medical College
Aurangabad.

NMC Services, Hyderabad

1) **Authorized Signature:**

.....

Name: R. Praveen Kumar

Title: **Founder and Director**

Date: 10 Jan 2020

SMO:**NMC Services**

Address: **Kakatiya hospitals,#12 -52, road no. 2, P&T colony, Medipally , Hyderabad - 500039**

NMC SERVICES ★ HYDERABAD-500 039 ★

2) **Authorized Signature:**

.....

Name: N. Gouthami

Title: **Associate Director**

Date: 10 Jan 2020

SMO:**NMC Services**

Address: **Kakatiya hospitals,#12 -52, road no. 2, P&T colony, Medipally , Hyderabad - 500039**

NMC SERVICES ★ HYDERABAD-500 039 ★

QRED CLINICAL RESEARCH SERVICES

Memorandum of Understanding

This Agreement is made on 01st Dec 2019, by and between **"Q RED Clinical Research Services (Q RED)"**a company registered under company act 1956 having its office at **134, Chitanvis Nagar, Umred Road, Nagpur-440024, Maharashtra, India** referred as a party- A **(here in after referred to as the "QRED")**

And

MAHATMA GANDHI MISSION's, MEDICAL COLLEGE & HOSPITAL (MGM HOSPITAL), N-6 CIDCO, Aurangabad-431003,Maharashtra, India referred as a party -B**(here in after referred to as the "Institution")**
The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfill conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties hereto as follows

MGM College & Hospital Aurangabad appoints **Q RED Clinical Research Services** as a Site management organization on **Exclusive basis for period of 10 years w.e.f 01st Dec 2019 to 31st Dec 2029.**

Obligations of Q RED Clinical Research Services:
Q RED Clinical Research Services (Q RED) is a Clinical Research Organizations and Site Management Organization based in Nagpur providing end to end clinical research services to the Sponsors, Pharmaceutical and Biopharmaceutical industry, Institutions and Offers a complete range of Clinical Research in all therapeutic areas. We expertise in Site Management Activities, Project Management, Medical Writing, Monitoring, Safety Reporting, Regulatory services, Potential Site Selection, Faster Patient Recruitment, Quality compliance& Maintenance, and Clinical Research Expertise in India.

Q RED Clinical Research Services is desirous of working with Institution for the purpose of conducting ICH-GCP complaint Phase I-IV clinical trials for new drug & treatment.

Q RED Clinical Research Services shall play vital role in getting clinical trials to the hospital / institution from the sponsors and CROs and execute them in institution.

Q RED Clinical Research Services will manage Study Operations and Study services as directed by Study protocol for the duration of the clinical trial.

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+91 9665094458 dadhe.pratik@gmail.com

Q RED Clinical Research Services will appoint a Clinical Research Coordinator (CRC) who will be a point of contact with Sponsor & CRO and ensure smooth conduct of trial at the site.

Q RED Clinical Research Services will appoint Project Manager (PM) who will be responsible to co-ordinate and over-see the progress and management of CRC activities & trial, ensure data quality, resolve screening, enrollment or general issue if any, follow up on post –monitoring action elements and study training as per needs and frequent discussion with investigator & Sponsor/CRO on trial progress.

Q RED Clinical Research Services will appoint Quality Check Experts (QC Experts) who will be responsible to ensure adherence to the protocol, regulatory requirements record keeping and retention. Study co-ordination, project management and quality management will be done by Q RED clinical research services. Q RED personnel, CRC, PM, QC Experts will assist PI and the Intuitions in all trial related activities.

Q RED Clinical Research Services will bear all the administrative cost related to the various activities undertaken by PM, CRC or any other staff placed by Q RED Clinical research services which includes telecommunication, travel cost, training cost at various centers across India or abroad.

Q RED Clinical Research Services will be conducting /managing all trial (Trials come from Q RED) at the Institution during the tenure of this agreement. This agreement will last for 10 (Ten) year and can be renewed further on mutual agreement.

Following activities will be carried out by appointed CRCs

1. Performing all the activities in strict adherence to the ICH-GCP guidelines, Schedule Y Indian GCP and regulatory requirement.
2. Preparation for Site selection visit and Site Initiation Visit (SIV).
3. Communication & Follow up with IEC Submission and Approval.
4. Accurate and complete documentation of relevant EC documentation.
5. Regulatory Documents Collection.
6. Patient Identification for assigned study from OPD or Hospital Database.
7. Maintenance and update of Trial Master File (TMF), site binders and relevant files.
8. Preparation for Site Monitoring Initiation Visit (SMV) and resolving all action items generated during previous.
9. Conduct study according to International Conference of Harmonization (ICH) E6 and Indian Good Clinical Practice (GCP) regulation.
10. Assisting Principal Investigator in administrating ICF and its procedures.
11. Ensure protocol & applicable regulatory guidelines compliance and adherence.
12. Patients pre-screening, screening enrollment and recruitment.
13. Preparing source notes and CRF filling.

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14. Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates.
15. Coordinate and schedule subject's regular follow up visits and procedures, maintain regular telephonic contact with patients to preventing lost to follow-up and missed visits.
16. Managing clinical trial materials (CTM) maintenance, Accountability, distribution and logistics at site.
17. Coordinate all site specific queries-medical, administrative, subject reimbursements and other.
18. Reporting and coordinating all AE/SAEs according to their timelines as per regulatory norms.
19. Filling up and maintaining trial related logs likes source documentation, drug dispensing logs, subject log, visit logs, Investigational product log, temperature log, logistics log, SAE and EC communication log.
20. Documentation of protocol deviation as appropriate and communicate any impacting subject safety to the ethics committee.
21. Coordinate with central and local lab for logistics and sample flow.
22. Attend study related meeting as appropriate.
23. Preparing sites for Monitoring / Auditing visits coordinate close out visit and Archival at site.
24. Any other required activities during the trials.
25. Identification of potential database from different therapeutic area of PIs.
26. Communication with Investigators/ Hospitals and conduct protocol specific feasibility.
27. Other duties as requested by Q RED Clinical Research Services Management.

B. Institution Permits

1. Institution will give the space and required facilities to appointed CRC & Q RED in order to perform clinical trials activities under respected PI.
2. Institution will allow Q RED and Sponsors of clinical trials to access the facility to verify source documents.
3. Institution will allow Q RED to bring Sponsors of clinical trials to meet with PI/SITE representatives at a mutually convenient time.
4. Institution shall permit Q RED to exclusively manage all clinical trials commenced by Q RED Clinical Research Services.

C. Term of Agreement

The term of this Agreement shall be for a period of 10 year commencing on the effective date 01st Dec 2019. However, this Agreement shall be reviewed annually by both parties.

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D. Relationship of the Parties

1. Hospital/ Institutions and Q RED are independent parties. Both parties agree that their relationship is that of an independent contractor and not employer and employee.
2. Neither party shall have express or implied rights nor authority to assume or create any obligation or responsibility on behalf of or in the name of the other party by reason of this Agreement, except as provided in this Agreement.

E. GCP, ICH and CFR Compliance

Institution/ Hospital agrees to comply with all requirements of Good Clinical Practices (GCP), International Conference of Harmonization (ICH) and Code of Federal Regulations (CFR) and any and all future regulations, requirements and writing promulgated there under.

F. Confidentiality

1. The parties hereto recognize and agree that due to the complex and competitive nature of the business, the confidentiality of information concerning both parties is of critical importance. Either party shall not, either during or after the term of this Agreement, disclose to any third party any confidential information and all information or information relative to the work or the business of either party without the written consent of either party. Q RED agrees that it shall not during, or at any time after the termination of this Agreement, directly or indirectly disclose or use any information for any reason whatsoever, without the prior written consent of SITE.
2. Institution/ Hospital shall not disclose to any third party any and all information about new studies received from Q RED.

G. Indemnification

Institution/ Hospital shall indemnify and hold harmless Q RED against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by SITE, its agents, directors or employees. Q RED shall indemnify and hold harmless hospital against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by Q RED, its agents, directors, or employees. In no event will either party be required to indemnify or hold harmless the other for the other's negligence or gross negligence.

H. Compensation and Agreement

1. The Institution/ Hospital, Principle Investigator, Q RED Clinical Research Services and Sponsor and/or CRO will enter into a quadripartite clinical trial agreement before/at the time of placement of each trial at the Institution.
2. All feasibilities and payments shall be routed through Q RED and pricing while bidding for the trial while bidding for the trials shall be discussed mutually and final correspondence

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with the Sponsor/CRO also would be handled by Q RED Clinical Research Services for Smooth and hassle-free finalization of Clinical Trial Agreements.

3. Getting payment from sponsor and giving to Institution and /or Investigator is the responsibility of Q RED Clinical Research Services.
4. Q RED Clinical Research Services will be payee for all trial related payment for each trial.
5. All payment shall be due and payable to the Institution on the basis of funds received from the sponsor/CRO on actual work i.e. number of subject randomized or visits completed.
6. The payment of remuneration shall be after deduction of all taxes under applicable laws.
7. All invoices will be requested from the hospital for study payment and all Study related payments will be done to MGM Medical College & Hospital Aurangabad, in a period of 15 working days after receiving the payment from the sponsor/CRO.
8. The details of study budget sharing in INR is as follows:
    - **100%** Study Payment will be paid to Q RED from Sponsor/CRO for each study
    - **65%** Study Payment will be paid to Hospital/Principal Investigator from Q RED:
    - **35%** Study Payment fees will be paid to Q RED
    - **100%** CRC fees will be paid to Q RED from Sponsor/CRO.
    - Additional **20%** Institute Overhead will be paid from Q RED
    - Q RED will pay lab cost, Subject Hospitalization, SAE Medical Management charges at actual basis to Hospital/ Principal Investigator.

(Note: Hospital/ Principal Investigator should provide dedicated working printer, stationary, electricity, working place, internet connection facility to our study team)

I. Termination of Agreement

1. This Agreement shall be terminated by mutual agreement by giving Sixty (60) days prior written notice by either party after the completion of any ongoing trials.

J. Permission to use Personal Information or Statement

For good consideration, the undersigned authorizes SMO and it's assigns to use, publish or reprint in whole or part any basic information about my identity, practice, and participation in clinical research including any specific details of my clinical research that do not conflict with a previously contracted privacy agreement.

The two parties shall consult with each other and mediate any disputes which may arise about the contract. If all attempts fail, the two parties can appeal to the organization of arbitration in judicial court of Maharashtra, India.

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Mahatma Gandhi Mission's Medical College and Hospital Aurangabad

Authorized Signature:	Witness Signature:
Name:- Dr Rajendra Bohra	Name:- DR. DEEPAK BHOSLE
Title:- Dean	Title:- PROF. & HOD
Date:- 23/12/19	Date:- 23/12/2019
Hopsital Name:- MGM Medical College & Hospital Aurangabad.	Hopsital Name:- MGM EDICAL COLLEGE & HOSPITAL, AURANGABAD

DEAN MGM'S MEDICAL COLLEGE AURANGABAD

Q RED Clinical Research Services

1) Signature: _____

Name:- **Mr. Pratik V. Dadhe**
Title:- Founder & Director,
Date:- 01st Dec 2019
SMO:- Q RED Clinical Research Services
Address:- 134, Chitanvis Nagar, Umred Road, Nagpur.

2) Signature: _____

Name:- Manisha Agade.
Title:- Project Manager
Date:- 01st Dec 2019
SMO:- Q RED Clinical Research Services
Address:- 134, Chitanvis Nagar, Umred Road, Nagpur

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DOCLIN
Clinical Research Services
Site Management Organisation

445 Maruti Galli, Main Road, Hangarge, Mandoli Belagavi, Karnataka 590 008.
Cell : 9591358733 E-mail : maruti.patil171@gmail.com

Memorandum of Understanding

This Agreement is made on 01st Jun 2020, by and between **"Doclin Clinical Research Services"** a company registered under company act 1956 having its office at **445 Maruti Galli, Main Road, Hangarge, Mandoli Belagavi -590008 Karnataka India** referred as a party- A**(Here in after referred to as Doclin)**

And

MAHATMA GANDHI MISSION's, MEDICAL COLLEGE & HOSPITAL (MGM HOSPITAL), N-6 CIDCO, Aurangabad-431003,Maharashtra, India referred as a party -B**(here in after referred to as the "Institution")**
The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfill conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties hereto as follows

MGM College & Hospital Aurangabad appoints **Doclin Clinical Research Services** as a Site management organization on **Exclusive basisfor period of 10 years w.e.f 01 Jun 2020 to 31 May 2030.**

Obligations of Doclin Clinical Research Services:
Doclin Clinical Research Servicesis a Clinical Research Organizations and Site Management Organization based in Belagavi Karnataka providing end to end clinical research services to the Sponsors, Pharmaceutical and Biopharmaceutical industry, Institutions and Offers a complete range of Clinical Research in all therapeutic areas. We expertise in Site Management Activities,Project Management, Medical Writing, Monitoring, Safety Reporting, Regulatory services, Potential Site Selection, Faster Patient Recruitment, Quality compliance& Maintenance, and Clinical Research Expertise in India.

Doclin Clinical Research Services is desirous of working with Institution for the purpose of conducting ICH-GCP complaint Phase I-IV clinical trials for new drug & treatment.

Doclin Clinical Research Services shall play vital role in getting clinical trials to the hospital / institution from the sponsors and CROs and execute them in institution.
Doclin Clinical Research Services will manage Study Operations and Study services as directed by Study protocol for the duration of the clinical trial.

Doclin Clinical Research Services will appoint a Clinical Research Coordinator(CRC)who will be a point of contact with Sponsor & CRO and ensure smooth conduct of trial at the site.

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Cell : 9591358733 E-mail : maruti.patil171@gmail.com

Doclin Clinical Research Services will appoint Project Manager (PM) who will be responsible to co-ordinate and over-see the progress and management of CRC activities & trial, ensure data quality, resolve screening, enrollment or general issue if any, follow up on post –monitoring action elements and study training as per needs and frequent discussion with investigator & Sponsor/CRO on trial progress.

Doclin Clinical Research Services will appoint Quality Check Experts (QC Experts) who will be responsible to ensure adherence to the protocol, regulatory requirements record keeping and retention. Study co-ordination, project management and quality management will be done by Doclin clinical research services. Doclin personnel, CRC, PM, QC Experts will assist PI and the Intuitions in all trial related activities.

Doclin Clinical Research Services will bear all the administrative cost related to the various activities undertaken by PM, CRC or any other staff placed by Doclin Clinical research services which includes telecommunication, travel cost, training cost at various centers across India or abroad.

Doclin Clinical Research Services will be conducting /managing all trial(Trials come from Doclin) at the Institution during the tenure of this agreement. This agreement will last for 10 (Ten) year and can be renewed further on mutual agreement.

Following activities will be carried outby appointed CRCs

1. Performing all the activities in strict adherence to the ICH-GCP guidelines, Schedule Y Indian GCP and regulatory requirement.
2. Preparation for Site selection visit and Site Initiation Visit (SIV).
3. Communication & Follow up with IEC Submission and Approval.
4. Accurate and complete documentation of relevant EC documentation.
5. Regulatory Documents Collection.
6. Patient Identification for assigned study from OPD or Hospital Database.
7. Maintenance and update of Trial Master File (TMF), sitebinders and relevant files.
8. Preparation for Site Monitoring Initiation Visit (SMV) and resolving all action items generated during previous.
9. Conduct study according to International Conference of Harmonization (ICH) E6 and Indian Good Clinical Practice (GCP) regulation.
10. Assisting Principal Investigator in administrating ICF and its procedures.
11. Ensure protocol &applicable regulatory guidelines compliance and adherence.
12. Patients pre-screening, screening enrollment and recruitment.
13. Preparing source notes and CRF filling.
14. Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates.
15. Coordinate and schedule subject's regular follow up visits and procedures, maintain regular telephonic contact with patients to preventing lost to follow-up and missed visits.

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16. Managing clinical trial materials(CTM) maintenance, Accountability, distribution and logistics at site.
17. Coordinate all site specific queries-medical, administrative, subject reimbursements and other.
18. Reporting and coordinating all AE/SAEs according to their timelines as per regulatory norms.
19. Filling up and maintaining trial related logs likes source documentation, drug dispensing logs, subject log, visit logs, Investigational product log, temperature log, logistics log, SAE and EC communication log.
20. Documentation of protocol deviation as appropriate and communicate any impacting subject safety to the ethics committee.
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24. Any other required activities during the trials.
25. Identification of potential database from different therapeutic area of PIs.
26. Communication with Investigators/ Hospitals and conduct protocol specific feasibility.
27. Other duties as requested by Doclin Clinical Research Services Management.

B. InstitutionPermits

1. Institution will give the space and required facilities to appointed CRC & Doclin in order to perform clinical trials activities under respected PI.
2. Institution will allow Doclin and Sponsors of clinical trials to access the facility to verify source documents.
3. Institution will allow Doclin to bring Sponsors of clinical trials to meet with PI/SITE representatives at a mutually convenient time.
4. Institutionshall permit Doclin to exclusively manage all clinical trials commenced by Doclin Clinical Research Services.

C. Term of Agreement

The term of this Agreement shall be for a period of 10 year commencing on the effective date 01st Jun 2020. However, this Agreement shall be reviewed annually by both parties.

D. Relationship of the Parties

1. Hospital/ Institutions and Doclin are independent parties. Both parties agree that their relationship is that of an independent contractor and not employer and employee.
2. Neither party shall have express or implied rights nor authority to assume or create any obligation or responsibility on behalf of or in the name of the other party by reason of this Agreement, except as provided in this Agreement.

E. GCP, ICH and CFR Compliance

445 Maruti Galli, Main Road, Hangarge, Mandoli Belagavi, Karnataka 590 008.
Cell : 9591358733 E-mail : maruti.patil171@gmail.com

Institution/ Hospitalagrees to comply with all requirements of Good Clinical Practices (GCP), International Conference of Harmonization (ICH) and Code of Federal Regulations (CFR) and any and all future regulations, requirements and writing promulgated there under.

F. Confidentiality

1. The parties hereto recognize and agree that due to the complex and competitive nature of the business, the confidentiality of information concerning both parties is of critical importance. Either party shall not, either during or after the term of this Agreement, disclose to any third party any confidential information and all information or information relative to the work or the business of either party without the written consent of either party. Doclin agrees that it shall not during, or at any time after the termination of this Agreement, directly or indirectly disclose or use any information for any reason whatsoever, without the prior written consent of SITE.
2. Institution/ Hospital shall not disclose to any third party any and all information about new studies received from Doclin.

G. Indemnification

Institution/ Hospital shall indemnify and hold harmless Doclin against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by SITE, its agents, directors or employees. Doclin shall indemnify and hold harmless hospital against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by Doclin, its agents, directors, or employees. In no event will either party be required to indemnify or hold harmless the other for the other's negligence or gross negligence.

H. Compensation and Agreement

1. The Institution/ Hospital, Principle Investigator, Doclin Clinical Research Services and Sponsor and/or CRO will enter into a quadripartite clinical trial agreement before/at the time of placement of each trial at the Institution.
2. All feasibilities and payments shall be routed through Doclin and pricing while bidding for the trial while bidding for the trials shall be discussed mutually and final correspondence with the Sponsor/CRO also would be handled by Doclin Clinical Research Services for Smooth and hassle-free finalization of Clinical Trial Agreements.
3. Getting payment from sponsor and giving to Institution and /or Investigator is the responsibility of Doclin Clinical Research Services.
4. Doclin Clinical Research Services will be payee for all trial related payment for each trial.
5. All payment shall be due and payable to the Institution on the basis of funds received from the sponsor/CRO on actual work i.e. number of subject randomized or visits completed.
6. The payment of remuneration shall be after deduction of all taxes under applicable laws.
7. All invoices will be requested from the hospital for study payment and all Study related payments will be done to MGM Medical College &Hospital Aurangabad, in a period of 15 working days after receiving the payment from the sponsor/CRO.

445 Maruti Galli, Main Road, Hangarge, Mandoli Belagavi, Karnataka 590 008.
Cell : 9591358733 E-mail : maruti.patil171@gmail.com

8. The details of study budget sharing in INR is as follows:
    - **100%** Study Payment will be paid to Doclin from Sponsor/CRO for each study
    - **65%** Study Payment will be paid to Hospital/Principal Investigator from Doclin:
    - **35%** Study Payment fees will be paid to Doclin
    - **100%** CRC fees will be paid to Doclin from Sponsor/CRO.
    - Additional **20%**Institute Overhead will be paid from Doclin
    - Doclin will pay lab cost, Subject Hospitalization, SAE Medical Management charges at actual basis to Hospital/ Principal Investigator.

(Note: Hospital/ Principal Investigator should provide dedicated working printer, stationary, electricity, working place, internet connection facility to our study team)

I. Termination of Agreement

1. This Agreement shall be terminated by mutual agreement by giving Sixty (60) days prior written notice by either party after the completion of any ongoing trials.

J. Permission to use Personal Information or Statement

For good consideration, the undersigned authorizes SMO and it's assigns to use, publish or reprint in whole or part any basic information about my identity, practice, and participation in clinical research including any specific details of my clinical research that do not conflict with a previously contracted privacy agreement.

The two parties shall consult with each other and mediate any disputes which may arise about the contract. If all attempts fail, the two parties can appeal to the organization of arbitration in judicial court of Maharashtra, India.

445 Maruti Galli, Main Road, Hangarge, Mandoli Belagavi, Karnataka 590 008
Cell : 9591358733 E-mail : maruti.patil171@gmail.com

Mahatma Gandhi Mission's Medical College and Hospital Aurangabad

Authorized Signature: _____ Name:- Title:- Date:- HopsitalName:-	WitnessSignature: _____ Name:- Title:- Date:- HopsitalName:-

DoclinClinical Research Services

1) Signature: _____

Name:-**Mr. Maruti Patil**
Title:- Founder & Director,
Date:-10 Jul 2020
SMO:-Doclin Clinical Research Services
Address:-445, Maruti Galli, Main Road Hangarge, Mandoli Belagavi-590008,Karnataka.

2) Signature: _____

Name:-**Dr Prasad Jadhav**
Date:-10 Jul 2020
SMO:-Doclin Clinical Research Services
Address:-445, Maruti Galli, Main Road Hangarge, Mandoli Belagavi-590008,Karnataka

SKYLINE CRS
INDIA PVT LTD
GST No. 27AVIPM3618H1ZG
Website: www.skylinecrsindia.com
E-mail: info@skylinecrsindia.com

This Agreement is made on 23st Dec 2021, by and between **"Skyline CRS India Pvt. Ltd"** having its Office at referred as a party- A **(here in after referred to as the "SMO")**

And

Mahatma Gandhi Mission (MGM) Medical College & Hospital, N-6, CIDCO, Aurangabad, Maharashtra 431003 **(here in after referred to as the "Institution")**

The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfill conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promise and mutual covenants herein contained and for Other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties here to as follows

Mahatma Gandhi Mission (MGM) Medical College & Hospital appoints **Skyline CRS India Pvt. Ltd** Services. As a site management organization on **Exclusive basis for period of 10 years w.e.f 23st Dec 2021 to 23st Dec 2031. (Will be reviewed and updated accordingly)**

Obligations of Skyline Clinical Research Pvt. Ltd Services:

Skyline CRS India Pvt. Ltd is a site management Organization based in Pune providing end to end clinical research services to the Hospitals and Offers a complete range of Clinical Research in all therapeutic areas. We expertise in site Management Activities, Project Management, Medical Writing, Monitoring, Safety Reporting, Regulatory services, Potential Site selection, Faster patient Recruitment, Quality compliance & Maintenance, and Clinical Research Expertise in India.

Skyline CRS India Pvt. Ltd Services is desirous of working with Hospital for the purpose of conducting ICH-GCP complaint phase I-IV clinical trials for new drug & treatment.

Skyline CRS India Pvt. Ltd Services shall play vital role in getting clinical trials to the hospital /Hospital from the sponsors and CROs and execute them in Hospital.

Skyline CRS India Pvt. Ltd Services will manage study Operations and study services as directed by study protocol for the duration of the clinical trial.

Skyline CRS India Pvt. Ltd Services will appoint a Clinical Research Coordinators (CRC)/existing site coordinator who will be a point of contact with Sponsor & CRO and ensure smooth conduct of trial at the site.

Skyline CRS India Pvt. Ltd will appoint project manager (PM) who will be responsible to coordinate and over-see the progress and management of CRC activities & trial, ensure data quality, resolve screening, enrollment or general issue if any, follow up on post -monitoring action elements and study training as per needs and frequent discussion with investigator & sponsor / CRO on trial progress.

Skyline CRS India Pvt. Ltd will appoint Quality check (QC Experts) who will be responsible to ensure adherence to the protocol, regulatory requirements record keeping and retention.

Study co-ordination, project management and quality management will be done by SMO **Skyline CRS India Pvt. Ltd** SMO **Mis. Namita Rathod (Director)** CRC. PM, QC Experts will assist PI and the Intuitions in all trial related activities.

Skyline CRS India Pvt. Ltd will bear all the administrative cost related to the various activities undertaken by PM, CRC or any other staff placed by SMO **Skyline CRS India Pvt. Ltd** which includes telecommunication, travel cost, training cost at various centers across India or abroad.

Skyline CRS India Pvt. Ltd will be exclusively conducting/managing all trial at the Hospital during the tenure of this agreement. This agreement will last for 10 (ten) years and can be renewed further on mutual agreement.

Following activities will be carried out by appointed CRCs

1. Performing all the activities in strict adherence to the ICH-GCP guidelines, Schedule Y India GCP and
   Regulatory requirement
2. Preparation for site selection visit and Site Initiation Visit (SIV)
3. Communication & Follow up with IRB/IEC Submission and Approval
4. Accurate and complete documentation of relevant EC documentation
5. Regulatory documents Collection
6. Patient Identification for assigned study form OPD or Hospital Database.
7. Maintenance and update of Trial Master File (TMF), site binders and relevant files
8. Preparation for site Monitoring Initiation Visit (SMV) and resolving all action items generated during
   Previous monitoring visits
9. Conduct Study according to International Conference of Harmonization (ICH) E6 and India Good Clinical Practice (GCP) regulation
10. Assisting Principal Investigator in administrating ICF and its procedures
11. Ensure protocol & applicable regulatory guidelines compliance and adherence
12. Patients pre- screening enrollment and recruitment
13. Preparing source notes and CRF filling
14. Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates
15. Coordinate and schedule subject's regular follow up visits and procedures, maintain regular Telephonic contact with patients to preventing lost to follow- up and missed visits.
16. Managing Clinical Trial Materials (CTM) maintenance, Accountability, distribution and logistics at site
17. Coordinate all site-specific queries- medical, administrative, subject reimbursements and other study
related activities.
18. Reporting and coordinating all AE/SAEs according to their timelines as per regulatory norms
19. Filling up and maintaining trial related logs likes source documentation, drug dispensing logs, subject
log, visit logs, Investigational product log, temperature log, SAE and EC communication log
20. Documentation of protocol deviation as appropriate and communicate any impacting subject safety
to the ethics committee
21. Coordinate with central and local lab for logistics and sample flow
22. Attend study related meeting as appropriate
23. Preparing sites for Monitoring / Auditing visits coordinate close out visit and Archival at site

SKYLINE CRS INDIA PVT. LTD. PUNE

24. Any other required activities during the trials.
25. Identification of potential database from different therapeutic area of PIs
26. Communication with Investigators/ Hospitals and conduct protocol specific feasibility
27. Other duties as requested by SMO **Skyline CRS India Pvt. Ltd.**

B. Hospital permits

1. Hospital will give the space and required facilities to appointed CRC &SMO **Skyline CRS India Pvt. Ltd** in order to perform clinical trials activities under respected PI.
2. Hospital will allow SMO **Skyline CRS India Pvt. Ltd** and Sponsors of Clinical trials to access the facility to verify source documents.
3. Hospital will allow SMO **Skyline CRS India Pvt. Ltd** to bring Sponsors of clinical trials to meet with PI/SITE representatives at a mutually convenient time.
4. Hospital shall permit SMO **Skyline CRS India Pvt. Ltd** to exclusively manage all clinical trial commenced by SMO **Skyline CRS India Pvt. Ltd.**

C. Term of Agreement

The term of this Agreement shall be for a period of 10 years commencing on the effective date 23st Dec 2021. However, this Agreement shall be reviewed annually by both parties if needed.

D. Relationship of the parties

1. Hospital and SMO **Skyline CRS India Pvt. Ltd** are independent parties. Both parties agree that their relationship is that of an Independent contractor and not employer and employee.
2. Neither party shall have express or implied rights nor did authority to assume or create any obligation or responsibility on behalf of or in the name of the other party by reason of this Agreement, except as provide in this Agreement.

E. GCP, ICH and CFR compliance

Hospital agrees to comply with International Conference of Harmonization & Good Clinical Practices (ICH-GCP) and all India regulations, CDSCO requirement and circulars there under.

F. Confidentiality

1. The parties here recognize and agree that due to the complex and competitive nature of the business, the confidential of information concerning both parties are of critical importance. Either party shall not, either during or after the term of this Agreement, disclose to any third party any confidential information and all Information or information relative to the work or the business of either party without the written consent of either party SMO **Skyline CRS India Pvt. Ltd** agrees that it shall not during, or at any time after the termination of this Agreement, directly or indirectly disclose or use any information for any reason whatever, without the prior written consent of SITE.
2. Hospital shall not disclose to any third party any and information about new studies received from SMO **Skyline CRS India Pvt. Ltd**.

G. Indemnification

Hospital shall indemnify and hold harmless **SMO Skyline CRS India Pvt. Ltd** against any losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by SITE, its agents, directors or employees, SMO **Skyline CRS India Pvt. Ltd** shall indemnify and hold harmless hospital against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of act or commission by SMO **Skyline CRS India Pvt. Ltd**, its agents, directors, or employees. In no event will either party be required to indemnify or hold harmless the other's negligence or gross negligence.

SKYLINE CRS INDIA PVT. LTD. PUNE

H. Compensation and Agreement

1. The Hospital, principle Investigator, SMO **Skyline Clinical Research Pvt. Ltd** and Sponsor and/or CRO will enter into a quadripartite clinical trial agreement before/at the time of placement of each trial at the Hospital.
2. All feasibilities and payments shall be routed through SMO **Skyline CRS India Pvt. Ltd** and pricing while bidding for the trial shall be discussed mutually and final correspondence with the Sponsor/CRO also would be handled by SMO **Skyline CRS India Pvt. Ltd** for smooth and hassle-free finalization of Clinical Trial Agreements.
3. Getting payment from sponsor and giving to Hospital and /or Investigator is the responsibility of SMO **Skyline CRS India Pvt. Ltd.**
4. SMO **Skyline CRS India Pvt. Ltd.** will be payee name for all trial related payment.
5. All payment shall be due and payable to the hospital on actual work i.e. number of subject randomized or visits completed.
6. The payment of remuneration shall be after deduction of all taxes under applicable laws.
7. All invoices will be requested from the hospital for study payment and all study related payment will be done to Mahatma Gandhi Mission (MGM) Medical College & Hospital, in a period of 15 working days after receiving the payment from the sponsor/CRO.
8. The details of study budget sharing in INR is as follow:
    - **100%** study payment will be paid to SMO **Skyline CRS India Pvt. Ltd** from Sponsor/ CRO for each study.
    - **65%** study payment will be paid to Hospital /Principal Investigator from SMO **Skyline CRS India Pvt. Ltd.**
    - **35%** study payment fees will be paid to SMO **Skyline CRS India Pvt. Ltd**.
    - **100%** CRC fees will be paid to SMO **Skyline CRS India Pvt. Ltd** from sponsor /CRO.
    - Subject Travel reimbursement amount will be paid to Hospital from SMO **Skyline CRS India Pvt. Ltd**.
    - Additional **30%** Institutional overhead will be paid from SMO **Skyline CRS India Pvt. Ltd** received from sponsor /CRO.
    - SMO **Skyline CRS India Pvt. Ltd** will pay Lab Cost, subject Hospitalization, SAE Medical Management charges at actual basis to Hospital /Principal Investigator received from sponsor /CRO.

(**Note**: Hospital/Principal Investigator should provide dedicated working printer, stationary, Electricity, Working place, Internet connection facility to our study team.)

I. Termination of Agreement

1. This Agreement shall be terminated by mutual agreement by giving sixty (60) days prior written notice by either party after the completion of any ongoing trials.

J. Permission to use personal Information or Statement

For good consideration, the undersigned authorizes SMO and its assigns to use, publish or reprint in whole or part any basic information about my identity, practice, and participation in clinical research including any specific details of my clinical research that do not conflict with a previously contacted privacy agreement.

The two parties shall consult with each other and medicate any disputes which may arise about the contact. If all attempts fail the two parties can appeal to the organization of arbitration in judicial court of the state of Maharashtra India.

SKYLINE CRS INDIA PVT. LTD. PUNE

Authorized Signature:

.....

Name: Dr. Rajendra Bohra

Title: Dean

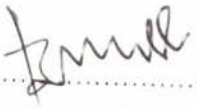
Date:

Hospital Name: Mahatma Gandhi Mission (MGM) Medical College & Hospital, Aurangabad.

Stamp:

DEAN
MGM'S MEDICAL COLLEGE
AURANGABAD

Professor & Head Dept. Of Pharmacology:



.....

Name: Dr. Deepak Bhosle

Title: Professor & Head Dept. Of Pharmacology

Date:

Hospital Name:

Mahatma Gandhi Mission (MGM) Medical College & Hospital, Aurangabad.

Stamp:

Professor & H.O.D.
Department of Pharmacology
MGM's Medical College
Aurangabad.

Skyline CRS India Pvt. Ltd SMO

1) Authorized Signature:

.....

Name: Ms. Namita Rathod

Title: Director–Clinical Operation

Date: **23 / Dec / 2021**

Address: **City Vista, Kolte Patil A wing, 1st Floor, Office No.12, Opposite Victorious School, Fountain road, Kharadi, Pune-411014, Maharashtra.**

Stamp:

Skyline CRS India Pvt. Ltd SMO

2) Authorized Signature:

.....

Name: Mr. Shantanu Deshmukh

Title: Operation Manager

Date: **23 / Dec / 2021**

Address: **City Vista, Kolte Patil A wing, 1st Floor, Office No.12, Opposite Victorious School, Fountain road, Kharadi, Pune-411014, Maharashtra.**

Stamp:

Memorandum of Understanding

This Agreement is made on **06th November 2020**, by and between **"ARDENT CLINICAL RESEARCH SERVICES (ACRS)"** a company registered under company act 1956 having its **Office No. 304, Level-3, Gagan Kapital Building, Opposite Kapila Hotel, Dhole Patil Road, Pune-01, MH, INDIA referred as a party- A (here in after referred to as the "ACRS")**

Ikon Multispecialty Hospital, Rose Park, Majnu Hill Rd, opp. Baba Auto Care, Shatabdi Nagar, Cidco, Aurangabad, Maharashtra 431001, INDIA referred as a party -B (here in after referred to as the "Institution")

The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfill conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties here to as follows

Ikon Multispecialty Hospital, Rose Park, Majnu Hill Rd, opp. Baba Auto Care, Shatabdi Nagar, Cidco, Aurangabad, Maharashtra 431001,INDIA appoints Ardent Clinical Research Services As a Site management organization on Exclusive basis for period of 05 years w.e.f 06th November 2020 to 05th November 2025. (will be reviewed and updated accordingly)

Obligations of Ardent Clinical Research Services:

Ardent Clinical Research Services (ACRS) is a Clinical Research Organizations and Site management Organization based in Pune providing end to end clinical research services to the Sponsors, Pharmaceutical and Biopharmaceutical industry, Institutions and Offers a complete range of Clinical Research in all therapeutic areas. We expertise in Site Management Activities, Project Management, Medical Writing, Monitoring, Safety Reporting, Regulatory services, Potential Site Selection, Faster Patient Recruitment, Quality compliance & Maintenance, and Clinical Research Expertise in India.

Ardent Clinical Research Services is desirous of working with Institution for the purpose of conducting ICH-GCP complaint Phase I-IV, BA/BE, Biospecimen collection clinical trials for new drug & treatment.

Ardent Clinical Research Services shall play vital role in getting clinical trials to the investigator from the sponsors and CROs and execute them in institution.

Office No.: 304, Level-3, Gagan Kapital Building, Opposite Hotel Kapila, Dhole Patil Road, Pune - 411 001, MH, India
Website: ardent-cro.com, **Email:** ardent@ardent-cro.com

Ardent Clinical Research Services will manage Study Operations and Study services as directed by Study protocol for the duration of the clinical trial.

Ardent Clinical Research Services will appoint a Clinical Research Coordinator (CRC) who will be a point of contact with Sponsor/CRO and ensure smooth conduct of trial at the site.

Ardent Clinical Research Services will appoint Project Manager (PM) who will be responsible to co-ordinate and over-see the progress and management of CRC activities & trial, ensure data quality, resolve screening, enrollment or general issue if any, follow up on post –monitoring action elements and study training as per needs and frequent discussion with investigator & Sponsor/CRO on trial progress.

Ardent Clinical Research Services will appoint Quality Check Experts (QC Experts) who will be responsible to ensure adherence to the protocol, regulatory requirements record keeping and retention.

Study co-ordination, project management and quality management will be done by Ardent clinical research services. Ardent personnel, CRC, PM, QC Experts will assist PI and the Intuitions in all trial related activities.

Ardent Clinical Research Services will bear all the administrative cost related to the various activities undertaken by PM, CRC or any other staff placed by Ardent Clinical research services which includes telecommunication, travel cost, training cost at various centers across India or abroad.

Ardent Clinical Research Services will be exclusively conducing /managing all trial at the Institution during the tenure of this agreement. This agreement will last for 05 (five) years and can be renewed further on mutual agreement.

Following activities will be carried out by appointed CRCs

1. Performing all the activities in strict adherence to the Indian Good Clinical Practice (GCP) regulation and New Drugs and Clinical Trials Rules, 2019.
2. Preparation for Site selection visit and Site Initiation Visit (SIV)
3. Communication & Follow up with IRB/IEC Submission and Approval
4. Accurate and complete documentation of relevant EC documentation
5. Regulatory Documents Collection
6. Patient Identification for assigned study from OPD, Hospital Database and PI referrals.

7. Maintenance and update of Trial Master File (TMF),site binders and relevant files
8. Preparation for Site Monitoring Visit (SMV), Remote Monitoring Visits (RMV) and resolving all action items of SMV and RMV within a 2 days post visit.
9. Conduct study according to International Conference of Harmonization (ICH) E6 (R2), Indian Good Clinical Practice (GCP) regulation and New Drugs and Clinical Trials Rules, 2019.
10. Assisting Principal Investigator in administrating ICF and protocol procedures and assessments.
11. Ensure protocol & applicable regulatory guidelines compliance and adherence
12. Patients pre-screening, screening enrollment and recruitment compulsory in each study
13. Preparing source notes and CRF filling
14. Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates
15. Coordinate and schedule subject's regular follow up visits and procedures, maintain regular telephonic contact with patients to preventing lost to follow-up and missed visits.
16. Managing clinical trial materials(CTM) maintenance, Accountability, distribution and logistics at site
17. Coordinate all site specific queries-medical, administrative, subject reimbursements and other
18. Reporting and coordinating all AE/SAEs according to their timelines as per regulatory norms
19. Filling up and maintaining trial related logs likes source documentation, drug dispensing logs, subject log, visit logs, Investigational product log, temperature log, logistics log, SAE and EC communication log
20. Documentation of protocol deviation as appropriate and communicate any impacting subject safety to the ethics committee
21. Coordinate with central and local lab for logistics and sample flow
22. Attend study related meeting or webinar as appropriate
23. Preparing sites for Monitoring / Auditing visits coordinate close out visit and Archival at site
24. Any other required activities during the trials.
25. Identification of potential database from different therapeutic area of PIs
26. Communication with Investigators/ Hospitals and conduct protocol specific feasibility
27. Other duties as requested by Ardent Clinical Research Services Management

B. Institution Permits

1. Institution will give the space and required facilities to appointed CRC & ACRS in order to perform clinical trials activities under respective PI.
2. Institution will allow ACRS and Sponsors of clinical trials to access the facility to verify source documents.

3. Institution will allow ACRS to bring Sponsors of clinical trials to meet with PI/SITE representatives at a mutually convenient time.
4. Institution shall permit ACRS to exclusively manage all clinical trial commenced by Ardent Clinical Research Services.

C. Term of Agreement

The term of this Agreement shall be for a period of 05 years commencing on the effective date 06th November 2020. However, this Agreement shall be reviewed annually by both parties if required.

D. Relationship of the Parties

1. Institution and ACRS are independent parties. Both parties agree that their relationship is that of an independent contractor and not employer and employee.
2. Neither party shall have express or implied rights nor authority to assume or create any obligation or responsibility on behalf of or in the name of the other party by reason of this Agreement, except as provided in this Agreement.

E. GCP, ICH and CFR Compliance

Institution agrees to comply with all requirements of Good Clinical Practices (GCP), International Conference of Harmonization (ICH) and Code of Federal Regulations (CFR) and any and all future regulations, requirements and writing promulgated there under.

F. Confidentiality

1. The parties here to recognize and agree that due to the complex and competitive nature of the business, the confidentiality of information concerning both parties is of critical importance. Either party shall not, either during or after the term of this Agreement, disclose to any third party any confidential information and all information or information relative to the work or the business of either party without the written consent of either party. ACRS agrees that it shall not during, or at any time after the termination of this Agreement, directly or indirectly disclose or use any information for any reason whatsoever, without the prior written consent of SITE.

2. Institution shall not disclose to any third party any and all information about new studies received from ACRS.

G. Indemnification

Institution/PI shall indemnify and hold harmless ACRS against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by SITE, its agents, directors or employees. ACRS shall indemnify and hold harmless hospital against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by ACRS, its agents, directors, or employees. In no event will either party be required to indemnify or hold harmless the other for the other's negligence or gross negligence.

H. Compensation and Agreement

1. The Institution, Principle Investigator, Ardent Clinical Research Services and Sponsor and/or CRO will enter into a quadripartite clinical trial agreement before/at the time of placement of each trial at the Institution.
2. All feasibilities and payments shall be routed through ACRS and pricing while bidding for the trial while bidding for the trials shall be discussed mutually and final correspondence with the Sponsor/CRO also would be handled by Ardent Clinical Research Services for Smooth and hassle-free finalization of Clinical Trial Agreements.
3. Getting payment from sponsor and giving to Institution and /or Investigator is the responsibility of Ardent Clinical Research Services.
4. All payment will come to Ardent Clinical Research Services by the sponsors/CRO and Ardent Clinical Research Services will be payee for all trial related payment for each trial
5. All payment shall be due and payable to the Institution on the basis of funds received from the sponsor/CRO on actual work i.e. number of subject randomized or visits completed.
6. The payment of remuneration shall be after deduction of all taxes under applicable laws.
7. All invoice will be requested from the hospital for study payment and all Study related payments will be done to Ikon Multispecialty Hospital(institution), in a period of 15 working days after receiving the payment from the sponsor/CRO.

1. The details of study budget sharing in INR is As follows :
    - **100** % Study Payment will be paid to ACRS from Sponsor/CRO for each study.
    - **60** % Study Payment will be paid to Hospital /Principal Investigator from ACRS.
    - **40** % Study Payment Fees will be paid to ACRS.
    - **100** % CRC fees will be paid to ACRS from Sponsor/CRO.
    - Additional **25** % Institutional Overhead will be paid from ACRS (if applicable)
    - ACRS will pay Lab Cost, Subject Hospitalization, SAE Medical Management charges at actual basis to Hospital /Principal Investigator. (if applicable)

(Note: Hospital /Principal Investigator should provide dedicated working Printer, Stationary, Electricity, Working place, Internet connection facility to our study team.)

I. Termination of Agreement

1. This Agreement shall be terminated by mutual agreement by giving Sixty (60) days prior written notice by either party after the completion of any ongoing trials.

J. Permission to use Personal Information or Statement

For good consideration, the undersigned authorizes SMO and its assigns to use, publish or reprint in whole or part any basic information about my identity, practice, and participation in clinical research including any specific details of my clinical research that do not conflict with a previously contracted privacy agreement.

The two parties shall consult with each other and mediate any disputes which may arise about the contract. If all attempts fail, the two parties can appeal to the organization of arbitration in judicial court of the State of Pune, MH, India.

Authorized Signature: _____ Name: Title: Date: Hospital Name:- **Ikon Multispecialty Hospital, Rose Park, Majnu Hill Rd, opp. Baba Auto Care, Shatabdi Nagar, Cidco, Aurangabad, Maharashtra 431001, INDIA**	Witness Signature: _____ Witness Name:- Title:- Date:- Hospital Name:- **Ikon Multispecialty Hospital, Rose Park, Majnu Hill Rd, opp. Baba Auto Care, Shatabdi Nagar, Cidco, Aurangabad, Maharashtra 431001, INDIA**

Ardent Clinical Research Services, Pune

1) Signature: _____

Name: -**Mr. Chandu Devanpally**
Title: - **Founder & Managing Director,**
Date:- 06/NOV/2020
SMO:- **Ardent Clinical Research Services**
Address: ***Office No. 304, Level-3, Gagan Kapital Building, Opposite Kapila Hotel, Dhole Patil Road, Pune-01, MH, INDIA***

Ardent Clinical Research Service Pune

2) Signature: _____

Name:- **Mrs. Pranjal Ausekar**
Title: - **Head-Operations & Project Manager**
Date:- 06 NOV. 2020
SMO:- **Ardent Clinical Research Services**
Address: ***Office No. 304, Level-3, Gagan Kapital Building, Opposite Kapila Hotel, Dhole Patil Road, Pune-01, MH, INDIA***

CLINICAL TRIAL AGREEMENT

THIS CLINICAL TRIAL AGREEMENT ("Agreement") is made and entered into as of 2nd day of May 2020 (hereinafter "Effective Date") by and between:

Serum Institute of India Pvt. Ltd. a company incorporated under Companies Act, 1956 having its registered office at 212/2, Off Soli Poonawalla Road, Hadapsar, Pune 411028, India. (hereinafter **"Sponsor"**);

DiagnoSearch Life Sciences Pvt. Ltd. a company incorporated under Companies Act, 1956 having its registered office at 702, Dosti Pinnacle, Plot No. E-7, Road No. 22, Wagle Industrial Estate, Thane- 400604, Maharashtra, India (hereinafter **"CRO"**), acting on behalf of **Serum Institute of India Pvt. Ltd. / the Sponsor;**

Dr. Tayade Deepak Narayan, MGM Medical College and Hospital,N-6, CIDCO, Aurangabad 431 003,Maharashtra, India :hereinafter referred to as **Investigator;**

MGM Medical College and Hospital, a deemed university having its office at N-6, CIDCO, Aurangabad 431 003, Maharashtra, India an unit of Mahatma Gandhi Mission (a Charitable Trust registered Societies Registration Act and Bombay Public Trust Act) hereinafter referred to as **Institution.**

WHEREAS CRO is engaged in the business of managing and providing clinical research services and related activities and has been appointed by Sponsor to arrange and administer a clinical Study entitled:

A Multicenter, Phase III, Double-Blind, Randomized, Placebo Controlled Study to Evaluate the Efficacy of Recombinant BCG VPM1002 in Reducing Infection Incidence and Disease Severity of SARS-COV-2/COVID-19 Among High-Risk Subject under Protocol no. – SII-rBCG/COVID-19/IN-01, Version 3.0 Dated: 11 April 2020 ("the Protocol") and has entered into an agreement with Sponsor or one of its affiliates concerning the management, funding and administration of the Study;

AND WHEREAS Sponsor intends to appoint Investigator relating to the said **SII-rBCG/COVID-19/IN-01,** Clinical Study and requires CRO to supervise the services / activities to be undertaken by Investigator along with the services provided by CRO to Sponsor.

AND WHEREAS Institution and Investigator have each reviewed sufficient information regarding Sponsor's vaccine viz. SII-rBCG VPM1002 (the "Study Vaccine"), the Protocol for the Study and the Investigator Brochure to evaluate their interest in participating in the Study and each desires to participate in the Study as more particularly described in this Agreement.

NOW, THEREFORE, subject to the terms, conditions and covenants hereinafter set forth CRO, Investigator and Institution agree as follows.

The Sponsor, CRO, Investigator and Institution are sometimes hereinafter individually referred to as a Party and collectively as Parties.

Article 1 – The Study

1.1 The Institution and the Investigator undertake to conduct the Study in strict accordance with various guidelines and applicable regulatory requirements including but not limited to (a) the current World Medical Association Declaration of Helsinki titled, "Ethical Principles for Medical Research Involving Human Subjects;" (b) the current ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95); (c) the current Indian Ministry of Health and Family Welfare guideline for good clinical practice titled, "Good Clinical Practices for Clinical Research in India;" (d) the current Indian Council of Medical Research ethical guideline for clinical research titled, "Ethical Guidelines for Biomedical Research on Human Subjects;" (e) the written requirements of all reviewing Institutional Ethics Committees and institutional review boards (collectively, the Institutional Ethics Committees) (f) Sponsor's Standard Operating Procedure (SOP)s, if required; Institution's own SOP, the Protocol which is approved by Sponsor, Investigator and the IRB and a copy of which is attached hereto as Schedule A (g) such other guidelines as may be issued by Indian Council of Medical Research and Ministry of Health and Family Welfare and (h) data privacy laws as may be applicable and subsequent amendments if any, to the above guidelines and such other regulations that may be pronounced by a competent authority from time to time (hereinafter "Regulatory Requirements"). It is understood and agreed that, in the event of a conflict among any of the Standards, the most stringent Standard shall apply.

1.2 The Investigator hereby certifies and undertakes that s/he is not and has not been debarred under the Drugs and Cosmetics Acts 1940, Drugs and Cosmetics Rules, 1945, and any legislation in connection with any of the services or work provided hereunder as amended, or any other similar legislation, or excluded by a regulatory authority from participating in the development or approval of a drug or biological or disqualified by a regulatory authority as a clinical investigator, and that this certification may be relied upon in any applications to the Federal Food and Drug Administration for drug approval. Furthermore, the Institution and Investigator hereby certify and undertake that they will not use the services of a person so debarred, and that such certification can be similarly relied upon. It is understood and agreed that this certification imposes a continuing obligation upon the Institution and Investigator to notify the CRO/Sponsor of any change in the truth of this certification.

1.3 The Investigator acknowledges and agrees that its obligations set forth herein are of a personal nature and that the character, competence and reputation of the Investigator were instrumental in the Sponsor's / CRO's selection of the Investigator for the conduct of the Study. Consequently, it is agreed that the Investigator may not in any way transfer, cede or assign, directly or indirectly, the rights granted herein to any third party. If Investigator should become unwilling or unable to conduct the Study, the Institution shall consult with the CRO regarding the appointment of a new principal investigator. In such an event, CRO shall supervise the services / activities undertaken by new principal investigator relating to the Study along with the services provided by CRO to Sponsor. If both Parties cannot agree on a substitute, all further enrolment of subjects into the Study shall immediately cease and decision on the continuation of subjects already recruited in the Study will be taken jointly by CRO & Sponsor on a case to case basis. However, it is agreed between the Parties that,

the outgoing Investigator shall be liable and responsible for all his acts, deeds, actions, omissions, and liabilities arising there from, during the period he / she acts as a Principle Investigator.

1.4 The Institution and the Investigator undertake to conduct the Study in an efficient and professional manner under the provisions of this Agreement and will use their best efforts to complete the Study within the time period agreed between the Parties.

1.5 Parties agree to coordinate the day-to-day management of the Study with each other and to comply with and perform their respective responsibilities and activities as set forth in this agreement.

1.6 CRO will act as a contact point for the Investigator, Institution and Sponsor, regarding any issue which may arise in the implementation of the Study.

1.7 Before commencing the Study, within seven (7) business days the Investigator will seek approval to conduct the Study from the IRB and shall obtain consent as per applicable local regulations of all Study Subjects (or, if permitted their legal representative) who participate in the Study, including consent to allow Sponsor and its Affiliates (hereinafter defined) to access personal and medical information as necessary to monitor the Study or to receive and use Study data. Investigator must deliver to the Sponsor/CRO the written approval for the conduct of the Study, the approved informed consent form and the terms of the Protocol from the IRB. Sponsor may terminate this Agreement under Article 9 (**Term and Termination; Effect of Termination**) upon the failure of the Investigator to seek the aforementioned approval from IRB. In this Agreement "Affiliate" means any entity that controls, is controlled by, or is under common control with the party being referred to. In this context, "control" shall mean (1) ownership by one entity, directly or indirectly, of at least fifty percent (50%) of the voting stock of another entity; or (2) power of one entity to direct the management or policies of another entity, by contract or otherwise;

1.8 The Sponsor/CRO is under no obligation to release Study Vaccine or any other related supplies as defined in Protocol to the Investigator unless and until satisfactory proof of IRB approval is submitted to the CRO.

1.9 The Investigator and Institution hereby warrants that they:

(a) shall use Study Vaccine only to conduct the Study in accordance with the Protocol; shall not chemically, physically or otherwise modify Study Vaccine, unless specifically required to do so by the Protocol; and shall handle, store, ship and dispose of Study Vaccine with appropriate care and in compliance with manufacturer's instructions in writing or over an email and all applicable local, state and federal laws, rules and regulations, including, but not limited to, those governing hazardous substances.

(b) shall not charge any Study subject or third-party payer for Study procedures required by the Protocol that are paid for by CRO/Sponsor under this Agreement or for any Study Vaccine that is provided or paid for by CRO/Sponsor.

(c) received a copy of the Investigator Brochure and has read and understood its contents.

(d) shall prepare, document and maintain records and case histories on the case report form supplied by the CRO, retain such data and records after completion of the Study, and obtain advance informed consent from each of the subjects, or their duly authorized representatives, as defined in the Protocol participating in the Study (hereinafter "Subjects").

(e) shall administer the preparation of laboratory tests for shipment (e.g., centrifuge, freezing, packing, labeling) and arrange for courier services with respect to the shipment of biological samples (e.g., completion of shipment forms, ensure the relevant shipment procedure and safe delivery of the shipment);

(f) shall report adverse events and serious adverse events as required by the regulation in force and amended from time to time. The definition of 'Adverse Events' and 'Serious Adverse Events' and the reporting procedure are included in the Protocol, which shall be followed for such reporting.

(g) agree to inform Sponsor / CRO promptly if they become aware of material non-compliance with the Protocol, ICH Good Clinical Practices, or any applicable laws, rules or regulations; incomplete or inaccurate recording of data; or any significant misconduct or other matters of concern relating to the performance of the Study at Institution.

1.10 Any change, amendment or modification to this Agreement or any Schedule hereto must be authorized in witting by all Parties. Provided however those changes to the Protocol may be made (i) in accordance with procedures outlined in the Protocol, or (ii) with the agreement of the Investigator, Institution and Sponsor. Any changes to the Protocol shall be accompanied by such notification, review and/or approval of the IRB as may be required by applicable law and/or the Protocol. The Institution and the Investigator shall not consent to any change in the Protocol requested by the relevant IRB without the prior written consent of CRO or SPONSOR.

1.11 The Investigator may appoint such other individuals as she/he, in accordance with applicable law and/or the Protocol, may deem appropriate as sub-investigators to assist in the conduct of the Study (such other individuals are collectively referred to hereinafter as "Sub-investigators"). All such Sub-investigators must be approved by CRO / Sponsor and copies of their curriculum vitae and other regulatory documentation as required (such as financial disclosure forms) forwarded to CRO/ Sponsor. The Investigator shall be responsible for leading any such team of Sub-investigators, and shall ensure that such Sub-investigators are properly qualified and licensed.

1.12 The Institution and the Investigator shall keep appropriate records of Study Vaccine received, dispensed, used, and returned to pharmacy/storage (and returned to CRO/Sponsor) in accordance with Regulatory Requirements.

1.13 Institution and Investigator agree that Sponsor / CRO may make public the names of the Investigator and the Institution as part of a list of Investigators and Institutions conducting the Study when making either protocol or results summary register postings. Institution and Investigator agree that Sponsor may make public the amount of funding provided to

Institution by Sponsor for the conduct of the Study and may identify Institution and Investigator as part of this disclosure. Investigator agrees that, if Investigator, consistent with the terms of this Agreement, speaks publicly or publishes any article or letter about a matter related to the Study or Study Vaccine or that otherwise relates to Sponsor, Investigator will disclose that he/she was an investigator for the Study.

1.14 The CRO/ Sponsor shall provide, without cost, sufficient amounts of the Study Vaccine to conduct the Study. The Institution and Investigator may not use or dispose of the Study Vaccine in any way other than as specified in the Protocol.

1.15 Institution agrees that any nationally-licensed medicinal products that are not the subject of the Study but are required for the routine care of a Study subject during and after the Study for the disease or condition to which the Study relates are expected to be available to the Study subject and funded through the usual operations of the local healthcare system independently from the Study and without expectation of support from CRO and/or Sponsor.

1.16 Institution/Investigator agree to record all side effects including laboratory abnormalities, whether serious or not, of which they may become aware in the appropriate Case Report Forms (CRFs) and in medical files of the subjects in accordance with the requirement set out in the Protocol.

1.17 Upon reasonable notice and at reasonable times, Institution and the Investigator shall permit representatives of the CRO and/or the Sponsor to examine their representative facilities, to validate case reports against original data in their files, to make copies of relevant records and monitor the work performed hereunder, and to determine the adequacy of the facilities and whether the Study is being conducted in compliance with this Agreement, and Regulatory Requirements. CRO/Sponsor representative should also be permitted to review the relevant financial documents related to the Study including but not limited to quotations, invoices, employee agreement, salary slips, attendance records, subject compensation logs, annual maintenance contract (applicable for instruments, equipments being used in the Study) agreements, physical verification of assets.

Article 2 – Compensation

2.1 All payments will be made by CRO/Sponsor as per payment schedule provided in schedule B hereto and assumptions provided thereunder.

2.2 The Parties hereby agree and covenant that Investigator / Institution will directly issue invoices to Sponsor which will be certified by CRO. The Parties agree that CRO shall act as a pure agent of Sponsor and facilitate payments to be made to the Investigator / Institution. Invoices shall be addressed to CRO and be sent at the following addresses:

DiagnoSearch Life Sciences Pvt. Ltd.
702, Dosti Pinnacle, Wagle Estate
Thane – 400 604, India

2.3 All amounts payable to the Investigator / Institution will be subject to Tax Deduction at source as required by the relevant tax provisions

2.4 It is understood that Sponsor enjoys exemption from GST by claiming status of Special Economic Zone (SEZ) unit and accordingly invoices will be raised without levying GST. Further, as per Rule 96A of Central Goods and Service Tax Act, 2017 Parties agree that:

(i) If invoices issued by CRO, Investigator and Institution are without levying GST, then such invoices shall specifically mention - "**Supply to SEZ Unit or SEZ Developer for Authorised Operations under Bond or Legal Undertaking without payment of Integrated Tax (LUT)"** Every such invoice must also mention the GSTIN No. 27AABCS4225M2Z6 of our SEZ unit and ARN no for LUT.

(ii) However, if CRO, Investigator and Institution opt to levy GST, then such invoices shall specifically mention - "**Supply to SEZ Unit or SEZ Developer for Authorised Operations on payment of Integrated Tax. The Integrated Tax paid will have to be claimed as refund and Sponsor will not reimburse GST paid."** Further these invoices should also mention GSTIN No 27AABCS4225M2Z6 of our SEZ unit.

(iii) However, the Sponsor shall reimburse the amount including but not limited to tax liability, interest and penalty thereon imposed on CRO/Investigator/Institution by any competent authorities arising out of breach, action, inaction or failure to comply with provisions of Central Goods and Service Tax Act by Sponsor.

2.5 The payment shall be made in either by electronic transfer to the beneficiary account details given below or cheques should drawn by the CRO and be made payable to **MGM Medical college, Aurangabad** and delivered to the following address

Clinical research unit, Department of pharmacology 4th floor MGM medical college and Hospital N-6 Cidco Aurangabad-431003, MH, India

Beneficiary Name	MGM Medical college ,Aurangabad
Bank Name:	IDBI bank
Bank Address	Adalat Road Branch,Survey No.20292,Ratnaprabha Building Kesarsinghpura Opp.LIC Bld.Aurangabad
Branch	Adalat Road Branch
Beneficiary Account No.	0376104000000107
TAX ID NUMBER (PAN)	AAATM4256E
IFSC Code	IBKL0000376

Article 3 – Institution Staff and Facilities

3.1 The Institution acknowledges that all payments for all necessary laboratory and other facilities, equipment, supplies (other than the Study Vaccine), and physicians and clinical support staff required to discharge its obligations under this Agreement are provided for in the compensation schedule as provided in Schedule B. Institution shall ensure that all such facilities and staff are arranged to support the Study.

3.2 All matters, terms and payment of compensation, benefits and other conditions of engagement of any nature for the Investigator, any Sub-investigators and any support staff used in the Study shall be solely a matter between the Institution and such individuals, regardless of whether such individuals are considered employees, agents or independent contractors of the Institution and no amounts payable by CRO under this Agreement shall be considered to be a salary payment by CRO or Sponsor to Investigator, sub-investigator or support staff. All Institution/Investigator staff performing Services under this Agreement shall at all times be employed or engaged by Institution/Investigator and shall not be employees or subcontractors of CRO or Sponsor. Accordingly Institution/Investigator shall deal with all issues relating to the employment or engagement of the Institution/Investigator staff including without limitation: payment of salary and any employment-related benefits; deduction of all Pay As You Earn, National Insurance and any other employee-related taxes and contributions; disciplinary and performance issues; grievances; issues relating to a member of staff's ill health; and issues relating to a member of staff's terms and conditions of employment or engagement

3.3 The Investigator and the Institution will take appropriate steps to inform each physician, Study staff of the terms of this Agreement, obtain their agreement to abide by the terms and conditions of this Agreement and ensure that those persons comply with the terms and conditions of this Agreement. "**Study Staff**" mean the individuals providing services under the supervision of the Investigator with respect to the conduct of the clinical study, including without limitation sub-investigators, study coordinators, and other trial Site employees, agents, any support staff etc.

Article 4 – Reports

4.1 The Investigator will maintain accurate and complete records in accordance with Regulatory Requirements and the Investigator will comply with all reporting requirements contained in the Protocol/SOPs/any other Sponsor's specification. The Investigator will provide the CRO/Sponsor with copies of all reports provided to the Investigator's IRB/IEC.

4.2 The Investigator shall keep the CRO advised of the status of the Study via periodic reports, which are to be transmitted via electronic means or other mutually agreeable method. The frequency of reports shall be mutually agreed to by both Parties. If required by the Sponsor, there shall also be a final report of the Study presented to the CRO/Sponsor.

4.3 All case report forms and other reports submitted to the CRO and all data including Study Data generated under this Agreement shall be the property and Confidential Information of the Sponsor and may be used by the Sponsor for any purpose without further obligation or liability to the Institution and/or the Investigator.

4.4 The Institution and the Investigator shall provide such expense statements/reports to Sponsor as CRO/Sponsor may request, on such forms as Sponsor may supply or as Sponsor may approve. During the time the Study is being conducted and for one year thereafter, Investigator and each sub-investigator shall update such forms promptly and provide the same to the Sponsor/CRO as may be requested by Sponsor and whenever any material changes occur in the information disclosed by the previous forms.

4.5 A Subject's individual medical records shall remain the property of the Investigator / Institution. The Investigator will, where duly authorized or where allowed by law, provide or make such medical records and individual Subject data available to the CRO / Sponsor and governmental agencies.

4.6 Institution shall make and retain records regarding the Study as required by the Protocol, applicable law or regulation, or ICH/GCP Guidelines, and in accordance with Institution's standard archiving procedures. Institution will retain such records for a minimum of fifteen (15) years from conclusion of the Study. Thereafter, Institution will contact Sponsor prior to any destroying such records and will retain the records if requested by Sponsor.

4.7 The Investigator agrees not to provide the Study data to any third party or to use the Study data in any way without the Sponsor's prior written consent. The Investigator also agrees to not identify, Subjects in order to benefit research conducted or sponsored by any third party, without the Sponsor's prior written consent.

4.8 All Study Data and reports and any other information that generated, provided to and created by Investigator or Institution, in the performance of their duties hereunder remain the property and confidential information of Sponsor at all times. The Parties hereby agree that, subject to the applicable laws and requirements and each Party's rights and obligations under this Agreement, Sponsor shall be the sole owner of all the information mentioned above and shall have the unrestricted right during and after the term of this Agreement, to use the same for any purpose; "Study Data" shall mean all records and reports, (other than Study Subject's medical records), generated, collected or created pursuant to or prepared in connection with the Study including, without limitation, reports (e.g. CRFs, data summaries, interim reports and the final report) etc.

Article 5 – Inventions

5.1 The Institution and Investigator hereby acknowledge and agree that Sponsor shall own all right, title and interest in and to the Protocol, all intellectual property rights arising from the Study including but not limited to reports, discoveries, data, inventions, developments, structures, designs, protocols, biochemical strategies, biological materials, formulations, compositions, analytic methodology, chemical and quality control procedures, devices, know-how, technologies, techniques, systems methods, products, processes, algorithms, concepts, formulas, processes, ideas, writings, trade names, business names, logos, design marks or other proprietary marks, technical research, development and manufacturing data, trade secrets or utility models in any stage of development, whether or not patentable and whether or not reduced to practice, and all improvements, modifications, derivative works from, other rights in and claims related to, any of the foregoing and whether or not made, discovered, conceived, invented, originated, devised or improved by the Institution, Investigator , Sub investigator and Study Staff in the performance of the Study or relating to the Study Vaccine or which incorporate Sponsor's confidential Information (collectively, the "Inventions"), and the Institution and Investigator hereby expressly and irrevocably assign, and will cause Sub-investigators and Study Staff to assign, to the Sponsor, all right, title and interests that they may have in any such Inventions without payment of additional consideration.

5.2 The Investigator shall promptly disclose to the CRO/Sponsor in writing any and all Inventions generated pursuant to this Agreement and undertake not to use such Inventions than for the purposes of this Agreement without the prior written consent of the Sponsor.

5.3 If CRO/Sponsor requests, Institution and Investigator shall execute, and will cause the Sub investigators and Study Staff to execute, any instruments or testify as Sponsor deems necessary for Sponsor and/or Sponsor's Affiliates to draft, file, and prosecute patent applications, defend patents, or to otherwise protect Sponsor 's interest in the Inventions . CRO/Sponsor will reasonably compensate Institution and/or Investigator (as applicable) for the time devoted to such activities and will reimburse Institution and or Investigator (as applicable) for reasonable and necessary expenses incurred. The Institution and the Investigator hereby grant to Sponsor an exclusive, worldwide, irrevocable, non-restrictive and full royalty free license under such Inventions to exploit the same for any purpose whatsoever.

5.4 The obligations of this Section shall survive termination of this Agreement.

Article 6 – Publication; Publicity

Except as otherwise expressly agreed between the Parties, Institution and Investigator agree that they will not issue nor allow their employees, sub-investigators or representatives to issue or disseminate any press release or statement, nor any communication of information regarding the Study, written or oral, to the communications media or any third party without the prior written consent of Sponsor. Additionally, all announcements or publicity concerning the Study, or this Agreement by Institution or Investigator may be approved by the Sponsor, at its sole discretion.

The Institution and the Investigator agree not to publish any Study related material, including the Results, other than in accordance with this Section 6.

Article 7 - Confidential Information

7.1 In connection with the performance of Study services, CRO and/or Sponsor may provide, or have provided, certain Confidential Information (hereinafter defined) to Institution and Investigator solely for the purpose of enabling the Institution and Investigator to conduct the Study. Institution and Investigator agree not to use, or permit the use of Confidential Information except for the performance of this Agreement and not to disclose Confidential Information to third parties except as necessary to conduct the Study and under an agreement by the third party to be bound by the obligations of this Section. Institution shall safeguard Sponsor / CRO Confidential Information with the same standard of care that is used with Institution's confidential information, but in no event less than reasonable care.

7.2 In this Agreement "Confidential Information" means all information (including, without limitation, study protocols, case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans, processes, procedures) of Sponsor / CRO or their Affiliates that are: (1) provided to Institution and Investigator in connection with this Agreement or the Study; (2) Study data, results, or reports created by Institution, Investigators, Sub-investigators or Study Staff in connection with the Study (except for a Study subject's medical records); and (3) cumulative Study data, results, and reports from all sites conducting the Study.

7.3 The obligations of confidentiality and limited use under this Section shall not extend to:

(i) any information that is or becomes publicly available, except through breach of this Agreement;

(ii) any information that Institution/ Investigator can demonstrate that it possessed prior to, or developed independently from, disclosure or development under this Agreement;

(iii) any information that Institution/ Investigator receives from a third party (other than Sponsor or its Affiliates) which is not legally prohibited from disclosing such information;

(iv) a Study subject's specific medical information, as necessary for the appropriate medical care of the subject.

7.4 Notwithstanding any termination of this Agreement the provisions of confidentiality will apply for a period of ten (10) years from the date hereof.

7.5 If Institution or Investigator is required by law to disclose certain confidential information to statutory authorities then it shall do so based on legal advice from its legal advisors and only to the extent required. It shall also intimate the CRO and Sponsor immediately on receipt of such disclosure request / notice / order so that CRO / Sponsor can take necessary steps if they wish to in order to limit the dissemination of the Confidential information.

Article 8 – Independent Contractor

The relationship of Sponsor, CRO, Institution and Investigator under the Agreement is that of independent contractors. The Parties do not intend to create a partnership or joint venture employer-employee relationship between themselves. Institution and/or Investigator are not an agent of CRO / Sponsor and have no right or authority to bind CRO and/or Sponsor in any manner to any agreement or obligation whatsoever.

Each Party shall act solely as an independent contractor and shall have no right to act for or to sign the name of or bind the other Party in any way or to make quotations or to write letters under the name of the other Party or to represent that such other Party is in any way responsible for any acts or omissions of such Party. This Agreement does not in any way create a master and servant relationship between Parties. Under no circumstances, the Employees of the Institution and Investigator shall be considered as employees of Sponsor /CRO nor shall such relationship be considered to exist.

Article 9 – Term and Termination; Effect of Termination

9.1 This Agreement shall commence on the Effective Date and shall, unless sooner terminated as herein expressly provided, continue until completion of the Study.

9.2 This Agreement may be terminated by the Sponsor or by the CRO acting solely on the instructions received from the Sponsor in this behalf, at any time, with or without cause, immediately upon notice to Investigator to this effect; a notice by CRO and/or Sponsor that the Study is terminated shall also constitute effective notice of termination of this Agreement.

9.3 Upon termination or expiry of this Agreement:

(a) Institution and Investigator will not enroll additional Study Subjects, and will cooperate with CRO and Sponsor in the orderly discontinuation of the Study;

(b) the Parties will meet and confer promptly to determine an appropriate phase-out for Subjects already enrolled in the Study;

(c) Institution and Investigator shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study;

(d) Investigator and Institution shall be entitled to receive payment by CRO of any amounts accrued as of the date of termination for Study- related work actually performed and expenses actually and reasonably incurred; in the event CRO has pre-paid Investigator and/or Institution for Study services not yet performed as of the date of termination, Investigator shall promptly refund to CRO all such pre-payments;

(e) Investigator and Institution shall deliver to CRO/Sponsor all case report forms and any other reports or documentation prepared during the course of the Study, whether completed or not, in their possession or under their control; and

(f) Investigator and Institution shall either return to CRO / Sponsor or destroy, in accordance with CRO / Sponsor's instructions and / or the terms of the Protocol, all unused or partially used Study Vaccine in their possession or under their control.

(g) All Confidential Information of Sponsor (except for such records that the Institution and Investigator are required by law or regulation to retain) which in the Institution's and/or Investigator's possession shall be promptly delivered to Sponsor, or at Sponsor's discretion destroyed with destruction certified in writing.

(h) Institution represents that medical care for the disease or condition to which the Study relates is available to Study subjects following the Study in accordance with local standard of care through the usual operations of the local healthcare system, and that upon completion of the Study, Institution will appropriate transition Study subjects from the Study to such medical care or refer Study subjects to a health care provider for such medical care.

(i) No termination hereunder shall constitute a waiver of any rights or causes of action that either Party may have based upon events occurring prior to the termination date. Articles 4, 5, 6, 7, 10, and 11 shall survive any termination or expiration of this Agreement, as well as any other terms which by their intent or meaning are intended to so survive.

Article 10 – Indemnification

10.1 Sponsor shall defend, indemnify, save and hold harmless the Institution, its directors, officers, employees, agents, assigns and the Investigator (each, an "Institution Indemnitee") from any and all liabilities, claims, actions or suits by third parties for bodily injury or death, that arise out of Institution's administration of the Study Vaccine or procedures provided for by the Protocol ("Institution Claim"), provided that Sponsor shall not indemnify any Institution Indemnitee for any Institution Claim to the extent the Institution Claim arose out of:

(a) failure by Institution Indemnitees to conduct the Study in accordance with (i) this Agreement and the Protocol, (ii) all written instructions delivered by CRO/Sponsor concerning conduct and administration of the Study, (iii) all applicable government laws, rules and regulations and (iv) the manner required of a reasonable and prudent clinical investigator or physician; and

(b) the negligence or willful malfeasance of any Institution Indemnitee, or any other person on the Institution's property or under its control, exclusive of CRO / Sponsor employees.

10.2 Sponsor's obligations under this Section with respect to an Institution Claim are conditioned on:

(a) Prompt written notification to Sponsor of the Institution Claim so that Sponsor's ability to defend or settle the Institution Claim is not prejudiced; and

(b) Institution Indemnitees' agree that CRO/Sponsor has full control over the defense or settlement of the Institution Claim and to fully cooperate with CRO/Sponsor in the defense or settlement of the Institution Claim; provided, that CRO/Sponsor will not settle any such Institution Claim under terms that include an admission of fault or wrongdoing by any Indemnitee or which requires an Indemnitee to undertake a future course of action without that Indemnitee's written consent to such components.

10.3 Additionally, Sponsor also agrees to compensate as required by the current compensation guidelines under the new Drugs and Clinical Trials Rules, 2019), and any amendment or new pronouncement notified by the Competent Authority

Notwithstanding clause 10.3, Sponsor shall not stand to pay any medical expenses of any human subject in the Study in the event of any adverse reaction arising out of or resulting from:

(i) A failure to adhere to the terms of this Agreement, Sponsor's written instructions relating to the Study (including the Study Protocol) and/or ICH-GCP guidelines and / or all applicable Standards. All the deviation from the Protocol need to be notified to Sponsor and CRO.

(ii) Institute shall be responsible for all the medical management expenses for the injury caused by negligent acts or omissions or intentional, reckless or willful malfeasance by Investigator, the Institution, or the Study Staff .

10.4 The Investigator, jointly and severally with Institution, will indemnify and hold the CRO, the Sponsor and their affiliated corporations, successors, directors, trustees, officers, employees

and agents harmless from any and all Liabilities suffered by same as a result of a claim asserted against same, arising, or are alleged to arise, from;

(a) negligence or intentional or gross fault on the part of the Institution, Investigator, or any other Study staff, personnel involved in the performance of the Study;

(b) activities contrary to the provisions of this Agreement, including a failure to use the Study Vaccine in compliance with the Protocol or to adhere to the terms of the Protocol;

(c) the Investigator's failure to obtain IRB review and approval;

(d) the Investigator's failure to obtain proper written informed consent from the Subjects; or

(e) a breach of any applicable laws by the Institution, Investigator, or any other Study personnel involved in the performance of the Study.

In the event a claim or action is or may be asserted, an Institution Indemnitee shall have the right to select and to obtain representation by separate legal counsel. If an Institution Indemnitee exercises such right, all costs and expenses incurred by such Institution Indemnitee for such separate counsel shall be fully borne by the Institution Indemnitee; provided, that without CRO/Sponsor prior written consent, the Institution Indemnitee shall make no admission to, or any settlement or agreement with, any person or party who is in any manner related to the Liabilities for which indemnification may be sought.

The obligations of this section shall survive termination of this Agreement.

Article 11 – Limitation of Liability

Except for as provided in 10.1 and 10.3, whether attributable to contract, tort, warranty, negligence, strict liability or otherwise, Sponsor/CRO's liability for any claims, damages, losses or liabilities arising out of or related to this Agreement or the Services performed hereunder shall not exceed the amounts paid by CRO to Investigator and/or Institution for Services under this Agreement.

IN NO EVENT SHALL EITHER PARTY BE LIABLE HEREUNDER FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR SPECIAL DAMAGES (INCLUDING BUT NOT LIMITED TO LOST PROFITS AND LOSS OF USE OF FACILITIES) SUSTAINED BY THE OTHER PARTY OR ANY OTHER INDIVIDUAL, THIRD PARTY OR OTHER ENTITY FOR ANY MATTER ARISING OUT OF OR PERTAINING TO THE SUBJECT MATTER OF THIS AGREEMENT. THE PARTIES EXPRESSLY ACKNOWLEDGE THAT THE FOREGOING LIMITATIONS HAVE BEEN NEGOTIATED BY THE PARTIES AND REFLECT A FAIR ALLOCATION OF RISK.

Article 12- Insurance

12.1 Sponsor Insurance: Sponsor shall at all times during the term of this Agreement obtain and maintain at its own cost and expense, clinical trial insurance policy, with respect to its activities

hereunder as required by the laws of India or laws as per the country where the clinical trial shall be conducted. Such insurance shall be placed at commercially appropriate levels of insurance.

12.2 Institution Insurance: Institution shall maintain medical professional liability insurance with limits in accordance with the laws of India or laws of the country where the clinical trial shall be conducted, for each medical professional involved in the Study or require that each medical professional maintain such insurance.

12.3 Evidence of Insurance: Upon request, Sponsor and Institution respectively, will provide to each other a certificate of insurance evidencing such coverage.

Article 13 - Human Rights

Institution represents that, with respect to employment and conducting the Study under this Agreement, Institution will comply with all applicable human rights/employment laws /labour laws, including but not limited to compliance with rules and regulations governing child labor, forced labor, safe and healthy work place, minimum wages, employee non-discrimination etc.

Article 14 - Anti-Bribery and Anti-Corruption

The Institution and Investigator represent and warrant that they shall not, directly or indirectly, take any action which would cause them, or their employees and sub-investigators to be in violation of any anticorruption or anti-bribery law or regulations applicable to the Investigator ("Anticorruption Laws").

Article 15 – Equipment

With respect to any equipment ("Loaned Equipment") provided to Institution by CRO or Sponsor exclusively to perform the Services pursuant to this Agreement Institution agrees that no title to nor any proprietary rights related to the Loaned Equipment is transferred to Institution, that the Loaned Equipment will be used only for the Study and only as described in the Protocol and any other written directions provided by CRO/Sponsor, that the Loaned Equipment will not be transferred by Institution to the possession of any third party without the written consent of CRO/Sponsor, and that, at the completion of the Study or at CRO's/Sponsor's request, Institution will return the Loaned Equipment and all related training materials and documentation to CRO /Sponsor.

(a) Investigator and Study Staff will attend scheduled training to use the Loaned Equipment following reasonable advance notice of scheduling. The Loaned Equipment will be kept in a safe and secure location and Institution will be responsible for any theft, damage, or loss to the Loaned Equipment other than normal wear and tear. Institution will be responsible for arranging and paying for any required electricity supply, backup power supply, internet connection, telephone line, and/or facsimile line as necessary to use the Loaned Equipment. Institution shall also be responsible for maintenance cost and annual calibration cost which is required to keep the loaned equipment in a working condition. If the Institution fails to return the Loaned Equipment within the timeframe specified by CRO/Sponsor, the Institution will be responsible for reimbursing CRO/Sponsor for any penalties, late fees, and/or replacement costs.

(b) Institution acknowledges that the Loaned Equipment may involve valuable patent, trademark, trade name, trade secret, and other proprietary rights of the Loaned Equipment manufacturer. Institution will not violate and will take appropriate steps and precautions to ensure that those with access to the Loaned Equipment do not violate these proprietary rights, including, without limitation:

(i) not removing any label or notice of Loaned Equipment ownership or other rights,
(ii) not making any copy, reproduction, changes, modification, or alteration of any software or firmware included with the Loaned Equipment or
(iii) not disassembling or decompiling any such software or firmware or otherwise attempting to discover any source code or trade secret related to such software or firmware.

Article 16 – Force Majeure and Delays

In the event either Party shall be delayed or hindered or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, failure of power, restrictive government or judicial orders, or decrees, riots, insurrection, war, Acts of God, inclement weather or other similar reason or cause beyond that Party's control, then performance of such act (except for the payment of money owed) shall be excused for the period of such delay; provided the Party provides notice of the existence of and reason for such nonperformance or delay in specific detail. In the event of a delay for a consecutive of 90 days, the non-affected Party will have right to terminate this Agreement by serving written notice to the other Party.

Article 17 – Applicable Law

This Agreement shall be construed, governed, interpreted, and applied in accordance with the laws of India and dispute under this Agreement and shall be subjected to the exclusive jurisdiction of courts of the City of Pune without regard to its conflict of laws provisions.

Article 18 - Recordkeeping and Regulatory Inspection:

18.1 Throughout the term of this Agreement, Institution/Investigator shall maintain and Investigator shall require Study Staff to maintain the complete and accurate books and records (including scientific, clinical and financial records) pertaining to all work performed and expenses incurred hereunder in connection with the Study and preserve them as per the directions of Sponsor/CRO for a minimum of fifteen (15) years from the date of completion of the Study or termination of this Agreement, whichever is earlier, or such longer period as required by the Protocol and the applicable laws and requirements. Archival of these records will be with Institution. Sponsor and its representatives shall have access to these records during the period of 15 years stated above. If required, Institution shall provide the copies of these records to Sponsor.

18.1.1 Sponsor or its designee shall have the right upon prior written notice to have their representatives review and copy all books and records of Investigator, the trial Site and the Study Staff relating to the Study, including without limitation books and records relating to any funds expended hereunder in connection with the Study. In each case access to such books and records

shall occur during regular business hours (or such other agreed time) following reasonable notice to Institution whose records are sought for review.

18.1.2 Sponsor or its designee upon reasonable advance notice, and during regular business hours (or such other agreed time), shall have the right to access the trial site to carry out Sponsor's rights and obligations hereunder and to inspect such trial site's facilities used in the conduct of the Study. The Parties agree to maintain the confidentiality of any subject-identifiable medical records should such information be made accessible under this Article 18.1.2.

18.2 The Investigator/Institution shall notify the Sponsor/CRO immediately by telephone or facsimile in case they receive any communication from Food and drug Administration or any other governmental or regulatory body with regard to Inspection/Audit of the Institution's facility relating to the Study during the term of this Agreement and shall allow CRO/Sponsor to be present at the inspection or participate in any response to the action, and provide to Sponsor/CRO copies of all materials correspondence, statements forms and records which the site receives, obtains or generate pursuant to any such Inspection. Investigator and Institution agrees to promptly take any reasonable actions requested by CRO/Sponsor to cure deficiencies noted during an inspection or audit.

Article 19 – Electronic Record and Electronic Signature

Investigator/ Institution acknowledges that Electronic Records (defined hereinafter), Electronic Signatures (defined hereinafter), and handwritten signatures executed to Electronic Records, utilized for capturing study related data and for performing services under this Agreement, will be trustworthy, reliable, and are equivalent to paper records and handwritten signatures executed on paper.

As defined in 21 CFR Part 11 "Electronic record" shall mean any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system. "Electronic signature" shall mean a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

Investigator/ Institution shall remain accountable and responsible for actions initiated under its Electronic Signature.

Article 20 – Representations and warranties

The Parties each represent and warrant that the execution, delivery and performance of this Agreement does not conflict with, violate or breach any agreement to which it is a party and no Party will enter into any, agreements, assignments or encumbrances binding on it or its respective Affiliates inconsistent with the provisions of this Agreement.

Article 21 - Assignment:

No Party may assign this Agreement or any interest hereunder without the prior written consent of other Party; provided, however, that Sponsor may assign this Agreement to any corporation with which it may merge or consolidate or to which it may sell all or substantially all of its assets, without obtaining the prior written consent of Institution. In the event of any assignment by any Party permitted under this Agreement, such assignment will be effective only if (i) the assignee has the requisite power, authority and capability to fulfill all obligations of the assignor Party under this Agreement and (ii) such assignee agrees in writing to other Party, in a form reasonably acceptable to the other Party, to fulfill all obligations and liabilities of the assignor Party under this Agreement. Each Party will promptly notify other Party of any such assignment. To the extent permitted above, this Agreement shall be binding upon and inure to the benefit of the Parties and their permitted successors and assigns.

Article 22 – Severability

If any provision(s) of this Agreement should be illegal or unenforceable in any respect, the legality and enforceability of the remaining provisions of this Agreement shall not be affected. In the event that the terms and conditions of this Agreement are materially altered as a result of this Article 20, the Parties will renegotiate the terms and conditions of this Agreement to resolve any inequities, adhering as closely as possible to the original intent of the Parties.

Article 23 – Waiver / Modification of Agreement

No waiver, amendment, or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of all Parties. Failure by a Party to enforce any rights under this Agreement shall not be construed as a waiver of such rights, nor shall a waiver by a Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

Article 24 – Miscellaneous

24.1 Institution will obtain written consent from staff involved in the Study that allows Sponsor, Sponsor affiliates, and third party suppliers working for Sponsor or its affiliates to hold and process personal data provided with respect to Study Staff anywhere in the world, both manually and electronically, for all purposes relating to the performance of this Agreement, for the purposes of administering and managing the business activities of any company in the SPONSOR group of companies, and for compliance with applicable procedures, laws, and regulations. Investigator consents to the use, storage and processing of his/her personal data as set out above.

24.2 This Agreement, including the annexed Schedules and Appendices , sets forth the entire understanding between the Parties herein, and there are no other understandings or promises, written or verbal, not set forth herein, relating to the subject matter hereof and supersedes all other prior agreements, discussions whether oral or in writing. This Agreement may not be changed or supplemented, except by a writing executed by all Parties.

24.3 All legal notices to be given by either Party to the other shall be made in writing by hand delivery or by registered or certified mail, return receipt requested or by other method reasonably capable of proof of receipt thereof and addressed to the Parties at their respective addresses first set forth above to the attention of:

If to the Institution, to:

MGM Medical college and hospital N-6 Cidco Aurangabad-431003,MH,India
Name: Dr. Rajendra Bohra
Designation: Dean
Address: MGM Medical College and hospital N-6 Cidco Aurangabad-431003, MH, India
Phone No.: 9225304660
Email: rajbohra@msn.com

If to the Investigator, to:

Dr. Tayade Deepak Narayan

MGM Medical College and Hospital N-6 Cidco Aurangabad431003, MH, India
Name: Dr. Tayade Deepak Narayan
Designation: Assistant Professor of Community Medicine
Address: MGM Medical College and Hospital N-6 Cidco Aurangabad431003, MH, India
Phone No.: 7776900089 / 8788416747
Email: drtayadepsm@gmail.com

If to the CRO, to:

Name: Mr. Mandar Vaidya, Director - Operations
DiagnoSearch Life Sciences Pvt. Ltd
702, Dosti Pinnacle, Plot No. E-7, Road No. 22,
Wagle Industrial Estate, Thane- 400604,
Maharashtra, India
Name: Mr. Mandar Vaidya
Phone No.: 022 6777 6314
Email: mandar.vaidya@diagnosearch.com

If to the Sponsor, to:

Dr. Hitt Sharma
Additional Medical Director
Serum Institute of India Private Limited 212/2 Hadapsar, Pune 411 028, India
Phone: 91-20-26602451
Facsimile: 91-20-26993921
Email: drhjs@seruminstitute.com

With a copy to:
Name: Makarand Karkare, General Counsel
Serum Institute of India Private Limited,
Sarosh Bhavan, 16/B-1, Dr. Ambedkar Road
Pune 411001
Phone: 91-20-26100341
Email: mac@seruminstitute.com

Or to such other address and any Party may designate in writing from time to time to the other. Any notice shall be effective as of its date of receipt.

24.4 The Parties hereby agree that, considering the current scenario of Novel COIVD 19 pandemic and non availability of stamp papers, the Agreement shall be executed on the plain paper and subsequently upon availability the stamp paper signed / initialed by all the Parties shall be appended to the Agreement which shall form an integral part of the Agreement.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed in multiple counterparts by their duly authorized representatives.

FOR Principal Investigator:

By: Tayade Date 11 May 2020
Name: Dr. Tayade Deepak Narayan
Title: Principal Investigator

FOR AND ON BEHALF OF:
MGM Medical College and Hospital
N-6 Cidco Aurangabad-431003, MH, India

By: Date 11 May 2020
Name: Dr. Rajendra Bohra
Title: Dean

FOR AND ON BEHALF OF:
DiagnoSearch Life Sciences Pvt. Ltd.

By: Date May 08, 2020
Name: Gajendra Sharma
Title: Controller Finance & Accounts

FOR AND ON BEHALF OF:
Serum Institute of India Pvt. Ltd.

By: Date 8th May, 2020
Name: Dr. Hitt Sharma
Title: Additional Medical Director

SCHEDULE A
PROTOCOL NUMBER: SII-rBCG/COVID-19/IN-01
CLINICAL TRIAL PROTOCOL SYNOPSIS

STUDY TITLE	A Multicenter, Phase III, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy of Recombinant BCG VPM1002 in Reducing Infection Incidence and Disease Severity of SARS-COV-2/COVID-19 Among High-Risk Subjects
SPONSOR	Serum Institute of India Pvt. Ltd.
CLINICAL RESEARCH ORGANIZATION (CRO)	DiagnoSearch Life Sciences Pvt. Ltd.
PROTOCOL ID	SII-rBCG/COVID-19/IN-01
CLINICAL DEVELOPMENT PHASE	Phase III
INDICATION	Protection of high-risk population from SARS-CoV-2/COVID-19 through immune boost/activation by rBCG (VPM1002) vaccination
NUMBER OF SITES	Approximately 40 sites will be initiated to enroll the required population
STUDY POPULATION	A total of 5946 male and female adults ≥18 years of age who are at a high risk of SARS-CoV-2/COVID-19 infection
DURATION OF PARTICIPATION	The maximum duration of study participation for a subject will be 194 days

STUDY RATIONALE

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection is accelerating globally leading to an increase in morbidity and mortality. Although individuals of any age can acquire SARS-CoV-2/COVID-19, certain individuals are at a higher risk of infection with SARS-CoV-2/ COVID-19. The high-risk group includes the health care workers (HCW) (physicians and paramedical staff) working amid SARS-CoV-2/COVID-19 infected patients and all other people including household contacts of SARS-CoV-2/ COVID-19 confirmed patients or people currently residing or working in SARS-CoV-2/ COVID-19 hotspots/outbreak areas where there is a high risk of transmission of COVID-19 infection. Though SARS-CoV-2/ COVID-19 infection may cause mild symptoms in many, nearly 14% develop severe disease that requires hospitalization and oxygen support, and 5% require admission to an intensive care unit (ICU). In severe cases, COVID-19 can be complicated by the acute respiratory distress syndrome, sepsis, septic shock and multiorgan failure with an estimated case fatality of 3.5% in China.

The COVID-19 pandemic is rapidly worsening in all parts of the world, overwhelming health systems. There is a serious threat to HCW capacity in a thickly populated country like India. Also, reports from all

over the world demonstrate that the disease takes a severe course in the elderly people and people with co-morbid conditions leading to higher mortality rates. Thus, there is an urgent need to ensure the safety and health of existing HCWs and all other people living in SARS-CoV-2/COVID-19 infected areas where there is a high risk of disease transmission and find strategies to reduce the incidence, duration and intensity of SARS-CoV-2/COVID-19 infection among such population. Evidence from experimental studies suggest that Bacille Calmette Guérin (BCG) vaccine has beneficial heterologous effects and proven antiviral and immune modulatory properties that protect against infectious diseases other than tuberculosis. BCG vaccine can potentiate immune responses to other vaccines through induction of trained innate immunity and heterologous adaptive immunity. Based on this evidence it is hypothesized that BCG vaccination may induce protection against susceptibility to SARS-CoV-2/COVID-19 infection. VPM1002, a genetically modified BCG vaccine, is being developed with an aim to replace BCG by a vaccine that has a better safety profile and superior efficacy. Evidence from pre-clinical and clinical studies demonstrate that VPM1002 is safer and more immunogenic. It is therefore anticipated that VPM1002 will perform well and may improve the clinical course of SARS CoV-2/COVID-19 infection. Even though vaccine manufacturers across the globe have embarked on rapid development, SARS-CoV-2 vaccines are many months away from widespread availability to the masses. VPM1002 rBCG may act to ameliorate disease severity and mitigate transmission. Even moderate individual efficacy can have dramatic impact at population level directly by reducing severe disease burden on health systems and possibly indirectly by reducing the disease transmission and spread thereby sustaining health systems through this crisis, using a safe, affordable and available vaccine. The manufacture of VPM1002 using state-of-the-art production methods will help hasten the production of millions of doses in a very short time and thus would be beneficial in the current situation. Investment in large scale manufacturing will depend on strong evidence of efficacy from randomized evaluation. Thus, the current study will evaluate the efficacy of VPM1002 in reducing infection incidence and disease severity of SARS-CoV-2/COVID-19 infection including hospital admissions and clinical consequences of SARS-CoV-2 infection in the high-risk subjects.	
INVESTIGATIONAL VACCINE	**VPM1002** The active ingredient of the recombinant BCG vaccine, VPM1002 is Mycobacterium bovis rBCG ΔureC::hly, freeze-dried and standardized to number of viable colony forming units (CFU) of mycobacteria per application available as lyophilized cake. After reconstitution with water for injection, 1 dose (0.1 ml) contains VPM1002, live, 2-8 x 10e5 CFU. A single dose of 0.1 ml of the reconstituted vaccine is to be administered as an intradermal injection in the arm, over the distal insertion of the deltoid muscle onto the humerus (approximately one

	third down the upper arm) OR lateral to posterior aspect of forearm.
COMPARATOR	**Placebo,** 0.1ml 0.9% sodium chloride, will be used as the comparator
PRIMARY OBJECTIVE	1. To reduce the incidence or severity of SARS CoV-2/COVID-19 infection up to 6 months (180 days) following vaccine administration among health care workers (HCW) 2. To reduce the incidence or severity of SARS CoV-2/COVID-19 infection up to 6 months (180 days) following vaccine administration among other high-risk subjects
PRIMARY ENDPOINT	1. Number of subjects with laboratory confirmed SARS-CoV-2/COVID-19 infection among HCWs 2. Number of subjects with laboratory confirmed SARS-CoV-2/COVID-19 infection among other high-risk subjects 3. Number of laboratory confirmed SARS-CoV-2/COVID-19 infection with severe, critical or life-threatening disease severity as assessed by the Investigator among HCWs 4. Number of laboratory confirmed SARS-CoV-2/COVID-19 infection with severe, critical or life-threatening disease severity as assessed by the Investigator among other high-risk subjects
SECONDARY OBJECTIVE	1. To reduce the duration of SARS-CoV-2/COVID-19 symptoms in HCWs 2. To reduce the duration of SARS-CoV-2/COVID-19 symptoms in other high-risk subjects 3. To reduce severe SARS-CoV-2/COVID-19 disease outcomes in HCWs 4. To reduce severe SARS-CoV-2/COVID-19 disease outcomes in other high-risk subjects 5. To reduce severe SARS-CoV-2/COVID-19 disease outcomes in elderly subjects (≥ 60 years of age) 6. To reduce severe SARS-CoV-2/COVID-19 disease outcomes in subjects with co-morbidities 7. To assess the safety of VPM1002 when administered as a single dose in subjects at a high-risk of disease exposure during the SARS-CoV-2 outbreak
SECONDARY ENDPOINT	1. Duration of SARS-CoV-2/COVID-19 symptoms in HCWs 2. Duration of SARS-CoV-2/COVID-19 symptoms in other high-

	risk subjects 3. Severe Disease Outcomes in HCWs: ● Cumulative incidence of hospital admission among HCWs due to documented SARS-CoV-2 infection ● Cumulative incidence of ICU admission among HCWs due to documented SARS-CoV-2 infection ● Cumulative incidence of requirement of mechanical ventilation among HCWs due to documented SARS-CoV-2 infection ● Cumulative incidence of deaths among HCWs due to documented SARS-CoV-2 infection 4. Severe Disease Outcomes in other high-risk subjects ● Cumulative incidence of hospital admission among other high-risk subjects due to documented SARS-CoV-2 infection ● Cumulative incidence of ICU admission among other high-risk subjects due to documented SARS-CoV-2 infection ● Cumulative incidence of requirement of mechanical ventilation among other high-risk subjects due to documented SARS-CoV-2 infection ● Cumulative incidence of deaths among other high-risk subjects due to documented SARS-CoV-2 infection 5. Severe Disease Outcomes among in elderly subjects (≥ 60 years) ● Cumulative incidence of hospital admission among elderly subjects due to documented SARS-CoV-2 infection ● Cumulative ICU admission among elderly subjects due to documented SARS-CoV-2 infection ● Cumulative incidence of requirement of mechanical ventilation among elderly subjects due to documented SARS-CoV-2 infection ● Cumulative incidence of deaths among elderly subjects due to documented SARS-CoV-2 infection 6. Severe Disease Outcomes among subjects with Co-morbidities (including hypertension, diabetes mellitus, COPD, asthma, any other cardiac conditions) ● Cumulative incidence of hospital admission among subjects with co-morbidities due to documented SARS-CoV-2 infection ● Cumulative incidence of ICU admission among subjects with

	co-morbidities due to documented SARS-CoV-2 infection ● Cumulative incidence of requirement of mechanical ventilation among subjects with co-morbidities due to documented SARS-CoV-2 infection ● Cumulative incidence of deaths among subjects with co-morbidities due to documented SARS-CoV-2 infection 7. Incidence of Adverse Events (AE) and Serious Adverse Events (SAE)
EXPLORATORY OBJECTIVE	Immunogenicity analysis will be performed in a subset of approximately 500 subjects who provide consent for the same. Blood samples will be collected at baseline prior to vaccine administration and at 3 months post vaccine administration

STUDY DESIGN

This is a placebo controlled, randomized, double blind, adaptive study to evaluate the reduction in infection incidence and severity of SARS-CoV-2/ COVID-19 infection among high-risk subjects by enhanced trained immune response through VPM1002 vaccine.

A total of 5946 subjects who fulfil the criteria for high-risk will be enrolled across various hospitals treating COVID-19 patients in India. The Investigator/site staff at each site will inform the Health care workers (HCWs) about the clinical trial while other high-risk subjects (household contacts or people living or working in SARS-CoV-2/ COVID-19 infected areas) will be recruited through contact tracing of confirmed SARS-CoV-2/ COVID-19 cases and through posters/advertisements.

All interested subjects will be requested to download a mobile application/portal designed for the study on their smart phone/tablet/laptops and to register themselves. The study has a screening period of up to 14 days during which subjects who provide informed consent will be assessed for eligibility criteria which includes RT-PCR testing to rule out SARS-CoV-2/ COVID-19 infection. Among the household contacts, the laboratory sampling to rule out SARS-CoV-2/ COVID-19 infection will be done 14 days after the last contact with the confirmed SARS-CoV-2/ COVID-19 patient while in other high risk subjects, the laboratory sampling will be performed on the day of screening. The subjects who fulfill all the eligibility criteria will be randomized in a 2:1 ratio to receive a single dose (0.1 ml) of either VPM1002 or placebo, administered as an intradermal injection. The preparation and administration of the study vaccine will be done by designated unblinded personnel who will not participate in any of the clinical study evaluations. Considering that India is currently in a lockdown situation, the vaccine administration may happen at the study clinic or at the place of isolation of the subject. All the study personnel working with the subjects will wear personal protective equipment with adequate gloves as recommended by Indian Council of Medical Research (ICMR) and Ministry of Health and Family Welfare (MoHFW). The study vaccine should be administered within 48 hours of randomization.

Post vaccination the subjects will be observed for 20 minutes for any hypersensitivity/anaphylactic

reactions.

While the monthly follow-up visits are telephonic for all subjects, in case of HCWs, these may be clinic visits depending on the circumstances (e.g., if they are reporting for their routine duty at the study site). Subjects can consult/visit the study site or request for home visit anytime during the study for emergencies or any safety concerns.

Follow-up information must be entered by the subjects regularly. In case the follow-up information is not completed within 7 days, subjects will receive reminders via the mobile application/portal and further telephonic reminders, if required. In case the subjects do not answer the telephone, information on subject's well-being and symptoms may be obtained from alternate contacts. Additionally, follow-up information regarding hospital admission, ICU admission or death will also be retrieved from the hospital.

The duration of follow-up will be based on the results of interim analysis however the maximum follow-up period will be up to 180 days.

Immunogenicity analysis is planned in a subset of approximately 500 subjects. Immunogenicity samples will be collected, from approximately 500 subjects who provide consent for the same, at two time-points, at baseline prior to vaccine administration and at the end of at 3 months (± 14 days) post vaccination. Based on the circumstances, if necessary, the immunogenicity sampling may be done at subject's place of isolation.

During the follow-up, if any subject experiences fever AND cough and/or shortness of breath, all attempts should be made to obtain a throat (nasopharyngeal and/or oropharyngeal) swab or any appropriate sample as directed by the treating physician. Subjects can consult/visit the study site anytime during the study for emergencies or any safety concerns. The sample will be collected by trained health care professionals who shall wear appropriate PPE with adequate gloves (as recommended by ICMR) while collecting the sample from the subject and maintain proper infection control when collecting specimens.

All treatment protocols for HCW and household contacts as recommended by ICMR and MoHFW will be permitted throughout the duration of the study.

Subjects will receive a notification on the mobile application/portal whenever the study ends and will be requested to fill in an end-of- study questionnaire. A subject is considered to have completed the study if he/she completes the end-of-study questionnaire. The end of the study is defined as the last subject's completion of end of study questionnaire in the mobile application/portal.

Interim analyses are planned at 2-monthly intervals during the study to assess the efficacy and futility based on which the study will be stopped.

An independent Data and Safety Monitoring Board (DSMB) will be appointed to review the safety and primary endpoint data for efficacy/futility. Safety data pertaining to incidences of SARS-CoV-2/COVID-19 infections, hospitalizations, ICU admissions and deaths and interim analysis data will be provided to the DSMB, at 2-monthly intervals. The DSMB will provide their observations to the sponsor with recommendations as to whether there are safety concerns and whether the study should continue without change, be modified, or terminated. The DSMB recommendations will be carefully considered by the

sponsor. The final decision rests with the sponsor.	
STUDY ELIGIBILITY CRITERIA	
INCLUSION CRITERIA	Subjects are eligible to be included in the study only if all of the following criteria apply 1. Male or Female subjects ≥ 18 years of age at high-risk of SARS-CoV-2/COVID-19 infection Subjects with high-risk of infection to COVID-19 cases defined as: ● Health care workers (physicians, nurses, ward boys, paramedical staff) working in direct contact with COVID-19 patients ● Other high-risk subjects: o House-hold contacts* defined as a resident in the same dwelling as a confirmed case of COVID-19 o People currently residing or working in COVID-19 hotspots/outbreak areas with a history of contact* with suspected or confirmed case of SARS-CoV-2/COVID-19 infection * Definition of contact ● Face-to-face contact with a suspected/confirmed case (as applicable) within 1 meter and for more than 15 minutes ● Direct physical contact with a suspected/confirmed case (as applicable) ● Direct care for a patient with a confirmed COVID-19 disease without using proper personal protective equipment, OR, ● Other situations as indicated by local risk assessments Adapted from WHO Definition [**Error! Reference source not found.**] 2. Test negative for SARS-CoV-2 infection (RT-PCR test) at screening ● For House-hold contacts, the sampling should be performed 14 days after the last contact with the confirmed SARS-CoV-2 patient and the result should be negative. ● For HCWs and other high- risk subjects, the sampling can be done on the day of screening 3. Capable of giving informed consent
EXCLUSION CRITERIA	Subjects are excluded from the study if any of the following criteria apply 1. Previous history of Tuberculosis or known active Mycobacterium tuberculosis infection 2. Received BCG vaccine within one year prior to screening

	3. Fever (≥ 38 ºC/100.4°F) or any other respiratory symptoms/illnesses within the past 14 days 4. Pregnant or lactating women 5. Women of child-bearing potential not agreeing to use adequate contraception 6. Current active viral or bacterial infection 7. Expected vaccination during the study period, independently of the type of vaccination 8. Severely immunocompromised subjects. This exclusion category comprises a) subjects with known infection by the HIV; b) subjects with solid organ transplantation; c) subjects with bone marrow transplantation; d) subjects under chemotherapy/radiotherapy; e) subjects with primary immunodeficiency; g) treatment with any anticytokine therapies. h) treatment with oral or intravenous steroids defined as daily doses of 10mg prednisolone or equivalent for longer than 3 months from the time of screening, or probable use of oral or intravenous steroids in the following four weeks 9. Active solid or non-solid malignancy or lymphoma within the prior two years 10. Individuals known to be hypersensitive to any component of the vaccine 11. Eczema or other significant skin lesion or infection at the site/s of injection. 12. Any other medical condition which in the opinion of the investigator may affect the subject's safety or study participation and conduct
SAFETY ASSESSMENTS	Subjects will be observed for 20-minutes post vaccination for any hypersensitivity/ anaphylactic reactions. After this, data regarding documented SARS-CoV-2/COVID-19 infections, hospitalizations, any other AEs will be obtained via various short questionnaires configured in the mobile application/portal. The investigators will review the safety data and if required, may call the subject to obtain more details or may ask the subject to visit the site for further evaluation. All AEs and SAEs will be collected from the time of informed consent

	until the end of study. The investigator/designee will report all SAEs, irrespective of causality or expectedness to the sponsor, DCG(I) and ethics committee (IEC) within 24 hours of occurrence of the SAE.
SAMPLE SIZE	This is adaptive design based on Bayesian approach. Since sufficient data is not available for COVID-19 disease if assumptions change then sample size re-estimation can be done. For initial sample size calculation, we used Fisher's exact test for testing two independent proportion in terms of Relative Risk (RR) [Hazard ratio (HR) for cox proportional hazard model], considering following assumptions: RR under H_1 = 0.7 (30% reduction in incidence of laboratory confirmed SARS-CoV-2/COVID-19 infection observed in Other High-Risk Subjects / HCWs. Same assumption is used for two primary endpoints defined for each strata), Power = ~ 90% α = 0.0125 (one-sided, adjusted for two primary endpoints analyzed for strata: Other High-Risk Subjects) Allocation Ratio: VPM1002 group: Placebo group = 2:1 The study is separately powered in "Other High-Risk Subjects" and "HCWs" treating them as strata. ● Other High-Risk Subjects: Assumption - Percentage of "Other High Risk" Subjects in Placebo group showing laboratory confirmed SARS-CoV-2/COVID-19 infection = 20% (same assumption is used for two primary endpoints) Thus, for stratum "Other High-Risk Subjects", the total sample size calculated is 2228 evaluable subjects, 1485 in VPM1002 group and 743 in Placebo group. Considering approximately 10% drop out rate we need to randomize 2478 subjects, 1652 in VPM1002 group and 826 in Placebo group. ● HCWs Assumption - Percentage of HCWs in Placebo group showing laboratory confirmed SARS-CoV-2/COVID-19 infection = 15% (same assumption is used for two primary endpoints) Similarly, for stratum "HCWs" for the total sample size calculated is 3119 evaluable subjects, 2079 in VPM1002 group and 1040 in Placebo group. Considering approximately 10% drop out rate we need to randomize 3468 subjects, 2312 in VPM1002 group and 1156 in

	Placebo group. Thus, we require 5946 randomized subjects in two strata distributed in 2:1 ratio in two groups VPM1002 and Placebo.
STATISTICAL ANALYSIS	Data will be reported quantitatively. Efficacy analyses will be performed on FAS population using the intention-to-treat principle. Two primary endpoints for each strata are "Number of HCWs / Other High-Risk Subjects with laboratory confirmed SARS-CoV-2/COVID-19 infection" and "Number of HCWs / Other High-Risk Subjects with laboratory confirmed SARS-CoV-2/COVID-19 infection with severe, critical or life-threatening disease severity as assessed by the Investigator". These endpoints are treated as Time-to-event data. The endpoints represent incidence of first laboratory confirmed SARS-CoV-2/COVID-19 infection with severe, critical or life-threatening disease severity as assessed by the Investigator. The events will be considered till time point when study is stopped due to decision rule of interim analysis or patient is discontinued due to any reason or followed up to maximum follow-up of 180 days (6 months follow-up). To analyze this endpoint hazard ratio (HR) is calculated and compared between VPM1002 vaccine group and Placebo group. Cox proportional hazards model will be used treating treatment groups as fixed effects and hospital, age, comorbidities, severity, time to recovery will be evaluated as covariates for including them in the model. Secondary endpoints related to severe disease outcomes in HCWs, Other high risk subjects, Elderly subjects (≥ 60 years) and subjects with co-morbidities measured in terms of incidence such as cumulative incidence of hospital admission due to documented SARS-CoV-2 infection, Cumulative incidence of ICU Admission due to documented SARS-CoV-2 infection, Cumulative incidence of death due to documented SARS-CoV-2 infection, Cumulative incidence of requirement of mechanical ventilation due to documented SARS-CoV-2 infection will be analyzed using cox proportional Hazard model. Secondary endpoints related to duration such as Duration of SARS-CoV-2/COVID-19 symptoms in HCWs and Other high-risk subjects will be analyzed by analysis of covariance using mixed model analysis. Continuous baseline characteristics will be reported as mean and

	standard deviation or median and inter-quartile range, as appropriate. Categorical baseline characteristics will be reported as count and percentage. No statistical testing for baseline characteristics will be performed. Safety data related to AE, SAE will be analyzed as frequency and % by System organ Class (SOC) and Preferred term (PT) Coded using MedDRA. The frequency and % will be provided for overall AEs, AEs by severity and relatedness.
INTERIM ANALYSIS	An interim analysis will be performed by the study statistician of the trial, once every 2 months. The results if available for futility or efficacy (with group level unblinding) will also be provided to the DSMB, once every 2 months along with safety data. In case of suggested futility or efficacy, the DSMB statistician may independently replicate the full data analysis before drawing conclusions. The Bayesian model used for primary endpoint yields a posterior distribution of the relative risk RR (hazard ratio (HR) of incidence rates). The posterior probability of the superiority hypothesis (RR < 1) will be calculated as well as the posterior probability of futility hypothesis (RR > 0.7). If during any of the interim analyses, the posterior probability of superiority is > 0.995 or the posterior probability of futility is > 0.99, a conclusion is reached, and the trial will be stopped. These posterior probability breakpoints have been chosen such that the type-1 error rate is <0.025 (similar to a two-sided alpha of 0.05) and the power of detecting superiority is > 90% if the true RR is 0.7.

SCHEDULE B
STUDY BUDGET AND PAYMENT SCHEDULE

No.	Budget Head	Unit	No. of Subjects	Unit Fees / Cost	Total
1	Investigator & Site Team Fees (Screening visit + vaccination)	Screening visit + vaccination	175	INR 6,500.00	INR 11,37,500.00
2	Investigator & Site Team Fees (Post screening visit data completion)	Post screening visit data completion	175	INR 4,700.00	INR 8,22,500.00
3	Investigator & Site Team Fees (End of study visit data completion)	End of study visit data completion	175	INR 2,000.00	INR 3,50,000.00
4	Transportation expenses for home visits (assumed average one per subject for High Risk Subject) *	Subject	100	INR 1,000.00	INR 1,00,000.00
5	Subject compensation (transportation expenses for site visits, if required) **	Subject			
	For Health care workers	04 visits (Per visit Rs. 500)	75	INR 2,000.00	INR 1,50,000.00
	For High Risk subjects	02 visits (per visit Rs. 500)	100	INR 1,000.00	INR 1,00,000.00
6	Advertisements, recruitment Related, Referrals expenses CRC marketing strategies, miscellaneous charges	Site	1	INR 10,000.00	INR 10000.00
7	Payment for screen failures ***	Screen failed subject**	18	INR 4,000.00	INR 72,000.00
8	Institutional overheads (applicable on Investigator & Site Team Fees and Payment for screen failures)	Percentage	25% on Sr. No.1,2,3		INR 5,77,500.00
9	Archival expenses	Site	1	INR 50,000.00	INR 50,000.00
	Total				**INR 33,69,500.00**

*	Transportation cost will be applicable for visits outside site i.e. for home visit of high risk subjects or in rare case Health Care workers as well
**	Average number of subjects estimated per site. Since recruitment will be competitive, the actual number per site may vary and even the proportion of Health Care worker and other High risk subjects may also vary accordingly subject compensation visits will also vary
***	Payment for screen failures refers to payment for the Investigator's and site team members' time towards activities conducted for screen-failed subjects. For each 10 eligible subjects, payment will be made for one screen failed-subject.
****	Cost of RT-PCR COVID test will be reimbursed.
*****	Expenses for medical care for related AEs and expenses related to treatment or compensation in case of related SAEs has not been included herein. These will be paid at actuals.
******	Personal Protective Equipment cost will be provided to the site.

In connection with the Study, Sponsor will pay in accordance with the terms set forth in the Budget (schedule B):

1. Recruitment for this Study will be through competitive enrolment, and Institution and Investigator may enroll more or less depending on the enrolment at other sites. Investigator agrees that enrolment in the Study will be restricted pursuant to the Protocol based on the Inclusion / Exclusion criteria. CRO/Sponsor retain the right, to be exercised at CRO's/Sponsor's sole discretion, to terminate this Agreement for any reason, including poor enrolment.

2. The Investigator /Institution shall complete and deliver the work to CRO/Sponsor (including any technical report and financial statement that may be required) by the date fixed in this Agreement or any additional period that may be granted by CRO/Sponsor. If the payment schedule on the face of this Agreement provides for a final payment upon completion of the work, this final payment shall be made only after satisfactory receipt of all deliverables called for under this Agreement, including any technical report and financial statement.

3. In full and complete consideration of Investigator's and Institution's participation in the Study and of their covenants and obligations hereunder, within the date agreed in the Agreement or any alternative that may be granted by the CRO/Sponsor (including submissions of technical report and financial statements that may be required under the Agreement), and to cover their respective costs connected with the conduct of the Study, CRO shall pay amount as set forth in Schedule B. Said amount is based on Subjects completing the Study in full compliance with the Protocol for whom completed case report forms have been delivered by Investigator to CRO/Sponsor or CRO's/Sponsor's designee and all queries have been resolved. The Parties agree that these payment terms are consistent with the principles of fair market value payments for the performance of Study-related activities. If the payment schedule on the face of this Agreement provides for a final payment upon completion of the work, this final payment shall be made only after satisfactory receipt of all deliverables called for under this Agreement, including any technical report and financial statement.

4. Institution agrees to apply all funds received from CRO, including all interest accrued on such funds, if any, toward the performance of the Study. Within the Study Budget as provided in Schedule B, Institution may adjust budget line item amounts as reasonably necessary for performance of this Agreement; provided, however, that such adjustments shall not exceed ten percent (10%) of any line item without the prior written approval of Sponsor. Without the prior written approval of Sponsor/CRO, the total payments to Institution shall not exceed the amounts set forth in the Study Budget.

5. If a subject does not complete the Study, the amount payable will be pro-rated according to the number of visits attended by said Subject; provided that, prior to any payment by CRO completed case report forms for such Subjects have been accepted by CRO/Sponsor.

6. There is no payment for Subjects who are chart screened, but who do not have a informed consent as required by the regulation for the research project and do not complete any of the Screening Visit procedures.

7. All payment obligations are conditioned upon Institution's and Investigator's compliance with the standards identified in this Agreement. CRO will not make payments for or, if payment has been made, Institution/Investigator will repay to CRO any payments for Study visits, procedures, or other work associated with a Study subject if CRO/Sponsor determine that the Study visits, procedures or other work associated with the subject was not conducted by Investigator, sub investigator or Study Staff in compliance with the Protocol, applicable law or regulation, or ICH/ GCP Guidelines.

8. Investigator and Institution are responsible for all applicable direct taxes including but not limited to State, Central and municipal taxes presently or hereafter imposed upon any and all such amounts, including but not limited to professional and incomes taxes, Wealth Tax, Transaction tax. However CRO agrees to pay any indirect tax that may be introduced by any local, state, Central Government / authority including but not limited to service tax, excise, Goods and service tax (GST) based on the revenue and /or out of pocket expenses that are paid/payable by CRO to the Investigator/Institution under this agreement.

9. The payments represent all Study costs, and no other money will be payable by CRO.

10. Payments (Investigator Grant, Institutional overheads and Patient Compensation) will be made on monthly basis for the amount proportional to the no. of subject visits completed in the preceding month. Site should submit the invoice for the completed subject visit at the end of each month. Sponsor/ designee will arrange to remit the funds to site within 45 days of receipt of correct invoice from the site. If for any reason, site is unable to randomize even one patient in the study, the advance payment(if applicable) will be returned to the Sponsor/ designee within a reasonable period (not exceeding 30 calendar days) on receipt of written communication from Sponsor/ designee to refund this amount.

11. Monthly invoices will be cleared by the Sponsor/ designee within 45 days of submission irrespective of the data being source verified by the monitors. However, site needs to ensure that source data is updated real time and electronic Case Report Form is filled within 05 working days of subject visit. While clearing the invoices at Sponsor/ designee end, in-house monitors will remotely review the compliance to the data entered vs. actual patient visit in the period of invoicing

12. Payment will be pro-rata based on the actual no. of visits completed by the subject.

13. Screen failures would be paid at 4000 INR per subject. Notwithstanding the foregoing, the maximum number of screen failures for which Investigator shall be compensated shall not exceed 10% of randomized subjects at site.

14. Reimbursement for any investigation performed for safety evaluation will be on actuals on submission of bills.

<u>Other Terms and conditions:</u>

1. Investigator acknowledges that the Study is a multicenter study and the recruitment for this Study will be through competitive enrolment, and investigator may enroll more or less depending on the enrolment at other sites. Investigator agrees that enrolment in the Study

will be restricted pursuant to the Protocol based on the inclusion / exclusion criteria. CRO / Sponsor retain the right, to be exercised at Sponsor's sole discretion, to terminate this Agreement for any reason, including poor enrolment.

2. Payment for drop outs or early terminated subjects would be pro-rated depending on the number of completed study visits. Invoice for completed visit will be raised at the end of each month.

3. If the payment towards the Institutional grant and subject compensation is paid to the investigator/institute directly by DiagnoSearch then it will be sole responsibility of the investigator/institute to pay the same to the concerned parties / individual (as applicable)

PAYMENT INSTRUCTIONS

1. All payments except subject compensation will be released after deduction of applicable taxes.

2. Payments will be made through cheque / bank transfer as per the payee details provided below.

Beneficiary Name	MGM Medical college ,Aurangabad
Bank Name:	IDBI bank
Bank Address	Adalat Road Branch, Survey No.20292,Ratnaprabha Building Kesarsinghpura Opp.LIC Bld.Aurangabad
Branch	Adalat Road Branch
Beneficiary Account No.	0376104000000107
TAX ID NUMBER (PAN)	AAATM4256E
IFSC Code	IBKL0000376

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Confidential

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Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA22977346562283U
Certificate Issued Date	:	07-Sep-2022 10:31 AM
Account Reference	:	NONACC (FI)/ kacrsfl08/ SHIVAJINAGAR1/ KA-SV
Unique Doc. Reference	:	SUBIN-KAKACRSFL0859351394205974U
Purchased by	:	GEORGE CLINICAL INDIA PRIVATE LIMITED
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	GEORGE CLINICAL INDIA PRIVATE LIMITED
Second Party	:	Dr SUDHIR GAJANAN KULKHARNI MGM MEDICAL COLLEGE
Stamp Duty Paid By	:	GEORGE CLINICAL INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	500 (Five Hundred only)

YMSSN (Branch) Authorised Signatory Bengaluru-560001

GEORGE CLINICAL INDIA PRIVATE LIMITED IN-KA22977346562283U RS. 500 07-SEP-2022 10:31 AM

Please write or type below this line

CLINICAL TRIAL AGREEMENT

Protocol # 417-201-00007

This Clinical Trial Agreement ("Agreement") dated as of the date of last signature and effective as of the date of last signature ("Effective Date") between

George Clinical India Private Limited, with principal offices located at Plot No.5, Prestige Khoday Towers, 12th Floor, Raj Bhavan Road, Bangalore –560 001, Karnataka, India("**CRO**")

and

Mahatma Gandhi Missions Medical College and Hospital, with a place of business at N-6 CIDCO, Aurangabad, Maharashtra 431003, India ("**Institution**")

and

Dr. Sudhir Gajanan Kulkharni, located at Department of Nephrology, MGM Medical College & Hospital, N-6 CIDCO, Aurangabad -431003, Maharashtra, India ("**Principal Investigator**").

"Party" means CRO, Institution or Principal Investigator equally, and "Parties" shall mean all of them.

BACKGROUND

By separate agreement, Otsuka Pharmaceutical Development & Commercialization, Inc. with a principal place of business at 2440 Research Boulevard, Rockville, Maryland 20850, United States ("Sponsor") has engaged George Clinical India Private Limited, a contract research organization with a principal place of business in the Plot No.5, Prestige Khoday Towers, 12th Floor, Raj Bhavan Road, Bangalore –560 001, Karnataka, Indiaacting as an independent contractor, to act on behalf of Sponsor for the purposes of transferring certain obligations in connection to this Agreement, said obligations including but not limited to carrying out the Trial (as defined below) as the investigational new drug application ("IND") holder in India, execution of the Agreement and payment administration for services performed. In addition, Sponsor has engaged Syneos Health, LLC, a contract research organization with a principal place of business at 1030 Sync Street, Morrisville, North Carolina 27560 USA and its affiliates acting as an independent contractor, to assist Sponsor with negotiating clinical agreements.

Sponsor wishes to support a clinical trial with Sponsor Drug (hereinafter defined) Sibeprenlimab, encoded 417-201-00007 entitled "A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Trial to Evaluate the Efficacy and Safety of Sibeprenlimab Administered Subcutaneously in Subjects with Immunoglobulin A Nephropathy" ("Protocol") to be conducted at Institution ("Trial") to involve patients participating in the Trial ("Trial Subjects").

The Parties agree as follows:

1. Investigators and Research Staff.

1.1 Principal Investigator. The Principal Investigator, being an employee/ of the Institution, will be responsible for the direction of the Trial in accordance with Applicable Law (hereinafter defined) and Institution policies. The Trial will be conducted under the supervision of the Principal Investigator at Mahatma Gandhi Missions Medical College and Hospital, at N-6 CIDCO, Aurangabad 431003, Maharashtra, India.

1.2 Sub-investigators and Research Staff. Principal Investigator may delegate duties and responsibilities to sub-investigators or research staff (sub-investigators and research staff collectively referred to as "Research Staff") who may be employees or consultants of the Institution or contracted third parties only to the extent permitted by Applicable Law governing the Trial conduct, as described below. Per ICH E6 R2, sections 4.2.5 and 4.2.6, as the Principal Investigator is responsible for supervising the Research Staff, he/she will ensure that only individuals who are appropriately qualified and trained assist in the conduct of the Trial and the Principal Investigator will ensure the integrity of the Trial-related duties and functions performed and any Trial Data (hereinafter defined) generated by the Research Staff.The Principal Investigator shall sign an undertaking in the form prescribed in Table 4 of the Third Schedule of the Rules .

1.3 Obligations of Institution and Principal Investigator. Institution and Principal Investigator will ensure that Research Staff is informed of and agree to abide by all terms of this Agreement applicable to the activities they performand shall also abide by the terms of any permissions and approvals for the conduct of the Trial in terms of applicable laws, including permission from the Central Licensing Authority for the Trial.Institution and Principal Investigator will assume all those responsibilities assigned under all applicable laws, rules, regulations, guidelines and standards including, without limitation, all relevant International Council forHarmonization Good Clinical Practice ("ICH GCP") guidelines and standards and the World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects" (2013), all applicable laws and guidance relating to clinical trials of medicines, the provisions of the New Drugs and Clinical Trials Rules, 2019 ("Rules") as may be amended from time to time, ethical guidelines for Biomedical Research on Human Participants issued by the Indian Council of Medical Researchand other applicable law, regulations, and governmental guidance, including without limitation, the laws of the Republic of India, all applicable laws relating to human rights, supply of medicines legislation, legislation relating to human tissue and biological samples, and all applicable laws relating to the confidentiality, privacy and security of Trial Subject information ("Applicable Law").The Principal Investigator as a signatory/confirming party to this Agreement acknowledges the liabilities and obligations as an 'investigator' contained in Rules.

1.4 No Substitution. Institution and Principal Investigator may not reassign the conduct of the Trial to a different investigator without prior written authorization from Sponsor. Any replacement principal investigator will be required to agree to the terms and conditions of this Agreement in a separate writing. In the event Sponsor does not approve a replacement principal investigator, Sponsor or CRO may terminate this Agreement in accordance with the termination provisions below.

1.5 Delegation of Duties by Principal Investigator. Principal Investigator may delegate duties and responsibilities to sub-investigators or research staff only to the extent permitted by Applicable Law governing the Trial conduct, as described below.

1.6 Compliance with Institutional Policies. Principal Investigator will comply with the policies and procedures of the organization(s) with which Principal Investigator is affiliated, including any applicable financial policies. Principal Investigator will notify Sponsor promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the parties will attempt to reach an appropriate accommodation.

1.7 Data Integrity. Data integrity is fundamental in the processing and disposition of Trial data collected and further used in decisions, related to Sponsor's product quality, safety, efficacy and compliance with regulatory requirements, that are made based on data that is recorded and reported from the Trial. This applies to all manual/paper-based data, electronic data, including metadata, and data in a hybrid format throughout the data lifecycle and allows for full reconstruction of GxP activities. Institution on behalf of itself and the Principal Investigator shall maintain appropriate documentation to support its compliance with these principals and furnish it promptly to Sponsor or CRO upon request. The Institution shall ensure that: (1) Only qualified and delegated staff conduct Trial activities at the Institution; (2) All ResearchStaff are trained in ICH E6(R2) & ALCOA+ Data Integrity procedures to conduct the Study activities as documented in the Protocol; (3) All Trial data (paper and electronic) is managed in accordance with ALCOA+ Data Integrity principles (e.g., strict adherence to data system access and zero tolerance to sharing of credentials); (4) all ResearchStaff understand the ownership and obligations to vigorously manage data controls at the Institution to prevent data falsifications; and (5) all ResearchStaff promptly document and escalate all potential data integrity issues to the Sponsor or the CRO within twenty-four (24) hours of knowledge of an issue.

2. Protocol. Institution and Principal Investigator will conduct the Trial in accordance with the Protocol (including any Protocol Amendments hereinafter defined), written instructions of CRO/Sponsor and Applicable Law.

2.1 Amendments. The Protocol may be modified only by a written amendment ("Protocol Amendment"), signed by Sponsor and the Principal Investigator. If applicable, the Parties acknowledge that Protocol Amendments are also subject to approval by the responsible Independent Ethics Committee ("IEC") and/or Regulatory Authority ("RA"). Sponsor may instruct a deviation from the Protocol on an emergency basis for the safety of the Trial Subjects. Institution and/or Principal Investigator will notify the responsible IECand/or RA as soon as practicable but, in any event, no later than five (5) business days after the deviation is implemented. Any emergency deviation will be followed by written Protocol Amendment.

2.2 Emergency Deviations/Urgent Safety Measures. If the Principal Investigator determines that it is necessary to deviate from the Protocol on an emergency basis for the safety of the Trial Subjects, Institution and/or Principal Investigator will notify Sponsor and the responsible IECand/or RA as soon as practicable but, in any event, no later than five (5) business days after the deviation is implemented

3. IEC and RA. The Parties will ensure that the Trial is initiated only after both the Trial and the informed consent form ("ICF") are approved by an IECand/or RA that complies with all Applicable Law. The Parties will further ensure that the Trial is subject to continuing oversight by the IECand/or RA throughout its conduct.

4. Sponsor Drug. Sponsor will provide Institution with sufficient quantities of the Sponsor product that is being studied ("Sponsor Drug") to conduct the Trial at no cost to the Institution and Principal Investigator. If required by the Protocol and unless otherwise agreed, Sponsor will also provide placebo or comparator drug ("Comparator Drug") at no cost to the Institution and Principal Investigator.

4.1 Custody and Dispensing. Institution and Principal Investigator will adhere to Applicable Law requiring careful custody and dispensing of Sponsor Drug or Comparator Drug, as well as appropriate documentation of such activities.

4.2 Control. Institution and Principal Investigator will maintain appropriate control of supplies of Sponsor Drug or Comparator Drug and will not administer or dispense it to anyone who is not a Trial Subject, or provide access to it to anyone except Research Staff.

4.3 Use. Institution and Principal Investigator will use Sponsor Drug or Comparator Drug only as specified in the Protocol. Any other use of Sponsor Drug or Comparator Drug constitutes a material breach of this Agreement.

4.4 Ownership of Sponsor Drug. Sponsor Drug is and remains the property of Sponsor. Sponsor grants Institution and Principal Investigator no express or implied intellectual property rights in the Sponsor Drug or in any methods of making or using the Sponsor Drug.

4.5 Payment for Sponsor Drug or Comparator Drug. Institution and Principal Investigator will not charge a Trial Subject or third-party payer for Sponsor Drug or Comparator Drug or for any services reimbursed by Sponsor or CRO under this Agreement.

5. Financial Arrangements. Compensation for services provided under this Agreement will be made by way of payments in accordance with Attachment A (Payment Terms) and Attachment B (Financial Arrangements Worksheet). All Parties acknowledge that amounts set forth in Attachment B represent fair market value of the services provided by Institution and Principal Investigator for conducting the Trial to the best of their knowledge. All amounts are inclusive of all direct, indirect, overhead and

other costs, including laboratory and ancillary service charges, and will remain firm for the duration of the Trial, unless otherwise agreed in writing by the Parties. Neither the Institution nor the Principal Investigator will directly or indirectly seek or receive compensation from Trial Subjects or third-party payers for any material, treatment or service that is required by the Protocol and provided or paid by Sponsor or its CRO, including, but not limited to, Sponsor Drug, Comparator Drug, Trial Subject screening, infusions, physician and nurse services, diagnostic tests, and Sponsor Drug and/or Comparator Drug administration. Once the Payee(s) (hereinafter defined) have been paid for the performance of the Trial, neither CRO nor Sponsor shall have any further obligation or liability whatsoever to pay Principal Investigator or Institution.

6. Reporting Obligations. Principal Investigator acknowledges that various laws, statutes, regulations, directives, and/or industry requirements (collectively, "Reporting Laws") require certain companies in the pharmaceutical/healthcare industry to disclose and report information regarding payments made and agreements entered into with healthcare professionals or other individuals and entities carrying out activities in certain countries. Accordingly, where such Reporting Laws are applicable, Principal Investigator acknowledges and agrees that information, including but not limited to: (i) name, address, qualifications and medical specialties, registration number; (ii) information regarding the Agreement; and (iii) information concerning all payments or benefits (in cash or in kind) made to Principal Investigator under the Agreement may be disclosed by CRO to Sponsor and/or to the relevant responsible authority for publication of such information publicly in accordance with the relevant Reporting Laws. The right of Principal Investigator to object to data collection and data processing pursuant to applicable privacy laws may not apply where the disclosure obligation results from a statutory requirement. Execution of this Agreement serves as Principal Investigator's consent to the data collection, processing and disclosure of the information set forth herein for the purposes stated.

7. Trial Subject Enrollment. Institution and Principal Investigator have agreed to enroll Trial Subjects in the Trial in accordance with the Protocol and in accordance with IECand/or RA approval. Sponsor may discontinue Trial Subject enrollment if the total enrollment needed for a multi-center Trial has been achieved, if applicable.

8. Informed Consent. Principal Investigator shall ensure that the ICF approved by Sponsor, IECand/or RA is signed on behalf of each Trial Subject before the first Trial related procedure starts for the Trial Subject.

9. Reporting Adverse Events and ICH GCP Breaches. Institution and Principal Investigator will report ICH GCP breaches as well as adverse events experienced by Trial Subjects at any time in accordance with instructions in the Protocol and Applicable Law.

10. Personal Data Protection and Privacy. The parties shall comply with all applicable privacy and data security laws and regulations, as provided under this Agreement, including for the avoidance of doubt, all local laws and regulations applicable to data protection, including but not limited to GDPR, and their related ordinances, regulations, directives, guidance and guidelines ("Information Protection Laws"), as applicable. "GDPR" means Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation). In addition, Institution and Principal Investigator shall comply with the following provisions:

10.1 Authorization to Use and Disclose Health Information. Institution and Principal Investigator shall provide an appropriate privacy notice to and will obtain a written privacy authorization, complying with Information Protection Law, for each Trial Subject which will enable Institution and Principal Investigator to provide Sponsor and other persons and entities designated by Sponsor access to completed case report forms (CRFs), source documents and all other information required by the Protocol.

George Clinical India Private Limited

10.2 Use of Trial Subject Personal Data. Use of Personal Data. Institution and Principal Investigator will collect and use personal information obtained from Trial Subjects collected by Institution and Principal Investigator for the sole purpose outlined in the Protocol ("Personal Data") and shall manage such Personal Data in accordance with Information Protection Law and this Agreement.

10.3 Disclosure of Personal Data. Institution and Principal Investigator shall not disclose personal data to CRO or the Sponsor except as is required to satisfy the requirements of the Protocol, for the purpose of monitoring or adverse event reporting, in relation to a claim or proceeding brought by a Trial Subject in connection with the Trial, or as required by law. In all such cases of disclosure, Institution and Principal Investigator shall respect the "data minimization" principle of privacy, including but not limited to the following example: implementing appropriate technical and organizational measures, de-identification of Personal Data prior to sharing it with Sponsor, CRO or other parties, actual Trial Subject names shall not be included on any invoices for payment submitted by Institution and Principal Investigator.

10.4 Right of Trial Subject.

a. The parties will respond to Trial Subjects' requests for access, amendment, transfer, blocking, or deletion of Personal Data in accordance with Information Protection Law and this Agreement. The parties acknowledge that in order to maintain the integrity of Trial results, the ability to amend, block, or delete Personal Data may be limited, in accordance with Information Protection Law. Institution and Principal Investigator and/or CRO will notify Sponsor within five (5) calendar days of receipt of any communication relating to a Trial Subject's right to access, modify or correct his or her Personal Data and will comply with all reasonable instructions of Sponsor before responding to such communication.

b. Institution and Principal Investigator and/or CRO will provide to Sponsor, and as otherwise required by Information Protection Law, written notice within twenty-four (24) hours of any security incident that involves, or which CRO and/or Institution and Principal Investigator reasonably believes involves, the unauthorized access, use, disclosure or other unauthorized processing of Personal Data; provided, further, CRO and/or Institution and Principal Investigator shall (i) provide updates to Sponsor as further information becomes available as to the breach, and (ii) at the earliest possible time, summarize in reasonable detail the impact on Sponsor of the breach or unauthorized use or disclosure of, or access to, Personal Data and the corrective action taken or to be taken by CRO and/or Institution and Principal Investigator; provided, further, CRO and/or Institution and Principal Investigator shall promptly take all necessary and appropriate corrective action including, without limitation, at the request of Sponsor and at CRO's and/or Institution and Principal Investigator 's expense, to provide notices to Trial Subjects whose Personal Data may have been affected, whether or not such notice is required by law; each party shall reasonably cooperate with the other party to facilitate compliance with Information Protection Laws, including but not limited to notification of affected individuals and regulatory authorities.

11. Confidential Information. During the course of the Trial, Institution and Principal Investigator may receive or generate information that is confidential to CRO, Sponsor or a Sponsor affiliate.

11.1 Definition. Except as specified below, confidential information ("Confidential Information") includes all information provided by Sponsor or CRO, or developed for Sponsor or CRO, Inventions (hereinafter defined) and all data collected during the Trial, including without limitation results, reports, technical and economic information, the existence or terms of this or other Trial agreements with the Sponsor or CRO, commercialization and Trial strategies, trade secrets and

know-how disclosed by Sponsor to Institution and/or Principal Investigator directly or indirectly, whether in writing, electronic, oral or visual transmission, or which is developed under this Agreement.

11.2 Exclusions. Confidential Information does not include information that is in the public domain prior to disclosure by Sponsor or CRO; becomes part of the public domain during the term of this confidentiality obligation by any means other than breach of this Agreement by Institution or Principal Investigator; is already known to Institution or Principal Investigator at the time of disclosure and is free of any obligations of confidentiality; or is obtained by Institution or Principal Investigator, free of any obligations of confidentiality from a third party who has a lawful right to disclose it.

11.3 Obligations of Confidentiality. Unless Sponsor provides prior written consent, Institution and Principal Investigator may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may Institution or Principal Investigator disclose Confidential Information to any third party except as authorized in this Agreement or as required by Applicable Law. Required disclosure of Confidential Information to the IECand/or RA is specifically authorized.The Institution and Principal Investigator agrees not to reveal Confidential Information to third parties, other than those Research Staff, agents, local service providers and/or contractors with a need to know directly involved in conducting the Trial or services in support of the Trial. Institution and Principal Investigator shall ensure that prior to any disclosure of Confidential Information to any such recipients are subject to similar confidentiality obligations no less onerous than those in this Agreement.

11.4 Disclosure Required by Applicable Law. If disclosure of Confidential Information beyond that expressly authorized in this Agreement is required by Applicable Law, that disclosure does not constitute a breach of this Agreement so long as Institution and Principal Investigator: (i) notify Sponsor in writing as far as possible in advance of the disclosure so as to allow Sponsor to take legal action to protect its Confidential Information; (ii) discloses only that Confidential Information required to comply with the legal requirement; and (iii) continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.

11.5 Survival of Obligations. For Confidential Information other than Trial Data and Biological Samples (hereinafter defined) analysis data, these obligations of nonuse and nondisclosure survive termination of this Agreement and continue for a period of ten (10) years after termination. Permitted uses and disclosures of Trial Data are described in Section 16 (Publications) of this Agreement.

11.6 Return of Confidential Information. If requested by Sponsor or CRO in writing, Institution and Principal Investigator will return all Confidential Information, at Sponsor's expense, except that required to be retained at the Institution by Applicable Law. However, Institution and Principal Investigator may retain a single archival copy of the Confidential Information for the sole purpose of determining the scope of obligations incurred under this Agreement.

12. Personal information of the parties. Prior to and during the course of the Trial, the Principal Investigator and other employees/contractors of Institution may be called upon to provide personal information to the Sponsor and other third parties involved in the conduct of the Trial, including the CRO. Personal information may include names, contact information, work experience and professional qualifications, publications, resumes, educational background and/or information relating to payments made pursuant to this Agreement ("Personal Information").

12.1 To the extent permitted by Information Protection Law, the Personal Information may be stored electronically by Sponsor and/or CRO and/or transferred to third parties (situated throughout the world) for the following purposes:

i. the conduct of clinical trials;

ii. verification by government or regulatory agencies, the Sponsor, CRO, and their agents and affiliates;

iii. compliance with legal and regulatory requirements;

iv. publication on www.clinicaltrials.gov and other websites and/or databases that serve a comparable purpose;

v. storage in databases to facilitate the selection of investigators for future clinical trials; and

vi. anti-corruption compliance.

Institution confirms that the Principal Investigator and its employees/contractors consent to provide the Personal Information to Sponsor and/or CRO to be electronically stored by Sponsor and/or CRO and for Sponsor and/or CRO to transfer to third parties as stated above.

12.2 Institution and Principal Investigator shall provide the information reasonably requested by Sponsor and/or CRO and shall authorize the processing and storage of certain Personal Information about the Principal Investigator, Institution personnel, research staff and other individuals involved in the Trial for the purpose of fulfilling legitimate business requirements relating to clinical trials and meeting regulatory requirements as well as for the purpose of evaluating Institution or Principal Investigator for inclusion in future clinical trials. Institution or Principal Investigator shall give an appropriate privacy notice and obtain consent as required from the Institution personnel, research staff and other individuals for the processing of their personal data under applicable Information Protection Law.

12.3 Institution shall process Personal Information relating to CRO employees/contractors only to the extent, and in such a manner as is necessary for the purposes of this Agreement and in compliance with the Information Protection Law. Institution shall not transfer such Personal Information relating to CRO's employees/contractors to a third party without the prior written consent of CRO.

12.4 During the term of this Agreement, the Institution and CRO will maintain a comprehensive privacy and security program designed to ensure that Personal Information will only be processed in accordance with this Agreement and pursuant to privacy and security regulations, including appointment of a data protection officer as required by applicable Information Protection Law.

Institution and CRO agree to implement administrative, technical, and physical security measures to protect Personal Information and ensure a level of security appropriate to the risk as required by applicable Information Protection Law. Institution and CRO agrees to regularly test, assess and evaluate the effectiveness of the measures for ensuring the security of processing.

12.5 The Institution agree to allow the Sponsor(s) or another auditor appointed by the Sponsor(s) to audit the Institution's compliance with the obligations described by the Information Protection Law, on reasonable notice subject to the Sponsor and/or to provide the Sponsor with evidence of its compliance with the obligations set out in the Information Protection Law.

12.6 Sponsor agrees: (a) to process Personal Information only for the limited and specified purposes under this Agreement and in compliance with the Information Protection Law; (b) to provide the same level of privacy protection as is required by the Information Protection Law; (c) upon reasonable notice, to permit its designees and/or CRO to perform an audit at Sponsor's own expense or to take other reasonable and appropriate steps to ensure that Institution and Principal Investigator effectively process the Personal Information transferred under this Agreement in a manner consistent with Sponsor's obligations under the Information Protection Law; (d) upon notice, to take reasonable and appropriate steps to stop and remediate any unauthorized processing hereunder; (e) to permit its designees and/or CRO to provide a summary or a representative copy of the relevant privacy provisions of this Agreement to supervisory authorities' request; and (f) to notify any competent supervisory or regulatory authorities and CRO, where required, if Institution and Principal Investigator determine it can no longer meet the obligations under this Section or if it otherwise breaches any obligations imposed under this Section.

12.7 Sponsor acknowledges and warrants that the sub processors or other third parties, engaged by Sponsor will be bound by obligations regarding the processing of Personal Data no less restrictive than those set forth herein.

12.8 Sponsor shall implement appropriate technical and organizational measures to meet the requirements of the Information Protection Law.

12.9 Each Party shall be responsible for its own processing of Personal Data in accordance with all Information Protection Law and with the Informed Consent Forms obtained from Trial Subjects and to the extent applicable, the Protocol.

12.10 If any Party becomes aware of a Personal Data breach in connection with the performance of this Agreement, that Party shall promptly notify the other Party/-ies. In such case, Parties will fully cooperate with each other in order to fulfil the (statutory) notification obligations timely.

13. Trial Data, Biological Samples, and Records.

13.1 Trial Data. During the course of the Trial, Institution and Principal Investigator will collect and submit certain data to Sponsor or its agent, as specified in the Protocol. This includes CRFs (or their equivalent) or electronic data records, as well as any other documents or materials created for the Trial and required to be submitted to Sponsor or its agent, such as X-ray, magnetic resonance imaging ("MRI"), or other types of medical images, electrocardiogram ("ECG"), electroencephalography ("EEG"), or other types of tracings or printouts, or data summaries (collectively, "Trial Data"). Institution and Principal Investigator will ensure accurate and timely collection, recording, and submission of Trial Data.

a. Ownership of Background Intellectual Property. All intellectual property rights and know how owned by or licensed to any of the Parties prior to and after the date of this Agreement, other than any intellectual property rights and know how arising from the Trial, are the exclusive property of the that Party and shall not be affected by this Agreement.

b. Ownership of Trial Data. Subject to Institution's and/or Principal Investigator's right to publish any Trial Data and the non-exclusive license that permits certain uses, Sponsor is the exclusive owner of all Trial Data.

c. Non-Exclusive License. Sponsor grants Institution and Principal Investigator a royalty free non-exclusive license, with no right to sublicense, to use Trial Data for internal non-commercial research or educational purposes.

d. Medical Records. Medical records relating to Trial Subjects that are not submitted to Sponsor may include some of the same information as is included in Trial Data; however, Sponsor makes no claim of ownership to those documents or the information they contain.

13.2 Biological Samples. If so specified in the Protocol, Institution and Principal Investigator may collect and provide to Sponsor or its designee Biological Samples ("Biological Samples").

a. Use. Institution and Principal Investigator will not use Biological Samples collected under the Protocol in any manner or for any purpose other than that described in the Protocol.

b. Sample Data. Sponsor or its designees will test Biological Samples as described in the Protocol. Unless otherwise specified in the Protocol, Sponsor will not provide the results of such tests ("Sample Data") to the Institution or Principal Investigator or Trial Subject. Sample Data will be treated as Trial Data; therefore, if Sponsor provides Sample Data to the Institution or Principal Investigator, that data will be subject to the permitted use of Trial Data as outlined in this Agreement.

13.3 Records. Institution and Principal Investigator will retain all records and documents pertaining to the Trial under storage conditions conducive to their stability and protection, for the longest of: (i) twenty five (25) years after termination of the Trial unless Sponsor authorizes, in writing, earlier destruction; or (ii) as otherwise required by Applicable Law. Institution and Principal Investigator further agree to permit Sponsor to ensure that the records are retained for a longer period if necessary, at Sponsor's expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

14. Inspections and Audits.

14.1 Access. Upon reasonable request, Sponsor, authorized representatives of Sponsor, and/or authorized representatives of the RA may, during and after the Trial, during regular business hours: (i) examine and copy: all CRFs and other Trial records (including Trial Subject records and medical charts, Trial Subject ICF documents, and Sponsor Drug and Comparator Drug receipt and disposition logs); (ii) examine and inspect the facilities and other activities relating to the Trial or the IEC; and (iii) observe the conduct of the Trial.

14.2 Notice. Institution and/or Principal Investigator shall: (i) inform Sponsor and CRO as soon as practicable of any effort or request by the government, the RA or other persons to inspect or contact the Institution, Principal Investigator or Research Staff with regard to the Trial; (ii) provide Sponsor and CRO with a copy of any communications sent by such persons; and (iii) provide Sponsor the opportunity to participate in any proposed or actual responses by Principal Investigator or Institution to such communications and to make reasonable efforts to ensure that Sponsor may be present or represented during any such visit.

14.3 Cooperation. Institution and Principal Investigator will ensure the full cooperation of the Research Staff and IEC members with any such inspection and will ensure timely access to applicable records and data. Institution and/or Principal Investigator will promptly resolve any discrepancies that are identified between the Trial Data and the Trial Subject's medical records.

15. Inventions. If the conduct of Trial results in any invention or discovery whether patentable or not ("Invention"), Institution and Principal Investigator will promptly inform Sponsor and CRO. Institution and Principal Investigator will assign all interest in any such Invention to Sponsor, free of any obligation or consideration beyond that provided for in this Agreement. Institution and Principal Investigator will provide reasonable assistance to Sponsor in filing and prosecuting any patent applications relating to Invention, at Sponsor's expense. Sponsor grants Institution and Principal Investigator a royalty free non-exclusive license, with no right to sublicense, to use Inventions for internal research or educational purposes.

16. Publications. Sponsor does not object to publication by Institution or Principal Investigator of the results of the Trial based on information collected or generated by Institution and Principal Investigator, whether or not the results are favorable to the Sponsor Drug. However, to ensure against inadvertent disclosure of Confidential Information or unprotected Inventions, Institution and Principal Investigator will provide Sponsor an opportunity to review at least sixty (60) days prior any proposed publication or other type of disclosure before it is submitted or otherwise disclosed. If in the Sponsor's judgment, publication or presentation at a given time would hinder the Sponsor's development of the Sponsor Drug, the Principal Investigator shall consider modifying the publication or presentation schedules accordingly. The Institution and/or Principal Investigator further agrees to delete information identified by CRO or the Sponsor as Confidential Information, prior to submitting such manuscript and/or abstract for publication or presentation, or defer publication or presentation of such manuscript and/or abstract at the request of the Sponsor, to permit the filing of any desired patent applications by the Sponsor. If part of a multi-center Trial, Institution and Principal Investigator agree that the first publication is to be a joint publication involving all Trial sites. Principal Investigator is free to decline to participate or be listed as an author in the joint publication. If a joint manuscript has not been submitted for publication within twelve (12) months of completion or termination of the Trial at all participating Trial sites, Institution and/or Principal Investigator are free to publish separately, subject to the other requirements of this Agreement.

17. Publicity. No Party will use the name of another Party or any of its employees for promotional or advertising purposes without written permission from the other Party. However, Sponsor reserves the right to identify the Principal Investigator and Institution in association with a listing of the Protocol in the National Institutes of Health (NIH) Clinical Trials Data Bank, other publicly available listings of ongoing clinical trials, or other patient recruitment services or mechanisms.

18. Advertising.

18.1 If applicable and in accordance with the Food and Drug Administration Amendments Act of 2007, Public Law 110-85, Sponsor agrees to fully register this Trial with the public registry at clinicaltrials.gov before enrollment of the first TrialSubject atInstitution, if applicable. Sponsor may use, refer to, and disseminate reprints of scientific, medical, and other published articles relating to the Trial which disclose the name of Institution consistent with U.S. copyright laws. Institution shall not publicly disclose the existence or the contents of this Agreement and any amendments. For example, Institution shall not post this Agreement on a public website. For purposes of internal reporting or internal advertising, Institution is specifically authorized to disclose a description of the Trial based on, and not exceeding, the information posted by Sponsor on clinicaltrials.gov. No party to this Agreement shall use the name of any other party hereto in connection with any advertising or promotion of product or service without the prior written permission of such party.

18.2 Use of Social Media for Trial Recruitment. Due to the highly regulated industry in which Sponsor operates, and the serious health concerns related to improper use of any Sponsor or its affiliates products, Institution shall not participate in any social media postings/activities related to Sponsor or its affiliates' products, investigational drugs, compounds or services, or this Trial unless expressly permitted in writing by Sponsor. This restriction shall not be construed as

prohibiting any conduct protected or required by Applicable Laws. Notwithstanding the foregoing, Institution may use social media content to recruit potential Trial Subjects to the Trial. Accordingly, Site shall:

i. submit for review and approval all Institution, Study recruitment initiatives and content in accordance with Sponsor's social media requirements.

ii. identify a Community Manager (as defined herein) if Institution's social media recruitment content: (i) will enable user generated commenting ("UGC"); or (ii) will not or cannot turn off UGC as required by specific social media platforms. For purposes of this Agreement, the "Community Manager" may be either an individual employed by the Institution or a third-party vendor ("Monitoring Vendor") that will be responsible for monitoring and managing the social media platform and/or social media content used for potential Trial Subject recruitment when UGC is enabled. Institution shall be responsible for all actions of its Community Manager.

iii. ensure that the Community Manager posts only Sponsor pre-approved content, monitors social media comments once each weekday (excluding public holidays except when the holiday is a Monday), and completes all required AE and Product Quality Complaint ("PQC") training prior to posting any Trial related social media content advertisement, and ensure all Research Staff given access to the social media platform, undergo training on how to compliantly manage and moderate the social media content for recruitment purposes.

iv. report all adverse events immediately in accordance with Section 9 (Reporting Adverse Events and ICH GCP Breaches) and all PQCs in compliance with this Agreement and Sponsor pharmacovigilance guidelines and training provided.

v. Any violations of this Section 18.2 shall be considered a material breach of this Agreement and cause for immediate termination by Sponsor. If Institution is unable to comply with 18.2 i-iv, Institution agrees it will not use social media that enables UGC to recruit potential Trial Subjects.

19. Indemnification. Sponsor agrees to indemnify, defend or cover costs of defense for, and hold harmless ("Indemnify") the Trial investigators; any institution at which the Trial is conducted, its officers, agents, and employees; and the IEC and/or RA that approved the Trial (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities and/or expenses arising out of a Trial Subject Injury (hereinafter defined), the design of the Trial, or the specifications of the Protocol. Trial Subject Injury means a physical injury or drug-related psychiatric event caused by administration or use of the Sponsor Drug required by the Protocol that the Trial Subject would likely not have received if the Trial Subject had not participated in the Trial ("Trial Subject Injury"). Sponsor further agrees to reimburse Institution and/or Principal Investigator for the actual cost of diagnostic procedures and medical treatment necessary to treat a Trial Subject Injury and where required under any Applicable Law, any necessary compensation to Trial Subject for Trial Injury in accordance with Applicable Law and rules determining the quantum of any such compensation which is commensurate with the nature of the injury. Institution and Principal Investigator agree to provide or arrange for prompt diagnosis and medical treatment of any Trial Subject Injury. Institution and Principal Investigator further agree to promptly notify Sponsor of any Trial Subject Injury.

19.1 Exclusions. Excluded from this Agreement to Indemnify are any claims for damages resulting from: (a) failure by an Indemnified Party to comply with the Protocol or written instructions from Sponsor; (b) failure of an Indemnified Party to comply with Applicable Law; or (c) negligence or willful misconduct by an Indemnified Party.

19.2 Notice and Cooperation. Institution and Principal Investigator agree to provide Sponsor with prompt notice of, and full cooperation in handling, any claim that is subject to indemnification. If so requested by Sponsor, Institution and Principal Investigator agree to authorize Sponsor to carry out the sole management of defense of an indemnified claim.

19.3 Settlement or Compromise. No settlement or compromise of a claim subject to this indemnification provision will be binding on Sponsor without Sponsor's prior written consent. Sponsor will not unreasonably withhold such consent of a settlement or compromise. Neither Party will admit fault on behalf of the other Party without the written approval of that Party.

19.4 Limit of Liability of CRO. The Parties agree that CRO expressly disclaims any and all liability whatsoever in connection with the Sponsor Drug or the Protocol and any claims or injuries arising therefrom, except to the extent that such liability arises from CRO's negligent act, omission or willful misconduct.

19.5 In no event will a Party's liability towards the other Party include any indirect damages (indirect damages meaning: loss of profit, loss of revenue, loss of reputation, loss of contracts, or anticipated savings and loss of business opportunities).

20. Termination.

20.1 Termination Conditions. This Agreement terminates upon the earlier of any of the following events:

a. IECand/or RA Rejection. If, through no fault of Institution or Principal Investigator, the Trial is never initiated because of IECand/or RA disapproval, this Agreement can be terminated by any Party immediately.

b. Trial Completion. For purposes of this Agreement, the Trial is considered complete after conclusion of all Protocol-required activities for all enrolled Trial Subjects; receipt by Sponsor or CRO of all relevant Protocol-required data, Trial documents and Biological Samples; and receipt of all payments due to either Party.

c. Early Termination of Trial. If the Trial is terminated early as described below, the Agreement will terminate after receipt by Sponsor or CRO of all relevant Protocol-required data, Trial documents and Biological Samples and receipt of all payments due to either Party.

(1) Termination of Trial upon Notice. Sponsor and/or CRO reserves the right to terminate the Trial for any reason upon thirty (30) calendar days written notice to Institution and Principal Investigator. Upon receipt of such notice, Institution and Principal Investigator agree to promptly terminate conduct of the Trial, to the extent medically permissible, for all Trial Subjects.

(2) Immediate Termination of Trial by Sponsor and/or CRO. Sponsor and/or CRO further reserves the right to terminate the Trial immediately upon written notification to Institution and Principal Investigator for causes that include failure to enroll Trial Subjects at a rate sufficient to achieve Trial performance goals; material unauthorized deviations from the Protocol or reporting requirements; circumstances that in Sponsor's opinion pose risks to the health or wellbeing of Trial Subjects; or regulatory agency actions relating to the Trial or the Sponsor Drug or Comparator Drug.

(3) Immediate Termination of Trial by Institution and/or Principal Investigator. Institution and/or Principal Investigator reserve the right to terminate the Trial immediately upon notification to Sponsor and/or CRO if requested to do so by the responsible IECand/or RA or if such termination is required to protect the health of Trial Subjects.

20.2 Payment upon Termination. If the Trial is terminated early in accordance with this Agreement, Sponsor or CRO will provide a termination payment equal to the amount owed for work already performed up to and including the effective date of termination, in accordance with Attachment B.

20.3 Less Payments Already Made. The termination payment will include any non-cancelable expenses, other than future personnel costs, so long as they were properly incurred and prospectively approved by Sponsor, and, only to the extent such costs cannot reasonably be mitigated. If the Trial was never initiated because of disapproval by the IECand/or RA, Sponsor or CRO/its designee will reimburse Payee for IEC fees and for any other expenses that were prospectively approved, in writing, by Sponsor.

20.4 Return of Materials. Unless Sponsor and/or CRO instructs otherwise in writing, Institution and Principal Investigator will promptly return all materials supplied by Sponsor and/or CRO, at Sponsor's expense, for Trial conduct, including CRFs and any Sponsor and/or CRO-supplied Equipment (hereinafter defined). Institution will return any unused Sponsor Drug or Comparator Drug, as applicable, at Sponsor's expense.

21. Insurance.

21.1 Institution and Principal Investigator will secure and maintain in full force and effect throughout the performance of the Trial (and following termination of the Trial to cover any claims arising from the Trial) insurance coverage for medical professional liability with limits in accordance with Applicable Law for all medical professionals conducting the Trial.

21.2 Sponsor will secure and maintain in full force and effect insurance coverage to fulfill its indemnification obligations expressed in this Agreement herein in accordance with Applicable Law.

22. Debarment, Exclusion, Licensure and Response. Institution and Principal Investigator represent that to the best of their knowledge that neither they nor any Research Staff are restricted or prevented under any healthcare or medicines law from taking part in clinical research activities and the Institution and Principal Investigator will not knowingly use in any capacity the services of any person who is so restricted or prevented under any such laws with respect to the service being performed under this Agreement. During the term of this Agreement and for one (1) year thereafter, the Institution and Principal Investigator will immediately notify the Sponsor and CRO if they become aware of any such restriction or prevention being applied to the Principal Investigator or any Research Staff. Institution and Principal Investigator represent that they and, to the best of their knowledge, the Research Staff are not the subject of any past or pending governmental or regulatory investigation, inquiry, warning or enforcement action, including a government-mandated corporate integrity agreement and that they have not violated any applicable anti-kickback or false claims laws or regulations related to their conduct of research that has not been disclosed to the Sponsor and CRO. Institution and Principal Investigator will promptly notify Sponsor and CRO if they become aware of any such action regarding compliance with ethical, scientific or regulatory standards for the conduct of research if such action relates to events or activities that occurred prior to or during the period in which the Trial was conducted.

23. Assignment and Delegation. The Parties agree that Sponsor may at any time and upon written notice to Institution and Principal Investigator assume the obligations and rights of CRO or substitute CRO with another independent contractor. None of the rights or obligations under this Agreement will be assigned or subcontracted by Institution or Principal Investigator to another without the prior written consent of Sponsor, and the express agreement of Institution, Principal Investigator, CRO, and the requisite new assignee or subcontractor. Principal Investigator and/or Institution must notify Sponsor, and/or CRO in advance, prior to moving to another location. This Agreement will bind and

inure to the benefit of the successors and permitted assigns of the Sponsor.

24. Equipment. Sponsor may provide, or arrange for a vendor ("Vendor") to provide, certain equipment for use by Institution and Principal Investigator during the conduct of the Trial ("Equipment"). Equipment use, ownership and disposition terms are further outlined in Attachment C (Equipment Use, Ownership & Disposition).

25. Anti-Bribery and Anti-Corruption Laws. Institution and Principal Investigator acknowledge that Sponsor and CRO are bound by anti-bribery and anti-corruption laws. As such, Sponsor and CRO employees, agents, contractors and/or representatives are prohibited from making or offering payment (or anything of value), directly or indirectly, to employees or officials of any foreign government, public international organization, political party, or candidates for political office in order to retain any business or secure any improper advantage. Institution and Principal Investigator shall ensure that neither they nor any of their officers, employees, collaborators, directors, consultants, agents, representatives or sub-contractors take any action which could render Sponsor or CRO liable under the anti-bribery and anti-corruption laws.

26. Sponsor as Third Party Beneficiary. The Parties to this Agreement recognize and agree that Sponsor takes the benefit of this Agreement as a third party beneficiary and agree that Sponsor may enforce such rights either directly itself or indirectly through CRO.

27. Survival of Obligations. Obligations relating to Financial Arrangements, Reporting Obligations, Personal Data Protection and Privacy, Confidential Information, Records, Inspections and Audits, Inventions, Publications, Publicity, Debarment, Exclusion, Licensure and Response, and Indemnification survive termination of this Agreement, as do any other provision in this Agreement or its Attachments that by its nature and intent remains valid after the term of the Agreement.

28. Entire Agreement. This Agreement contains the complete understanding of the Parties and will, as of the Effective Date, supersede all other agreements between the Parties concerning the specific Trial. This Agreement may only be extended, renewed or otherwise amended in writing, by the mutual consent of the Parties, except for certain mutually agreeable changes in the Trial budget as identified in Attachment B. No waiver of any term, provision or condition of this Agreement, or breach thereof, whether by conduct or otherwise, in any one or more instances will be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or any prior, contemporaneous or subsequent breach thereof, of any other term, provision or condition of this Agreement whether of a same or different nature.

29. Conflict with Attachments. To the extent that terms or provisions of this Agreement conflict with the terms and provisions of the Protocol, the terms and provisions of this Agreement will control as to legal and business matters, and the terms and provisions of the Protocol will control as to technical research and scientific matters unless expressly agreed in writing between the Parties.

30. Severance.In case any one or more of the provisions of this Agreement should be invalid, illegal or unenforceable in any respect, the validity, legality and enforceability of the remaining provisions contained in this Agreement shall not in any way be affected or impaired.

31. Relationship of the Parties. The relationship of Institution and Principal Investigator to CRO is one of independent contractor and not one of partnership, agent and principal, employee and employer, joint venture, or otherwise.

32. Force Majeure. Neither Party will be liable for delay in performing or failure to perform obligations under this Agreement if such delay or failure results from circumstances outside its reasonable control (including, without limitation, any act of God, governmental action, accident, strike, terrorism, bioterrorism, lock-out or other form of industrial action) and are promptly notified to the other Party ("Force Majeure"). Any incident of Force Majeure will not constitute a breach of this

Agreement and the time for performance will be extended accordingly; however, if it persists for more than thirty (30) calendar days, then the Parties may enter into discussions with a view to alleviating its effects and, if possible, agreeing on such alternative arrangements as may be reasonable in all of the circumstances.

33. Governing Law. Subject to the terms of the Trial conduct as outlined above, this Agreement shall be governed by and construed in accordance with the laws of India, without giving effect to conflict of law provisions.

34. Notices. All notices required under this Agreement will be in writing and be deemed to have been given when hand delivered, sent by overnight courier or certified mail, as follows, provided that all urgent matters, such as safety reports, will be promptly communicated via telephone, and confirmed in writing:

Sponsor:
Otsuka Pharmaceutical Development & Commercialization, Inc.
2440 Research Boulevard
Rockville, Maryland 20850 USA

With a copy to:
George Clinical India Private Limited
Plot No.5, Prestige Khoday Towers, 12th Floor, Raj Bhavan Road,
Bangalore –560 001, Karnataka, India
Attention: CEO
Email: contracts@georgeclinical.com

Institution:
Mahatma Gandhi Missions Medical College and Hospital N-6 CIDCO
Aurangabad-431003, Maharashtra, India.
Attention: Dr. Deepak Bhosle
Telephone: **+91-0240-6601100-Ext.174/329**
Email: **drdeepakmgm@gmail.com**

Principal Investigator:
Dr Sudhir Gajanan Kulkarni
Department of Nephrology, MGM Medical College and Hospital Aurangabad-431003, Maharashtra, India.
Telephone: +9422713691
Email: **sudhirkul1979@gmail.com**

In case of any changes in the address, name, subordination, or other identifying information, the Party to the Agreement shall notify the other Party on the fact in writing, no further amendments to this Agreement are required.

35. Financial Disclosure. The Institution and/or Principal Investigator shall complete and return to CRO or the Sponsor in a timely manner, financial certification or disclosure forms, as applicable, provided to the Institution and/or Principal Investigator by CRO or the Sponsor. The Institution and/or Principal Investigator shall also complete and return to CRO or the Sponsor, all disclosure updates, as so instructed by CRO or the Sponsor, for the duration of the Trial, and for one (1) year thereafter. The Institution and/or Principal Investigator shall ensure that all sub investigators, performing a Trial-related function shall complete and return all financial certification/disclosure forms as described in this Section.

36. Counterparts and Signatures. In the eventthat the Parties execute this Agreement by exchange of electronically signed copies or facsimile signed copies, the Parties agree that, upon being signed by all

Parties, this Agreement will become effective from Effective Date and binding and that facsimile copies and/or electronic signatures will constitute evidence of a binding agreement with the expectation that original documents may later be exchanged in good faith. Where this Agreement is executed by Institution and/or Principal Investigator through the use of an electronic or digital signature, Institution and/or Principal Investigator agree that: (i) their electronic or digital signature has same effect as a handwritten signature; (ii) signature by electronic or digital means is permitted under Applicable Law for the execution of the Agreement; (iii) the electronic or digital signature platform used to generate such signature meets the requirements under Applicable Law for creating a valid advanced electronic or digital signature; and (iv) Institution and/or Principal Investigator shall provide to CRO and/or to Sponsor any further necessary certification or supporting documentation around their electronically generated signatures in compliance with this Section.

[SIGNATURE PAGE FOLLOWS]

Agreed to and accepted:

CRO - GEORGE CLINICAL INDIA PRIVATE LIMITED

Signature

Mr. Abby Abraham
Printed Name

Country Head, India
Title

7/Sep/22
Date

INSTITUTION Mahatma Gandhi Mission's Medical College & Hospital

Signature

Dr. Rajendra Bohra
Printed Name

Dean
Title

DEAN
MGM'S MEDICAL COLLEGE
AURANGABAD

19 Sep 2022
Date

Name and Designation of Authorized person to sign the Agreement as witness of Principal Investigator, Institution & Sponsor

Signature

Dr. Deepak Bhosle
Printed Name

Professor & Head of Pharmacology Department, Clinical Trial Center
Title

19 Sep 2022
Date

Professor & H.O.D.
Department of Pharmacology
MGM's Medical College
Aurangabad.

PRINCIPAL INVESTIGATOR

Signature

DR. Sudhir Gajanan Kulkarni
Printed Name

Principal Investigator (Associate professor & Head of Nephrology Department)
Title

19 Sep 2022
Date

Dr. Sudhir G. Kulkarni
M.D. D.M. Nephrology
Professor & HOD Nephrology
MGM Medical College & Hosp.A'bad
Reg. No.38466

ATTACHMENT A

PAYMENT TERMS

A-1. General Terms. Payee will be compensated as outlined on Attachment B for Trial Subjects properly enrolled in the Trial. This amount constitutes the full compensation for the work to be completed by the Institution and Principal Investigator, including all work and care specified in the Protocol for the Trial, along with all overhead and administrative services. No compensation will be available for Trial Subjects enrolled in the Trial in violation of the Protocol.

A-2. Payment Terms. Payments for each Trial Subject will be made quarterly and based on CRF data entered by Institution and/or Principal Investigator supporting enrolled Trial Subject visitation. Payments will be made for completed visits and treatment related costs in accordance with Attachment B unless otherwise noted in the Agreement. Invoices will be paid by CRO via electronic fund transfer or wire transfer as soon as practicable upon receipt of invoices but no later than forty five (45) calendar days of receipt of an undisputed invoice. For Trial Subject visits that may be payable under the terms of this Agreement, Payee will be paid the total amount earned, less ten percent (10%), for the Final Payment (hereinafter defined). Monitoring will occur approximately every five to six weeks based on site enrollment and completion of data entry. All queries must be resolved within five (5) business days of receipt by Institution and/or Principal Investigator any time during the Trial. Payee must submit any final invoices within thirty (30) calendar days after the close-out visit of the Trial at the Institution. Any invoices received thereafter may not be paid. Payee will have sixty (60) calendar days after the date of the close-out visit of the Trial at the Institution to dispute any payment discrepancies or missing payments

A-3. Pass-Through Payments from Sponsor. Payments due under this Agreement are pass-through payments from Sponsor that will be sent after such payments are received by CRO from Sponsor. CRO shall have no liability for any failure to make payments if required funding is not provided to CRO in advance by Sponsor.

A-4. Additional Non-Procedural Costs or Trial Related Costs. Payee will be paid for additional non-procedural costs or additional Trial related costs that are pre-approved by Sponsor, as set forth in Attachment B. To request payment for such costs, Payee will remit an itemized invoice to Sponsor or CRO with documentation and receipts substantiating agreed-upon pass-through expenses. Any additional non-procedural costs or additional Trial related costs will be invoiced only in the amount actually incurred with no mark-up, up to the maximum amounts shown in Attachment B.

A-5. Final Payment. At the conclusion of the Trial, all CRFs and Trial-related documents will be promptly made available for Sponsor review. The final payment ("Final Payment") will be paid once: all CRFs have been completed and received; data queries have been satisfied; all Sponsor Drug is returned; and all close out issues are resolved and procedures completed, including final IECand/or RA notification, if applicable.All outstanding queries that affect the Final Payment must be resolved within five (5) business days of receipt by Institution and/or Principal Investigator. Sponsor or CRO will perform final reconciliation of all payments made to date against total amount due and will promptly pay Payee amounts remaining unpaid, if any. Payee will promptly reimburse Sponsor any unearned or overpaid amounts previously paid to Payee within thirty (30) calendar days of notification by Sponsor or CRO.

A-6. Taxes.

(1) Payments shown in Attachment B do not includeGood and Services Tax ("GST"). If the Payee is GST registered, and if GSTis required under the Applicable Law, GST should be added and shown on the invoice by the Payee at the applicable GST rate, along with Payee's GSTregistration

number.

(2) Payee acknowledges and agrees that it is solely responsible for the payment of any and all contributions and taxes imposed by any applicable authority with respect to or measured by compensation paid to Payee under this Agreement. CRO or Sponsor will not be responsible for the withholding or payment of any such required contributions or taxes. Payee accepts full responsibility for reporting all payments received, under this Agreement, to the relevant taxation authorities as required by Applicable Law.

A-7. Screen Failures. A Screen Failure is a consented Trial Subject who fails to meet the screening visit criteria and is thus not eligible for enrollment into the Trial ("Screen Failure"). Screen Failures will be reimbursed, if at all, as outlined in Attachment B.

A-8. Necessary Procedures. Payee will be reimbursed for valid necessary visits and procedures not covered under Attachment B. Payment for any necessary procedure due to Trial Subject safety will be reimbursed at the agreed upon unit cost in Attachment B if available, or if there is no such unit cost in Attachment B, Payee will be compensated based on actual costs incurred by Institution and Principal Investigator, and will require a separate invoice with documentation for the medical necessity of the procedure. Where practicable, Sponsor's or CRO's prior written consent will be obtained, unless it will compromise the integrity of the Trial or affect Trial Subject safety, in which case Sponsor will be notified as soon as practicable after the fact.

A-9. Payee. The payments will be made to the following Payee and address ("Payee"):

Payee Name: MGM Medical College, Aurangabad
Payee Address: MGM Medical College & Hospital
Payee Tax Identification Number: GST Not Applicable
Payee Contact Email address: mgmaccounts@themgm group.com
Payee Contact Person: 7770087870 (Dr Deepak Bhosle)

Payee Bank Account Details:
Bank Name: IDBI Bank
Bank Address: Adalat Road Branch, Survey number 20292, Ratnaprabha Building, Kesarsingpura Opp. LIC Bld Aurangabad, Maharashtra.
Bank Account Number: 0376104000000107
IBAN Number: N/A

SWIFT Code IBKLINBBABD

A-10. Invoices. All invoices must be **issued** to the following as instructed in English:

Otsuka Pharmaceutical Development & Commercialization, Inc.
C/O George Clinical India Private Limited
Plot No.5, Prestige Khoday Towers, 12th Floor, Raj Bhavan Road,
Bangalore –560 001, Karnataka, India
Attn: Local CRA
Email: anzpfinvoice@georgeclinical.com

All invoices and payment related queries -must be **sent** to: Email: anzpfinvoice@georgeclinical.com

In case hard copy invoices need to be processed, they must be sent to George Clinical address stated in above Section.

Each invoice must contain: (1) Sponsor's name, (2) Protocol number, (3) Project Code, (4) Principal Investigator's name, (5) site number, (6) Payee contact telephone number and email address, (7) a summary of the reimbursement to be made in compliance with the Budget, and (8) if the Payee is VAT registered, the Payee's VAT registration number.

Payee will not receive any payments for pass through expenses whereby Payee has failed to produce actual copy invoices or other documentation clearly substantiating that the expenditures were actual, reasonable, and verifiable in the amount submitted for compensation. For any costs not in scope of Agreement, requests for payment or reimbursement or invoices must not be submitted by Payee until a contract amendment or a budget modification letter has been executed.

A-11. Amendments: The following Trial budget changes may be documented by a modification letter signed by CRO or its authorised agent: (1) increases in the total Trial budget, with or without modification of the payment schedule, or (2) modification of the payment schedule with no change in total Trial budget.

ATTACHMENT B

FINANCIAL ARRANGEMENTS WORKSHEET

FINANCE SUMMARY BOX	
Invoice Currency: Payment Base: CRO Contracting Entity:	INR Visit-based George Clinical India Private Limited

George Clinical India Private Limited

Sponsor Name:	**Otsuka Pharmaceutical Development & Commercialization, Inc. (OPDC)**
Protocol / Version:	**417-201-00007 / 03-Jan-2022**
Country:	**India**
Currency:	**INR**
Site PI:	**Site 082/ Dr. Sudhir Kulkarni**
Indication:	**IgAN**

	Cost per occurrence	Screening	Intervention Period										
			-	W4	W5	W8	W12	W16	W20	W21	W24	W28	W29
		D-60 to D-1	D1	D29	D36	D57	D85	D113	D141	D149	D169	D197	D205
			#1	#2		#3	#4	#5	#6		#7	#8	
Study Subject Care Related:													
Informed consent	INR 1,439	1,439											
Inclusion/Exclusion criteria	INR 1,270	1,270	635										
Medical History with Demographics	INR 3,164	3,164											
Blood sample collection for Hemoglobin A1c, Serology, Serum chemistry and Hematology, for Central lab	INR 526	526	526	526		526		526			526		
Urine sample collection for Urinalysis for Central lab	INR 379	379	379	379		379		379			379		
Lab handling and/or shipping of specimen(s)	INR 467	467	467	467		467		467			467		
IMP administration	INR 1,203		1,203	1,203		1,203	1,203	1,203	1,203		1,203	1,203	
Assessment of injection site	INR 383		383	383		383	383	383	383		383	383	
Pain VAS	INR 487		487	487		487	487	487	487		487	487	
Vitals signs outside of Physical examination (including weight, if applicable)	INR 1,038			1,038			1,038	1,038	1,038			1,038	
12-lead ECG (including interpretation and report)	INR 2,154	2,154											
Full physical examination (including Vital signs, height and weight as applicable)	INR 3,552	3,552	Invoice										
Symptom-directed physical examination (including Vital signs and weight as applicable)	INR 1,994		Invoice			1,994					1,994		
Body Mass Index (BMI)	INR 899	899											
Adverse events	INR 518	518	518	518	518	518	518	518	518	518	518	518	518
Concomitant medications	INR 518	518	518	518	518	518	518	518	518	518	518	518	518
Blood sample collection for total IgA, IgG and IgM; APRIL; g-d IgA1 and anti-IgA1 autoantibody, IgA-containing circulating immune complexes; markers of complement activation; ADA and exploratory assessments	INR 1,481	1,481	1,481	1,481		1,481	1,481		1,481		1,481		
Lab handling and/or shipping of specimen(s)	INR 474	474	474	474		474	474		474		474		
24-hour urine collection (creatinine, protein and albumin) for Central lab	INR 754	3,016											
Spot urine sample for uPCR determination and Urine sample for exploratory research for Central lab	INR 379		379	379		379	379		379		379	379	
Blood sample for PK for Central lab	INR 979			979	979				979	979	979	979	979
PK sample handling/shipping to Central lab	INR 474			474	474				474	474	474	474	474
SF-36	INR 476		476		476		476				476		
Brief Fatigue Inventory	INR 925		925		925		925				925		
Total Study Subject Care Related Per Visit		19,857	8,851	9,306	3,890	8,809	7,882	5,519	7,934	2,489	11,663	5,979	2,489
Outside Services:													
Physician Fee, Complex (initial and final visits) (includes review of Kidney biopsy)	INR 5,592	5,592											
Physician Fee, Simple (interim visits)	INR 2,939		2,939	2,939	2,939	2,939	2,939	2,939	2,939	2,939	2,939	2,939	2,939
SC Fee, Complex (initial and final visit) (including recruitment, monitoring visits, CRF completion, randomization at D1, queries, dose modification as needed, dispensing/accountability of study drug and compliance)	INR 3,067	3,067	3,067										
SC Fee, Simple (interim visits) (including recruitment, monitoring visits, CRF completion, queries, dose modification as needed, dispensing/accountability of study drug and compliance)	INR 2,889			2,889	2,889	2,889	2,889	2,889	2,889	2,889	2,889	2,889	2,889
Total Outside Services Per Visit		8,659	6,006	5,828	5,828	5,828	5,828	5,828	5,828	5,828	5,828	5,828	5,828
Subtotal		28,516	14,857	15,134	9,718	14,637	13,710	11,347	13,762	8,317	17,491	11,807	8,317
Overhead (%)		8,555	4,457	4,540	2,915	4,391	4,113	3,404	4,129	2,495	5,247	3,542	2,495
30%													
TOTAL		37,071	19,314	19,674	12,633	19,028	17,823	14,751	17,891	10,812	22,738	15,349	10,812

		Intervention Period												
	Cost per occurrence	W32	W36	W40	W44	W48	W52	W56	W60	W64	W68	W72	W76	W80
		D225	D253	D281	D309	D337	D365	D393	D421	D449	D477	D505	D533	D561
		#9	#10	#11	#12	#13	#14	#15	#16	#17	#18	#19	#20	#21
Study Subject Care Related:														
Informed consent	INR 1,439													
Inclusion/Exclusion criteria	INR 1,270													
Medical History with Demographics	INR 3,164													
Blood sample collection for Hemoglobin A1c, Serology, Serum chemistry and Hematology, for Central lab	INR 526	526		526		526		526		526		526		526
Urine sample collection for Urinalysis for Central lab	INR 379	379		379		379		379		379		379		379
Lab handling and/or shipping of specimen(s)	INR 467	467		467		467		467		467		467		467
IMP administration	INR 1,203	1,203	1,203	1,203	1,203	1,203	1,203	1,203	1,203	1,203	1,203	1,203	1,203	1,203
Assessment of injection site	INR 383	383	383	383	383	383	383	383	383	383	383	383	383	383
Pain VAS	INR 487	487	487	487	487	487	487	487	487	487	487	487	487	487
Vitals signs outside of Physical examination (including weight, if applicable)	INR 1,038	1,038	1,038	1,038	1,038		1,038	1,038	1,038	1,038	1,038		1,038	1,038
12-lead ECG (including interpretation and report)	INR 2,154													
Full physical examination (including Vital signs, height and weight as applicable)	INR 3,552													
Symptom-directed physical examination (including Vital signs and weight as applicable)	INR 1,994					1,994						1,994		
Body Mass Index (BMI)	INR 899													
Adverse events	INR 518	518	518	518	518	518	518	518	518	518	518	518	518	518
Concomitant medications	INR 518	518	518	518	518	518	518	518	518	518	518	518	518	518
Blood sample collection for total IgA, IgG and IgM; APRIL; g-d IgA1 and anti-IgA1 autoantibody, IgA-containing circulating immune complexes; markers of complement activation; ADA and exploratory assessments	INR 1,481	1,481	1,481		1,481	1,481	1,481		1,481	1,481		1,481		
Lab handling and/or shipping of specimen(s)	INR 474	474	474		474	474	474		474	474		474		
24-hour urine collection (creatinine, protein and albumin) for Central lab	INR 754			3,016			3,016							
Spot urine sample for uPCR determination and Urine sample for exploratory research for Central lab	INR 379	379	379		379	379	379	379		379		379		379
Blood sample for PK for Central lab	INR 979		979						979					
PK sample handling/shipping to Central lab	INR 474		474						474					
SF-36	INR 476			476			476					476		
Brief Fatigue Inventory	INR 925			925			925					925		
Total Study Subject Care Related Per Visit		7,853	7,934	9,936	6,481	8,809	10,898	5,898	7,555	7,853	4,147	10,210	4,147	5,898
Outside Services:														
Physician Fee, Complex (initial and final visits) (includes review of Kidney biopsy)	INR 5,592			5,592			5,592							
Physician Fee, Simple (interim visits)	INR 2,939	2,939	2,939		2,939	2,939		2,939	2,939	2,939	2,939	2,939	2,939	2,939
SC Fee, Complex (initial and final visit) (including recruitment, monitoring visits, CRF completion, randomization at D1, queries, dose modification as needed, dispensing/accountability of study drug and compliance)	INR 3,067			3,067			3,067							
SC Fee, Simple (interim visits) (including recruitment, monitoring visits, CRF completion, queries, dose modification as needed, dispensing/accountability of study drug and compliance)	INR 2,889	2,889	2,889		2,889	2,889		2,889	2,889	2,889	2,889	2,889	2,889	2,889
Total Outside Services Per Visit		5,828	5,828	8,659	5,828	5,828	8,659	5,828	5,828	5,828	5,828	5,828	5,828	5,828
Subtotal		13,681	13,762	18,595	12,309	14,637	19,557	11,726	13,383	13,681	9,975	16,038	9,975	11,726
Overhead (%)		4,104	4,129	5,579	3,693	4,391	5,867	3,518	4,015	4,104	2,993	4,811	2,993	3,518
30%														
TOTAL		17,785	17,891	24,174	16,002	19,028	25,424	15,244	17,398	17,785	12,968	20,849	12,968	15,244

	Intervention Period						Post-treatment Follow-up	End-of-Study	TOTAL	Alternative Visits (each) [3]	Conditional Visit
	Cost per occurrence	W84	W88	W92	W96	W100	W104	W112			
		D589	D617	D645	D673	D701	D729	D785		Home Health Vendor	ED
Study Subject Care Related:		#22	#23	#24	#25	#26					
Informed consent	INR 1,439								1,439		
Inclusion/Exclusion criteria	INR 1,270								1,905		
Medical History with Demographics	INR 3,164								3,164		
Blood sample collection for Hemoglobin A1c, Serology, Serum chemistry and Hematology, for Central lab	INR 526		526		526		526	526	8,942		526
Urine sample collection for Urinalysis for Central lab	INR 379		379		379		379	379	6,443		379
Lab handling and/or shipping of specimen(s)	INR 467		467		467		467	467	7,939		467
IMP administration	INR 1,203	1,203	1,203	1,203	1,203	1,203			31,278		
Assessment of injection site	INR 383	383	383	383	383	383			9,958		
Pain VAS	INR 487	487	487	487	487	487			12,662		
Vitals signs outside of Physical examination (including weight, if applicable)	INR 1,038	1,038	1,038	1,038	1,038				20,760		
12-lead ECG (including interpretation and report)	INR 2,154								2,154		
Full physical examination (including Vital signs, height and weight as applicable)	INR 3,552								3,552		
Symptom-directed physical examination (including Vital signs and weight as applicable)	INR 1,994					1,994		1,994	11,964		
Body Mass Index (BMI)	INR 899								899		
Adverse events	INR 518	518	518	518	518	518	518	518	16,576		518
Concomitant medications	INR 518	518	518	518	518	518	518	518	16,576		518
Blood sample collection for total IgA, IgG and IgM; APRIL; g-d IgA1 and anti-IgA1 autoantibody, IgA-containing circulating immune complexes; markers of complement activation; ADA and exploratory assessments	INR 1,481	1,481			1,481	1,481	1,481	1,481	29,620		1,481
Lab handling and/or shipping of specimen(s)	INR 474	474			474	474	474	474	9,480		474
24-hour urine collection (creatinine, protein and albumin) for Central lab	INR 754						3,016		12,064		3,016
Spot urine sample for uPCR determination and Urine sample for exploratory research for Central lab	INR 379	379	379		379	379		379	7,959		
Blood sample for PK for Central lab	INR 979	979						979	10,769		
PK sample handling/shipping to Central lab	INR 474	474						474	5,214		
SF-36	INR 476						476	476	4,284		476
Brief Fatigue Inventory	INR 925						925	925	8,326		925
Total Study Subject Care Related Per Visit		7,934	5,898	4,147	7,853	7,437	8,780	9,590	243,926	0	8,780
Outside Services:											
Physician Fee, Complex (initial and final visits) (includes review of Kidney biopsy)	INR 5,592						5,592	5,592	27,960		5,592
Physician Fee, Simple (interim visits)	INR 2,939	2,939	2,939	2,939	2,939	2,939			79,353	2,939	
SC Fee, Complex (initial and final visit) (including recruitment, monitoring visits, CRF completion, randomization at D1, queries, dose modification as needed, dispensing/accountability of study drug and compliance)	INR 3,067						3,067	3,067	18,402		3,067
SC Fee, Simple (interim visits) (including recruitment, monitoring visits, CRF completion, queries, dose modification as needed, dispensing/accountability of study drug and compliance)	INR 2,889	2,889	2,889	2,889	2,889	2,889			75,114	2,889	
Total Outside Services Per Visit		5,828	5,828	5,828	5,828	5,828	8,659	8,659	200,829	5,828	8,659
Subtotal		13,762	11,726	9,975	13,681	13,265	17,439	18,249	444,755	5,828	17,439
Overhead (%)		4,129	3,518	2,993	4,104	3,980	5,232	5,475	133,427	1,748	5,232
30%											
TOTAL		17,891	15,244	12,968	17,785	17,245	22,671	23,724	578,182	7,576	22,671

Total Per Study Subject:	INR 578,182

Additional Treatment Related Costs (inclusive of the applicable overhead)	
Screen Failure on Screening Visit [1]	INR 37,071
Screen Failure on D1 [1]	INR 19,314
Re-screening	INR 37,071
Advertising (if applicable) [6]	TBD
Study Subject Stipend (per visit), including meals	INR 2,000
Study Subject Stipend (per visit) 24h urine collection	INR 4,000
Travel expenses (ground transportation) [2]	INR 897
Pregnancy Test (Urine or Serum) (if applicable)	INR 1,050
Re-consent	INR 1,871
Kidney biopsy (including anesthesia) (outside SOC)	INR 123,734
Surgical pathology (gross and microscopic examination, including report) (outside SOC)	INR 9,285
12-lead ECG (including interpretation and report) (repeated, per Investigator's discretion)	INR 2,800
Full physical examination (including Vital signs and weight) (applicable for D1 visit, if has not been performed within 1 week of the visit or for the Unscheduled visit, per Investigator's discretion)	INR 4,618
Symptom-directed physical examination (including Vital signs and weight) (applicable for D1 visit if a full physical examination has been performed within 1 week of the visit)	INR 2,592
Blood sample for Future biospecimen research (optional)	INR 1,925
Blood sample for ADA (in the event of immunogenicity related clinical condition)	INR 1,925
Blood sample for PK (in the event of immunogenicity related clinical condition)	INR 1,273
PK/ADA/FBR specimen sample handling/shipping to Central lab	INR 616
Blood sample collection for Hemoglobin A1c, Serology, Serum chemistry and Hematology, for Central lab (repeated, as applicable)	INR 684
Lab handling and/or shipping	INR 607
24-hour urine collection (creatinine, protein and albumin) for Central lab (applicable for re-testing, due to non-viable sample)	INR 980
Photo of injection site reaction	INR 517
ACE/ARB Treatment [7]	TBD
Nurse Fee (per visit) [4]	INR 1,915
Travel expenses for site staff (applicable for homecare visit which is done by site) [5]	TBD
Chart review (per chart, up to the max of 250 charts)	INR 1,560
Unscheduled Visits (if applicable)	INR 7,498

Additional Study Related Costs	
Study Start-Up Fee/Site Set-Up Fee (one time fee)	INR 52,518
Pharmacy: Set-Up Fee (one time fee)	INR 31,973
Document Storage, Archiving Total Cost (one time fee)	INR 51,087
IRB prep Fee (one time fee)	INR 36,708
IRB Maintenance Fee (annual)	INR 23,817
Site Administrative fee (annual)	INR 29,296
Principal Investigator meeting attendance and Study Coordinator forum (30 min monthly, for each)	INR 3,212
Technology/E-platform learning fee (one time fee for sites who utilize eSource only)	INR 37,432

[1] Screen Failures will be reimbursed at the amount set forth above for the first 5 (five) Study Subjects. There will be a limit of reimbursement of one (1) Screen Failure for every one (1) Study Subject randomized after reimbursement for the first 5 (five) Screen Failures. Additional Screen Failures may be approved by CRO upon written approval.
[2] Higher Study Subject Travel Reimbursement/Additional kind of transport, including air travel will require CRO/Sponsor approval.
[3] Applicable for home visits only, if performed by Home health vendor, starting from W4 visit.
[4] Additional Nurse fee is applicable for home visits, if performed by site staff.
[5] Will be reimbursed after receipt of invoice reflecting actual costs.
[6] Additional funding may be approved and reimbursed based in CRO project management approval.
[7] This can be considered on a case by case basis.

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	**IN-KA71249236019135U**
Certificate Issued Date	:	11-Jul-2022 11:02 AM
Account Reference	:	NONACC (FI)/ kaksfcl08/ BANGALORE8/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKAKSFCL0862595617487092U
Purchased by	:	PAREXEL INTERNATIONAL CLINICAL RESEARCH PVT LTD
Description of Document	:	Article 4 Affidavit
Description	:	AFFIDAVIT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	PAREXEL INTERNATIONAL CLINICAL RESEARCH PVT LTD
Second Party	:	NA
Stamp Duty Paid By	:	PAREXEL INTERNATIONAL CLINICAL RESEARCH PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Please write or type below this line

Clinical Site Agreement

THIS AGREEMENT is made by and between

(1) **Parexel International Clinical Research Private Limited,** CoWrks, RMZ EcoWorld, Ground floor, Bay Area- Adjacent to Building 6A, Outer Ring Road, Devarabeesanahalli Village, Bangalore -560103, India.

(hereinafter CRO)

And

(2) **Mahatma Gandhi Mission's Medical College & Hospital**, MGM Medical College & Hospital N-6 CIDCO, Aurangabad - 431003, Maharashtra, India.

(hereinafter Institution)

And

(3) **Dr. Prashant Prabhakar Udgire**, Mahatma Gandhi Mission's Medical College & Hospital, MGM Medical College & Hospital N-6 CIDCO, Aurangabad - 431003, Maharashtra, India.

(hereinafter Investigator)

together the "**Parties**" and each a "**Party**".

regarding

Protocol No: D6402C00001 (hereinafter Protocol)

"A Phase 2b, Randomised, Double-Blind, Active Controlled, Multi Centre Study to Evaluate the Efficacy, Safety and Tolerability of Oral AZD9977 and Dapagliflozin Treatment in Patients with Heart Failure and Chronic Kidney Disease." (hereinafter Study)

AZD9977 and Dapagliflozin (hereinafter Study Drug)

of

SPONSOR: AstraZeneca AB
at 151 85 Södertälje, Sweden

hereinafter SPONSOR

WHEREAS, SPONSOR is the sponsor of the multi-center/multi-centre Study to clinically evaluate the Study Drug and CRO (or its Affiliate) has been retained by SPONSOR (under a separate written agreement) to act as SPONSOR's contractor and designee in managing the Study for SPONSOR; and

WHEREAS Institution and Investigator shall Fully Cooperate with CRO and shall permit CRO to perform any and all of the SPONSOR's Study obligations and to exercise any and all of SPONSOR's Study rights that lie with SPONSOR, on the basis of Applicable Law and GCP regulations as though such rights were CRO's own rights, as has been delegated by SPONSOR to CRO.

WHEREAS, Investigator is an employee of Institution; and

WHEREAS, Institution and Investigator each desires to participate in the Study as described in this Agreement; and

WHEREAS, this Agreement explains the joint and several obligations and rights of Institution and Investigator and the obligations and rights of CRO with respect to the performance of the Study.

WHEREAS, under this Agreement CRO does not act, or purport to act, as SPONSOR's contractual agent, but rather as SPONSOR's appointed Designee for managing the Study.

1. DEFINITIONS

Definitions for terms used in this Agreement are in Exhibit B.

2. CONDUCT OF THE STUDY

2.1 Institution agrees, and commits itself to CRO, to allow Investigator and other Study Personnel to conduct the Study at Institution and warrants that Investigator and other Study Personnel are either employed by Institution or contractors bound in writing to equivalent obligations as are contained in this Agreement.

2.2 Investigator agrees, and commits itself to CRO, to conduct the Study at Institution. Investigator shall personally supervise the conduct of the Study by the Study Personnel to the full extent contemplated by the Protocol and by Applicable Law.

2.3 Investigator and Institution acknowledge that SPONSOR is the sponsor of the Study, and as such is an intended third-party beneficiary of this Agreement, whereas SPONSOR transfers any or all of the SPONSOR's Study related functions to CRO in compliance with ICH-GCP, sec. 5.2.1. The Parties acknowledge that conferring third-party beneficiary status upon the SPONSOR and its affiliates is a direct and material purpose of the Parties entering into this Agreement. To the extent Applicable Law does not allow vesting of any rights directly in SPONSOR under this Agreement, such rights will vest in the CRO, who shall enforce such rights upon SPONSOR's written instruction. In addition to the foregoing, Investigator and Institution agree that CRO may disclose any and all Study Documentation and/or Materials relating to this Agreement, and/or relating to Investigator's and Institution's participation in the Study (including without limitation any Reports or other documents or materials provided by Investigator or Institution to CRO hereunder), to SPONSOR. All references to SPONSOR herein (whether in the context of delivery of Study Documentation, submission of applications, financial terms, or anything else) derive from SPONSOR's status as such, as set out by Applicable Law and GCP regulations, and Investigator and Institution agree to all such instances. Investigator and Institution will fully cooperate with CRO's requests relating to SPONSOR.

2.4 Investigator and Institution acknowledge that CRO is the recipient of Services described in this Agreement and, for the avoidance of any doubt, that SPONSOR is not the recipient of Services described in this Agreement.

2.5 Institution and Investigator specifically agree, and commit themselves to CRO, to (and warrant that Study Personnel will) conduct the Study in a diligent, efficient, and skilful manner, in strict compliance with the terms and conditions of this Agreement, the Protocol including subsequent amendments, any specific Study Instructions, Applicable Law, all requirements of the Institution or facility, and any other professional standards applicable to their professional industries and fields. Neither Institution nor Investigator nor any Study Personnel shall make any unauthorized warranties to any person (including Subjects) concerning the product being tested in the Study.

2.6 Investigator shall obtain the written approval of the appropriate Institutional Review Board (IRB) or Ethics Committee (EC) prior to commencement of the Study and will furnish CRO or SPONSOR with the IRB/EC's letter of approval.

2.7 If required by Applicable Law, CRO shall make the necessary submissions or notifications to the regulatory authorities. The Study may not commence until the Investigator has been informed by CRO that such authorization has been granted.

2.8 Investigator shall, prior to a Subject's participation in the Study, obtain the Subject's written informed consent to participate in the Study. Each Subject's written informed consent shall be in a form that is in accordance with the Protocol.

2.9 Investigator shall enroll the number of duly qualified (according to the Protocol) Subjects for the Study as set forth in Exhibit A and shall do so according to the timetable set forth in Exhibit A. Notwithstanding the foregoing, Investigator agrees that SPONSOR or CRO may unilaterally revise the number of Subjects that Investigator shall enroll, and/or the timeframe for such enrollment, via Study Instructions at any time.

2.10 Institution and Investigator shall (a) keep a detailed and written inventory of all clinical supplies, equipment and Study Drug provided by SPONSOR or CRO or its Affiliates and shall store such Materials according to the Protocol or Study Instructions and (b) retain all necessary Subject records and/or documents whether

electronic, paper, or in any other form relating to the Study for fifteen (15) years after the end or the premature termination of the Study and (c) not destroy any Study Documentation without the prior written approval of the SPONSOR. Institution and Investigator shall provide to CRO or its Affiliates all study data collected on case report forms as instructed by CRO.

2.11 Institution and Investigator agree that they are not presently under any agreement or obligation which conflicts with the duties and obligations owed to SPONSOR or CRO under this Agreement, and further agree not to undertake any such obligation or agreement during the course of the Study. Investigator warrants that no Study Personnel are presently under any agreement or obligation which conflicts with the duties and obligations owed to SPONSOR or CRO under this Agreement and shall ensure that no Study Personnel will undertake any such obligation or agreement during the course of the Study.

2.12 Institution shall, throughout the duration of the Study, provide, keep available to the Study Personnel and maintain all necessary Resources for the adequate performance of the Study. Investigator shall, throughout the duration of the Study, ensure that adequate Study Personnel are available to complete the Study. Institution and Investigator shall inform CRO promptly in writing (including by email) about all changes impacting the Resources and/or the Study Personnel.

2.13 The Protocol, including any amendments thereto, constitutes an integral part of this Agreement by reference. In case of any inconsistency between this Agreement and the Protocol, the Protocol shall take precedence on matters of medicine, science and conduct of the Study; otherwise, the terms of this Agreement shall prevail.

2.14 Institution and Investigator agree that if any Study Personnel is a government employee, official and/or performing a governmental function, such relationship may be disclosed to the SPONSOR and any compensation that such individual receives with respect to the Study may be disclosed to the Institution and is hereby approved.

2.15 Institution and Investigator warrant that neither they, nor any Study Personnel are officials, agents, or representatives of any government or political party or international organization where they may be in positions of authority to be able to improperly help CRO or SPONSOR obtain a business advantage. Institution and Investigator further warrant that neither they nor any Study Personnel shall make any payment, either directly or indirectly, of any money or other consideration (hereinafter Payment), to government or political party officials, officials of international organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (hereinafter collectively Officials) where such Payment would constitute violation of any law, including the U.S. Foreign Corrupt Practices Act. In no event shall Institution, Investigator, or any Study Personnel make any Payment either directly or indirectly to Officials if such Payment is for the purpose of influencing decisions or actions with respect to the subject matter of this Agreement or any other aspect of CRO's or SPONSOR's business. Institution and Investigator shall report any violation of this warranty promptly to CRO and agree to respond to any CRO inquiries about any potential violations and make appropriate records available to CRO or SPONSOR upon request. At any time upon the request of CRO, Institution and Investigator agree to promptly certify in writing their ongoing compliance (and the compliance of all other Study Personnel) with the warranties contained in this Section 2.15.

2.16 If CRO or SPONSOR requests Institution and/or Investigator to source marketed/comparator drug, CRO will reimburse Institution and Investigator according to Exhibit A. Institution and Investigator warrant that they will only source drug products that comply with the specifications of the Protocol.

2.17 Investigator and/or Study Personnel may be invited to attend and participate in meetings relating to the Study. The Parties agree that there will be no additional compensation for attendance or participation at such meetings by the Investigator or any Study Personnel. If the Investigator and/or Study Personnel are required to perform any additional tasks, over and above those required for the conduct of the Study, the terms and obligations for the provision of such services shall be subject to a separate agreement.

3. REPORTS, MONITORING AND COOPERATION

3.1 Institution and Investigator shall submit to CRO, and CRO has a right to claim under this Agreement, all completed eCRFs or CRFs resulting from the Study within a reasonable time period and in accordance with any Study Instructions. Institution and Investigator warrant that all eCRFs or CRFs submitted to CRO are

true, complete, correct and accurately reflect the results of the Study. Institution and Investigator shall also provide CRO with copies of all Reports, and any updates that are required by the EC/IRB.

3.2 Institution and Investigator shall Fully Cooperate with CRO and will meet with representatives of CRO, or its Designee, at mutually convenient times according to a schedule set forth in Study Instructions for monitoring visits, consultations and to allow direct inspection of all Study related records, including Subject medical files, as requested by CRO and for any other purposes relating to the Study as deemed necessary by CRO. Investigator shall ensure that all Study Personnel Fully Cooperates with CRO, including meeting with personnel of CRO, or its Designee, as set forth in the preceding sentence.

4. AUDITS AND REGULATORY INSPECTIONS

4.1 Institution and Investigator shall Fully Cooperate with audits or inspections, applicable to the Study, performed during or after completion of the Study, by SPONSOR or CRO. Institution and Investigator shall allow SPONSOR, CRO and governmental or regulatory authorities, including but not limited to the U.S. Food and Drug Administration, access to Resources used to perform tasks related to the Study, shall make all requested documents available to them and shall provide them with any further Study Documentation as may be requested.

4.2 In the event the audit or regulatory inspection identifies a lack of compliance with this Agreement on the part of Institution or Investigator (or failure by any Study Personnel to act in accordance with the terms and conditions of this Agreement), CRO may terminate this Agreement in accordance with Section 16.1 (a).

4.3 Institution and Investigator shall immediately notify CRO by telephone, email or fax if a governmental or regulatory authority, including but not limited to the Drugs Controller General of India (DCGI), requests to carry out an inspection of Institution's facilities, or does so. Institution and Investigator shall allow SPONSOR and CRO to be present during such inspection and shall provide to SPONSOR and CRO copies of all Materials, correspondence, statements, forms and records that Institution and Investigator receives, obtains or generates pursuant to or in connection with any such inspection.

5. FINANCIAL DISCLOSURE

5.1 During the conduct of the Study and for one (1) year after its completion, Investigator shall, and Institution shall cause the Sub-Investigator(s) if applicable, and Study Personnel to, execute and update such forms, disclosures and certifications now or subsequently required by SPONSOR or any applicable regulatory bodies related to his/her financial interests in the SPONSOR and/or the Study Drug. This obligation shall survive the expiration or termination of this Agreement.

6. CONFIDENTIAL INFORMATION

6.1 Institution and Investigator agree that they shall at all times keep confidential the Confidential Information that they receive from CRO, SPONSOR, or otherwise in connection with this Agreement. The Institution and Investigator shall safeguard the Confidential Information with at least the same level of care as it would afford to its own confidential information and shall not use the Confidential Information for any purpose other than to perform its obligations under this Agreement. Institution and Investigator may disclose Confidential Information to Study Personnel, or other employees or staff who require access thereto for the purposes of this Agreement provided, however, that prior to making any such disclosures Institution and/or Investigator bind such Study Personnel, employees or staff by obligations of confidentiality at least as restrictive as those contained in this Agreement.

6.2 The obligations on the Institution and Investigator set out in Clause 6.1 above shall survive for ten (10) years after the expiry or termination of this Agreement, but shall not apply to any information which:

6.2.1 was in the Institution's or Investigator's possession (with full right to disclose) prior to receiving it from the CRO and/or SPONSOR, as demonstrated by written records;

6.2.2 is public knowledge otherwise than as a result of any breach of this Clause or any similar Clause in any other relevant agreement; or

6.2.3 the Institution and/or Investigator can demonstrate was developed independently without reference to the Confidential Information or was received from a third party who had the right to disclose such information in a non-confidential manner.

6.3 The Institution or Investigator may disclose Confidential Information to the extent required by a court of competent jurisdiction, by a governmental, supervising or regulatory body, or otherwise in order to comply with Applicable Laws (including freedom of information legislation), provided always that (i) to the extent it is legally permitted to do so, the disclosing party gives the SPONSOR as much notice of such disclosure as possible; and (ii) the disclosing party complies with the SPONSOR's reasonable directions for taking legally available steps to resist or narrow such requirement (at the SPONSOR's reasonable expense) and in any event restricts the disclosure to only those parts of the Confidential Information lawfully required to be disclosed.

7. RIGHTS TO INFORMATION AND INVESTIGATIONAL PRODUCT

7.1 All Materials and Study Drug provided to Institution or Investigator for purposes of the Study are and will remain SPONSOR's property. Institution, Investigator, (and Study Personnel) shall not acquire any rights of any kind whatsoever with respect to the Study Drug or such Materials as a result of performance under this Agreement or otherwise.

7.2 Institution and Investigator shall deliver all Materials, unused Study Drug and clinical specimens to SPONSOR, CRO or their respective Designee in a timely manner throughout the performance of the Study, as provided in the Protocol or Study Instructions, and in no event later than ten (10) business days after (i) the date of termination of this Agreement or (ii) the date on which SPONSOR or CRO otherwise requests delivery of Materials, unused Study Drug and clinical specimens.

7.3 The Materials and Study Documentation (including publication) may be used by SPONSOR in any manner it deems appropriate to comply with its business interests, both during, and following termination of, this Agreement.

8. PUBLICITY

8.1 No party to this Agreement shall use the name, symbols, trademarks or imagine of any other party hereto, or SPONSOR's name, symbols, trademarks or image, in connection with any advertising or promotion of any product or service without the prior written consent of such party or SPONSOR, as appropriate.

9. PUBLICATION

9.1 The Institution and the Investigator shall be entitled to publish the results of, or make presentations related to, the Study, provided that any publications or presentations to be made within two (2) years of completion of the Study shall require the SPONSOR or CRO's prior written consent. All such publications or presentations shall (i) be consistent with academic standards and International Committee of Medical Journal Editors guidelines, (ii) not be false or misleading, (iii) comply with all Applicable Laws, (iv) not be made for any commercial purpose.

9.2 The Institution and/or the Investigator shall provide the SPONSOR with copies of any Materials relating to the Study, or the Developed Technologies that either intends to publish (or submit for publication) or make any presentations relating to, at least thirty (30) days in advance of publication, submission or presentation.

9.3 At the request of the SPONSOR or CRO, the Institution and/or the Investigator:

9.3.1 shall not include in or shall remove from any proposed publication any Confidential Information, errors or inaccuracies; and

9.3.2 shall withhold publication, submission for publication or presentation for a period of ninety (90) days from the date on which the SPONSOR receives the material to allow the SPONSOR to take such measures as the SPONSOR considers necessary to preserve its proprietary rights and/or protect its Confidential Information.

9.4 The Institution and the Investigator shall include the following acknowledgement in all publications and presentations relating to the Study, the Study Documentation or the Developed Technologies, as well as in any financial disclosure information relating to the Study: "AstraZeneca sponsored this clinical trial." A copy of any publications and presentations relating to the Study, the Study Documentation and/or the Developed Technologies shall be provided to the SPONSOR on publication or presentation, and the SPONSOR shall be entitled to make copies of and distribute the publication or presentation as it considers necessary.

9.5 Subject to Clause 8, no Party shall mention or otherwise use the name, trade mark, trade name or logo of any other Party or the SPONSOR in any publication, press release or promotional material with respect to the Study without the prior written approval of such Party or the SPONSOR; provided, however, that the SPONSOR shall have the right to identify the Institution, the Investigator and the responsible Study Personnel in any Study recruitment activities or other Study-related meetings.

9.6 The SPONSOR has a long-standing commitment to transparency, and the Institution and the Investigator acknowledge that the SPONSOR shall post the Study on clinical trial registries and publish the results on clinical trial results databases in such format (including www.astrazenecaclinicaltrials.com), and/or provide such results to the governmental and/or regulatory authorities.

9.7 If the SPONSOR invites the Investigator to be an author of a SPONSOR-managed publication, the Investigator shall direct, draft and/or review the proposed publication, and approve the final version of the publication to be published. No compensation shall be provided in respect of any such authorship. Any authorship, medical writing, editorial or logistical support provided to the Investigator or the Institution by the SPONSOR in respect of publication shall be subject to the SPONSOR's publications policy, details of which are available at www.astrazeneca.com.

10. INTELLECTUAL PROPERTY

10.1 Except as expressly set out in this Agreement, no Party nor the SPONSOR shall acquire any right, title or interest in or to the Intellectual Property of any of the other Parties or the SPONSOR's or their licensors.

10.2 The SPONSOR shall own all rights and title in any Intellectual Property arising from the Study or relating to the Study Drug, any Developed Technology and the Study Documentation, except to the extent that the Institution and Investigator are required to retain any Study Documentation in accordance with the Applicable Laws. The Institution and the Investigator shall promptly disclose any such Intellectual Property to the SPONSOR and CRO in writing or in such other format as the Parties may agree.

10.3 To the extent capable of prospective assignment, the Institution and the Investigator hereby assign to the SPONSOR (or its Designee) all their rights, title and interest in and to all Intellectual Property falling within Clause 10.2 above. To the extent that any such Intellectual Property cannot prospectively be assigned, the Institution and the Investigator shall assign, and shall procure that the Study Personnel shall assign, such Intellectual Property to the SPONSOR (or its Designee) on creation.

10.4 The Institution and the Investigator shall ensure that the Study Personnel take all steps as the SPONSOR and/or CRO may reasonably require from time to time in order to enjoy the full benefit of the rights assigned under this Clause 10.

10.5 The SPONSOR grants to the Institution a perpetual, royalty-free non-exclusive licence to use the Intellectual Property arising only from the Study for internal research and educational purposes only, and with no right to grant sub-licences. The provisions of Section 6 and 9 of this Agreement shall continue to apply in relation to any such licence.

11. DATA PROTECTION & PRIVACY

11.1 Institution and/or Investigator hereby represent and warrant that they shall obtain all necessary consents in writing from:

(a) all Subjects as per the informed consent form; and

(b) the key members of Study Personnel and Investigator participating in the Study for administrative / study management and any other purpose required by law so that such Subjects', Study Personnel's and Investigator's Personal Data can be Processed by (including transferred to) CRO, any of its Affiliates, and SPONSOR or any of its Affiliates and regulatory authorities in each case within or outside the country where such data originates.

11.2 The Parties agree, and CRO confirms Sponsor agrees, to adhere to the principles of medical confidentiality in relation to Subjects involved in the Study and to comply at all times with their respective obligations under all data protection Applicable Laws in relation to this Agreement and the protection of the Personal Data of Subjects and Study Personnel, where CRO, Sponsor and the Institution shall act as Data Controllers with regard to the processing and protection of this Personal Data each of them undertakes.

11.3 Both the CRO and the Institution shall maintain, and CRO confirms Sponsor shall maintain, appropriate technical and organisational security measures to protect the Subjects' and the Study Personnel's Personal Data they process in relation to this Agreement.

11.4 The Institution shall appoint a person that shall act as a primary point of contact and shall respond to all Data Subjects' rights exercised by the Subjects and/or the Study Personnel in respect to the processing of their Personal Data in relation to this Agreement ('Data Subject's Request'). The Institution shall inform Sponsor and CRO and request their assistance in responding to a Data Subject's Request only to the extent the Institution is unable to manage and respond to the Data Subject's Request without information which could only be provided by the Sponsor and/or CRO. To the extent, the Sponsor and/or CRO needs to provide information to the Institution, the Institution shall inform the Sponsor and/or CRO within three (3) days upon receiving the Data Subject's Request. Under such circumstances, the Sponsor and/or CRO shall cooperate with the Institution and shall provide the Institution with, subject to Applicable Law, the requested information and undertake any reasonable actions to enable the Institution to respond to the Data Subject's Request. The Institution shall, upon the reasonable request by Sponsor and/or CRO, provide Sponsor and/or CRO with any information, undertake any actions or provide assistance to the Sponsor and/or CRO as may be required by the Sponsor and/or CRO to respond to a Data Subject's Request.

11.5 If a Personal Data Breach occurs in relation to any Subjects' or Study Personnel's Personal Data processed in relation to this Agreement and it is likely that such breach poses a risk to an individual's rights and freedoms (a "Reportable Breach"), the Institution must notify the relevant supervisory authority without undue delay and at the latest within 72 hours after having become aware of such breach. If such Reportable Breach poses a high risk to the affected individuals, then the Institution shall also inform them, unless the Institution has put in place effective technical and organisational protection measures that ensure that the risk is no longer likely to materialise. The Institution shall notify the Sponsor and/or CRO of any Reportable Breach no later than 24 hours after having become aware of such Reportable Breach.

11.6 The Parties shall, and CRO confirm Sponsor shall, indemnify, defend, and hold each other harmless from and against any and all liabilities, claims, losses, suits, judgments, and reasonable legal fees arising from any breach, negligent act, error or omission of relevant data protection obligations under this Agreement by the other Party, its staff or Subcontractors.

12. INDEMNIFICATION

12.1 Any indemnification of the Institution and Investigator by SPONSOR shall be through a separate written agreement (or letter) between Institution, Investigator and SPONSOR directly. CRO shall act as the intermediary to coordinate the provision of any such agreement or letter of indemnity by SPONSOR and shall have no other obligation in connection therewith. Requests for such letters should be made in writing to the address below:

Investigator Contracts
Study #250951
Parexel International Clinical Research Private Limited
CoWrks, RMZ EcoWorld,
Ground floor, Bay Area- Adjacent to Building 6A,
Outer Ring Road, Devarabeesanahalli Village,
Bangalore -560103, India.

Such requests must include the full legal names and addresses of all parties who are requested to be indemnified by SPONSOR.

12.2 CRO shall be liable under this Agreement for damages resulting from its negligence or wilful misconduct in the execution of its obligations hereunder.

13. INSURANCE

13.1 The Parties acknowledge that SPONSOR will ensure adequate provision is made by way of insurance or indemnity arrangements sufficient to meet its obligations and liabilities under Applicable Laws as the sponsor of the Study, in particular towards Study subjects for personal injury arising as a result of participation in the Study.

14. DEBARMENT

14.1 Institution and Investigator hereby certify that neither Institution, Investigator nor any person employed by Institution or Investigator to work on the Study (including any subcontractor permitted pursuant to Section 17.2) has been:

(a) debarred by any relevant authorities, pursuant to any Applicable Law, including but not limited to Section 306(a) and (b) of the US Federal Food, Drug and Cosmetic Act, or disqualified as a clinical investigator under Applicable Law;

(b) threatened to be debarred or indicted for a crime or otherwise engaged in conduct for which a person can be debarred under Applicable Law;

(c) disciplined by and/or banned by a relevant authority from carrying out clinical trials.

For purposes of this Section, any of the foregoing shall be deemed to constitute being "debarred".

In addition, Institution and Investigator agree that no debarred person will in the future be employed or otherwise engaged (including on a contract basis) by Institution or Investigator to work on the Study. If during the course of the Study, Institution or Investigator becomes debarred or learns that any person connected with the Study is debarred, or that there is a threat of debarment of any such person, then Institution and Investigator must immediately notify SPONSOR and CRO. CRO may immediately terminate this Agreement in the event any of the foregoing occurs.

15. PAYMENT TERMS AND CONDITIONS

15.1 In full consideration for the Services of Institution, Investigator and Study Personnel rendered in compliance with the Protocol, CRO agrees to pay the fees and expenses set forth in Exhibit A. Such fees and expenses will be paid solely to the Institution, except as otherwise expressly set forth in Exhibit A. The parties agree that Exhibit A – Payment Schedule is part of this Agreement clarifying the schedule of payments associated with this Agreement and that the fees and expenses set forth in Exhibit A represent the fair market value for the Services provided by Institution and Investigator. Payments shall be made in accordance with the provisions set forth in Exhibit A, with the last payment being made after Institution and Investigator complete all of their obligations under this Agreement and any Exhibits thereto. Institution and Investigator shall not seek reimbursement for any medical services or Study Drug from any third-party payers if such costs are already covered by payments made under this Agreement.

15.2 Institution and Investigator shall comply with all obligations with respect to taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement including, without limitation, those that relate to any payments made hereunder to Institution, Investigator, Study Personnel or, as the case may be, those that relate to any payments made by Institution or Investigator to Study Personnel. All fees and expenses payable to the Institution and Investigator are exclusive of all taxes and social security contributions applicable, other than GST.

15.3 Institution and Investigator acknowledge and agree that its, his or her judgment with respect to its, his or her advice to and care of each Subject is not and shall not be affected by the compensation Institution and/or Investigator receive in accordance with the Study.

15.4 Institution and Investigator agree that SPONSOR and CRO may disclose the fees and expenses payable or paid under this Agreement to any governmental authorities according to Applicable Law.

16. TERMINATION

16.1 This Agreement will become effective upon the date it is fully executed by all parties and shall continue in effect for the full duration of the Study according to the Protocol unless sooner terminated in accordance with the provisions of this Section. CRO may terminate this Agreement immediately at any time upon written notice to Institution and Investigator for any reasons, including without limitation upon any of the following occurrences:

(a) Institution or Investigator has failed to cure a breach to this Agreement within thirty (30) days of receipt of written notice specifying such breach; or

(b) Investigator becomes personally unavailable to conduct the Study and a SPONSOR or CRO-approved replacement has not been identified by Institution and Investigator; or

(c) two months after shipment of the Study Drug, Investigator has failed to meet the enrolment target for Subjects set forth in Exhibit A, or has recruited such a low number of Subjects that it can be reasonably assumed by CRO that the agreed number of Subjects will not be reached in accordance with the schedule set forth in Exhibit A; or

(d) the authorization/authorisation and approval to perform the Study is withdrawn by the regulatory authority governing Institution; or

(e) the audit or regulatory inspection identifies a serious breach or lack of compliance with this Agreement; or

(f) if any of the circumstances permitting termination pursuant to Section 14.1 occur.

16.2 This Agreement may be terminated by Institution or Investigator, upon sixty (60) days' prior written notice, for breach of contract by CRO if the breach is not cured within thirty (30) days of notification.

16.3 If this Agreement is terminated prematurely in accordance with Section 16.1 or 16.2 or 16.3, Institution and Investigator shall/must use its, his or her reasonable efforts to:

(a) minimize further costs while maintaining good medical care of the Subjects; and;

(b) ensure that all Subjects shall complete the Study according to the Protocol unless dictated otherwise by Study Instructions.

16.4 Should Investigator conclude that continuation of the Study is no longer medically justifiable, due to (i) unexpected results, (ii) the severity or prevalence of serious adverse events or (iii) the efficacy of the treatment with Study Drug appears to be insufficient; then he/she will promptly notify CRO and the EC/IRB in writing, and may suspend treatment of Subjects until such time as CRO (based on consultations with SPONSOR) and Investigator reach agreement as to the best course of action.

16.5 Termination of this Agreement by any party shall not affect the rights and obligations of the parties accrued prior to the effective date of termination of this Agreement. Any provision of this Agreement that should survive expiration or termination of this Agreement in order to give proper effect to its intent, shall survive expiration or termination of this Agreement. The following provisions shall survive the termination or expiry of the CSA to the extent necessary to preserve the rights and obligations under them: (Monitoring and Audit by SPONSOR/CRO); (Intellectual Property); (Confidential Information); (Rights to Publication); (Any Compliance provisions relating to: Transparency, Anti-bribery, Anti-corruption and Conflicts of Interest); (Third Party Rights for SPONSOR).

17. INDEPENDENT CONTRACTOR

17.1 The relationship of Institution and Investigator to CRO is that of independent contractor. Institution and Investigator commit themselves to perform the Services only as independent contractor and nothing contained herein shall be construed to be inconsistent with that relationship or status. Institution, Investigator, and Study Personnel shall not be considered employees or agents of CRO or SPONSOR and, as such, shall not be entitled to any benefits available to employees of CRO or SPONSOR.

17.2 Institution and Investigator shall not retain any subcontractor to perform any of its obligations under this Agreement without the prior written consent of CRO. Any such consent shall not relieve Institution and Investigator of its obligations hereunder, and Institution and Investigator shall remain fully liable for all acts and omissions of any such subcontractor. CRO shall be permitted to assign the discharge of service obligations it assumed under this Agreement to any of its Affiliates (or adequately qualified third party subcontractors), without releasing CRO from its responsibility for the appropriate performance of such assigned service obligations towards Institution and Investigator.

17.3 This Agreement shall not constitute, create or in any way be interpreted as, a joint venture, partnership, or business organization of any kind.

18. CONTRACTUAL

18.1 Titles to the Sections of this Agreement are solely for convenience and do not constitute a substantive part of this Agreement.

18.2 If any provision of this Agreement is held illegal, invalid or unenforceable by a court of law, the remainder of this Agreement shall not be affected thereby.

18.3 Failure to insist upon compliance with any of the terms and conditions of this Agreement shall not constitute a general waiver or relinquishment of any such terms or conditions, and the same shall remain at all times in full force and effect.

18.4 The Institution and Principal Investigator acknowledge that the SPONSOR is the sponsor of the Study and in order to satisfy pre-existing contractual obligations owed by the CRO to SPONSOR, the Parties agree that the SPONSOR and its affiliates are the intended third-party beneficiaries of the rights under this CSA (in particular the IP rights under Section 10). The Parties acknowledge that conferring third-party beneficiary status upon the SPONSOR and its affiliates is a direct and material purpose of the Parties entering into the CSA. To the extent Applicable Law does not allow vesting of any rights directly in SPONSOR under this CSA, such rights will vest in the CRO. Rights under this Section 18.4 cannot be modified without SPONSOR's consent. Except for the third-party beneficiary rights granted to the SPONSOR and its affiliates in this CSA, any person who is not a party to this CSA shall not have any rights under it and shall not be able to enforce any term of this CSA.

18.5 The respective signatories of the parties to this Agreement represent and warrant that they have the authority and ability to enter into the terms, provisions and conditions of this Agreement on behalf of their respective parties.

18.6 Neither party shall be responsible for any default under this Agreement by reason of strikes, riots, hostilities, wars, fire, acts of terrorism, acts of God, death of Investigator, or any other cause beyond its reasonable control.

18.7 This Agreement may not be assigned by Institution or Investigator without the prior written consent of CRO.

18.8 CRO may assign this Agreement to any of its subsidiaries, Affiliates or to any third party.

18.9 This Agreement constitutes the entire agreement and final understanding of the parties with respect to the subject matter hereof and supersedes and terminates all prior and/or contemporaneous understandings and/or discussions between the parties, whether written or verbal, express or implied, relating in any way to the subject matter hereof. This Agreement may not be altered, amended, modified or otherwise changed in any way except by a written agreement, signed by all parties.

18.10 All notices necessary or appropriate to be given pursuant to this Agreement shall be effective when delivered to the appropriate party at the address below:

To CRO:
Parexel International Clinical Research Private Limited
CoWrks, RMZ EcoWorld,
Ground floor, Bay Area- Adjacent to Building 6A,
Outer Ring Road, Devarabeesanahalli Village,
Bangalore -560103, India.
notices@parexel.com

To Investigator:
Mahatma Gandhi Mission's Medical College & Hospital,
MGM Medical College & Hospital N-6 CIDCO,
Aurangabad - 431003, Maharashtra, India.
Attn: Dr. Prashant Prabhakar Udgire
Phone: +91-9503181111
Email: prashant_udgire@rediffmail.com

To Institution:
Mahatma Gandhi Mission's Medical College & Hospital,
MGM Medical College &Hospital N-6 CIDCO,
Aurangabad - 431003, Maharashtra, India
Attn: Dr. Rajendra Brijmophan Bohra, Dean and HOD of ENT Department &
Dr. Deepak Bhosle, HOD- Clinical Research Centre, Pharmacology Department

18.11 Any party may change its address or number for notice by giving notice in accordance with Section 18.10 and 18.12.

18.12 Any delivery that is called for under this Agreement shall be complete when made by personal delivery, fax, email, registered post, certified post or courier, in each case with confirmation of delivery/receipt

18.13 The parties agree that this Agreement shall be governed by the laws of India, without regard to the conflicts of law provisions thereof. In case a dispute is brought before a court of law, the courts of Bangalore will have sole jurisdiction over the litigation.

IN WITNESS WHEREOF, the parties hereto have set their hands in triplicate with the intention that this is a binding agreement as provided herein.

(1) **Parexel International Clinical Research Private Limited:**

(Signature of Authorized Official)

Sanjay Vyas, EVP, India Country Head and MD
(Name of Authorized Official)

17 AUG 2022
Date

(2) **Mahatma Gandhi Mission's Medical College & Hospital:**

(Signature of Authorized Official)

Dr. Rajendra Brijmophan Bohra, Dean and HOD of ENT Department
(Name of Authorized Official)

29 AUG 2022
Date

(3) **Mahatma Gandhi Mission's Medical College & Hospital:**

(Signature of Authorized Official)

Dr. Deepak Bhosle, HOD- Clinical Research Centre, Pharmacology Department
(Name of Authorized Official)

29 AUG 2022
Date

(4) **Investigator:**

(Signature of Investigator)

Dr. Prashant Prabhakar Udgire
(Name of Investigator)

29 AUG 2022
Date

Exhibit A—Payment Schedule and Budget

Protocol No: D6402C00001

Protocol Title: "A Phase 2b, Randomised, Double-Blind, Active Controlled, Multi Centre Study to Evaluate the Efficacy, Safety and Tolerability of Oral AZD9977 and Dapagliflozin Treatment in Patients with Heart Failure and Chronic Kidney Disease"

1. Payee Details

Payee	Payee Details
Protocol Number	D6402C00001
Site Number	3509
Payee Name	MGM Medical College
Payee Address	N-6
Address Line 2	CIDCO
Address Line 3	N/A
Province/State/Country	Maharashtra
City	Aurangabad
Postal Code	431003
Country	India
Payee Contact	Dr. Prashant Prabhakar Udgire
Payee Contact Phone Number	+91-9503181111
Remittance E-mail Address	prashant_udgire@rediffmail.com
General Finance contract e-mail address if different from above	drdeepakmgm@gmail.com
NPI	N/A
Tax ID (VAT/GST Registration/TIN/SSN)	Pan: AAATM4256E GST not applicable.
Bank Account Holder Name	MGM Medical College
Bank Account Number	0376104000000107
IBAN (International Bank Account Number)	N/A
Bank Name	IDBI Bank
Bank Number	New Osmanpura, Aurangabad
Bank Branch Number	N/A
Bank Identification Code	IFSC code: IBKL0000376
Bank Type	N/A

To ensure proper payment please ensure that all fields above are completed.

In the event that payee details are modified during the course of the study, the parties agree that no amendments to this Agreement shall be required, provided that Investigator provides written notification to CRO with revised payee details to the following e-mail address InvestigatorPaymentSupportDesk3@PAREXEL.com. CRO accepts no liability for incorrect payee details provided by the Investigator or its representative.

2. Enrolment

This study is designed to evaluate subjects in accordance with the Protocol. The Investigator will use best efforts to enrol subjects as contemplated under this Agreement. When enrolment is complete for the study, the Investigator will be notified in writing and will dis-continue enrolling subjects.

3. Fees per Completed Subject:

The amount to be paid to the Investigator per completed subject is outlined in the attached Budget. CRO will withhold ten (10%) of the Fees per Completed Subject. All payments will be made on a quarterly basis via electronic wire and will be based on completed visits verified and entered in the subject EDC (electronic data capture system).

4. Site Fees and Equipment:

Payment for other fees or expenses that are not included in the Fees per Completed Subject (as defined in Section 3) will be made according to the following rates:

SCREENING FAILURE: Screening failures will be paid up to the amount of 50 % of the overall number of screened Subjects. A screening failure is considered a Subject who signs the informed consent form and completes screening but fails under inclusion/exclusion criteria and will not be randomized to the maintenance phase. The single screening failure will be remunerated on per procedure basis according to the fees stipulated **in the Attachment 1 to the Agreement - Detailed Budget – Fees per Completed Subject**. For the sake of clarity, the Parties confirm that CRO will pay for each procedure/visit performed by a Subject till the visit on which a Subject is considered Screen Failure. Payments for screening failures over 50 % will be at SPONSOR's discretion. Payment will be made upon receipt of the corresponding invoice.

START UP FEES: A non-refundable payment as outlined in the attached **Detailed Budget – Site Costs** for start-up related activities (e.g. initial pharmacy fees, preparation of regulatory documents, preparation, administration and submission of protocol and related documents to the IRB/EC, etc.) will be made upon execution of the Agreement, IRB/EC approval, and site initiation. This payment is considered full and final compensation for all activities associated with Study initiation. Payment to Institution will be made upon receipt of the corresponding invoice.

SUBJECT TRAVEL REIMBURSEMENT: A maximum amount as outlined in the attached **Detailed Budget – Conditional Fees** per visit will be paid for Subject travel reimbursement when the Subject travels to the Institution for Study visits. This amount needs to be reflected in the informed consent form as it will be provided to the Subject. In case the Subject travel reimbursement amount exceeds the amount outlined in the Detailed Budget, Institution shall seek prior CRO's/Sponsor's written approval. Such increase will not require the amendment of this Agreement. The reimbursement will be paid against the receipt of the invoice and corresponding support documentation.

ARCHIVING FEES: One-time payment at a rate outlined in the attached **Detailed Budget – Site Fees** will be paid at the end or at the premature termination of the Study after the close-out visit to cover the costs associated with archiving of the Study records for 15 years after the end or the premature termination of the Study. The reimbursement will be paid against the receipt of the invoice and corresponding support documentation.

UNSCHEDULED VISIT: Unscheduled visit performed as part of the Study that is outside of the normal standard of patient care and visit schedule will be paid per procedure done, according to the rates outlined in the attached **Detailed Budget – Conditional Fees**. Processing of payment will begin upon receipt of invoice with adequate supporting documentation in accordance and approval of CRO.

Investigator shall submit invoices for Services performed and expenses incurred under Section 4, all payments will be made within forty-five (45) days of receipt from the date of receipt of valid invoice in accordance with this Agreement. All payments will be made by electronic wire to the bank account stated above.

EQUIPMENT: All equipment needed for the development of the Study (and sub-study if applicable) will be supplied to the Institution by CRO or its Affiliates for its strict and sole use in performing the Study. Such equipment must be returned to CRO or its Affiliates following the closure of the site at the Institution and CRO or its Affiliates shall coordinate its return with the Institution, to ensure that all equipment is returned within 30 calendar days after site closure at the Institution.

The list of equipment:

Item Description	Unit Price
ECG Machine [GE MAC 2000]	1088 EURO (88,583 INR)
Sony HDRCX405 9.2MP HD Handycam Camcorder for audio-visual (AV) recording and infrastructure to store the recordings	458.2 USD (36,475.00 INR)

5. Pro-Rata Payments:

5.1 Payment for Subjects who do not complete the Study may be made to Investigator on a pro rata basis. Payment will include only those Subjects who were enrolled before the premature termination of the Study or the date that notice is received of such premature termination, whichever is later.

5.2 Should CRO or SPONSOR terminate the Study prior to completion, pro-rated expenses and fees shall be paid as set forth in Section 3 for each Subject visit performed before the premature termination of the Study or the date notice is received of such premature termination, whichever is later.

5.3 If other non-cancelable costs are incurred by Investigator in accordance with Section 16.4, of the Agreement, written justification must be provided to CRO for review and approval, and payment of such costs is subject to CRO or SPONSOR's approval.

5.4 In any instance where the Investigator has been received unearned funds, such funds shall be returned to CRO within forty-five (45) days of notification.

6. Protocol Violators

Payments for Study Subjects who are deemed to have been in violation of the Protocol may be paid up to the point that the violation occurred at the discretion of SPONSOR and/or CRO.

7. Invoices

Please send original, correct and itemized invoices to the following address:

Preferred
Invoices may be e-mailed to: ipo@parexel.com

Parexel International Clinical Research Private Limited,
CoWrks, RMZ EcoWorld,
Ground floor, Bay Area- Adjacent to Building 6A,
Outer Ring Road, Devarabeesanahalli Village,
Bangalore-560103, India.

All invoices must contain the following information:

(a) Protocol Number
(b) Invoice Number
(c) Invoice Date
(d) Place, Date & Description of Services Provided

(e) CRO Project Number
(f) Total amount payable
(g) Exchange rate used (where applicable)
(h) Investigator Name
(i) Site Number
(j) Investigator National Provider Identification (NPI) Number
(k) Payee Name and Address (per this Agreement)
(l) CRO Address listed above
(m) Date of Supply

Invoices and associated documentation should be de-identified of patient personal information (e.g. name, date of birth, initials, etc.) prior to being submitted to CRO.

8. Final Payment

Notwithstanding the foregoing, the final payment including the withholding outlined above shall be paid upon the completion of the following activities:

(n) all required Subject visits have been completed
(o) SPONSOR has received all Subject data in a form suitable for analysis
(p) all data clarification queries have been resolved to SPONSOR's satisfaction
(q) SPONSOR has verified that all required regulatory documentation is complete
(r) Institution has returned all required equipment, drugs and other material
(s) the Study close-out visit has been completed

Investigator shall have sixty (60) days from the receipt of the final payment under this Agreement to identify discrepancies and resolve any payment disputes with CRO.

All invoices for Study payments, as outlined herein, must be submitted to the CRO within sixty (60) days of the Institution's Study close-out visit. Invoices received after this time will not be reimbursed.

9. TAX

All fees and expenses in this Schedule are exclusive of GST or any applicable tax. All payments are subject to withholding tax as applicable.

Where the payee is GST registered then payment will not be made by CRO without receipt of a valid GST invoice. In addition to the above invoice requirements, GST registered payees must also include the following information:

(t) GST registration number of the supplier (payee), prefixed with their country code (if applicable); and
(u) Name, address and GST registration number of the customer (CRO);and
(v) GST, Net & Gross Amount (if applicable); and
(w) GST Rate (if applicable)

Exhibit A - Payment Schedule and Budget

Detailed Budget – Fees per Completed Subject

Fees per Completed Subject

Procedure	Qty	OH	Budget	PSC-OPT	SV	SRun-in	PRand	V3-BL	V4-D3	V5-D8	V6-D15	V7-D22	V8-D43	V9-D64	V10-D85EOT	SFU
Informed consent	1	✔	1,525.38		1,525.38											
Inclusion/exclusion criteria	3	✔	1,525.38		1,525.38	1,525.38		1,525.38								
Demography & baseline characteristics (smoking history and alcohol consumption included)	1	✔	1,445.10		1,445.10											
Physical examination - Brief	4	✔	2,247.94		2,247.94			2,247.94							2,247.94	2,247.94
Body weight, Height	2.5	✔	1,204.25		1,204.25			602.13							602.13	602.13
Medical/surgical history	2	✔	3,050.77		3,050.77			3,050.77								
Concomitant Medication	11	✔	722.55		722.55		722.55	722.55	722.55	722.55	722.55	722.55	722.55	722.55	722.55	722.55
Adverse Event review	9	✔	883.12					883.12	883.12	883.12	883.12	883.12	883.12	883.12	883.12	883.12
Vital signs (Blood preassure and pulse)	10	✔	1,284.53		1,284.53			1,284.53	1,284.53	1,284.53	1,284.53	1,284.53	1,284.53	1,284.53	1,284.53	1,284.53
Digital 12-lead safety ECG	6	✔	1,685.95		1,685.95			1,685.95	1,685.95		1,685.95		1,685.95		1,685.95	
Local echocardio-graphy	1	✔	26,172.39		26,172.39											
Interpretation and Report:Local echocardio-graphy	1	✔	10,276.28		10,276.28											
Local laboratory blood samples for clinical chemistry and haematology	1	✔	2,087.37		2,087.37											
Local laboratory urine sample for albumin, creatinine, and urinalysis	1	✔	401.42		401.42											
Local laboratory plasma sample for NT proBNP	1	✔	3,693.04		3,693.04											
Local laboratory serum/plasma samples for K+ and Na+	9	✔	1,364.82				1,364.82	1,364.82	1,364.82	1,364.82	1,364.82	1,364.82	1,364.82	1,364.82	1,364.82	
Local laboratory serum/plasma samples for creatinine including eGFR calculation	8	✔	722.55					722.55	722.55	722.55	722.55	722.55	722.55	722.55	722.55	
Central laboratory blood samples for clinical chemistry and haematology; and plasma sample for K+ measurement	9	✔	321.13					321.13	321.13	321.13	321.13	321.13	321.13	321.13	321.13	321.13
Central laboratory serum sample for creatinine for eGFR calculation	1	✔	321.13				321.13									
Central laboratory serum sample for cystatin C for eGFR calculation	10	✔	321.13				321.13	321.13	321.13	321.13	321.13	321.13	321.13	321.13	321.13	321.13
Central laboratory blood samples HbA1c, cholesterol and lipids	3	✔	321.13					321.13							321.13	321.13
Central laboratory urinalysis	4	✔	722.55					722.55					722.55		722.55	722.55
Central laboratory urine samples for albumin, creatinine, (for UACR calculation), Na+, K+, uric acid, urea, osmolality, glucose, and cortisol	7	✔	722.55				722.55			722.55		722.55	722.55	722.55	722.55	722.55
Predose sample for AZD9977 and dapagliflozin plasma concentrations	3	✔	1,043.68							1,043.68		1,043.68			1,043.68	
Blood samples for NT proBNP, aldosterone, renin, ACTH, cortisol, copeptin, and FPG	5	✔	321.13					321.13		321.13		321.13			321.13	321.13
Serum/plasma samples for cardiovascular biomarkers	4	✔	321.13					321.13				321.13			321.13	321.13
sample preparation for shipping to central lab	10	✔	561.98				561.98	561.98	561.98	561.98	561.98	561.98	561.98	561.98	561.98	561.98
urinalysis : local lab	1	✔	802.83		802.83											
Procedures Sub Total (INR)				**Rs 0.00**	**Rs 58,125.18**	**Rs 1,525.38**	**Rs 4,014.16**	**Rs 16,979.92**	**Rs 7,867.76**	**Rs 8,269.17**	**Rs 7,867.76**	**Rs 8,590.30**	**Rs 9,312.86**	**Rs 6,904.36**	**Rs 14,170.00**	**Rs 9,353.00**

Non Procedure	Qty	OH	Budget	PSC-OPT	SV	SRun-in	PRand	V3-BL	V4-D3	V5-D8	V6-D15	V7-D22	V8-D43	V9-D64	V10-D85EOT	SFU
Study Coordinator, Simple - Study data entry,	10	✔	4,062.34		8,124.69			4,062.34	4,062.34	4,062.34	4,062.34	4,062.34	4,062.34	4,062.34	4,062.34	
Pharmacy, Simple - Study treatment dispensation,Study treatment accountability	9	✔	971.43			971.43		971.43	971.43	971.43	971.43	971.43	971.43	971.43	971.43	
PI TIME	11	✔	3,620.78		7,241.56	3,620.78		3,620.78	3,620.78	3,620.78	3,620.78	3,620.78	3,620.78	3,620.78	3,620.78	
Study Nurse	11	✔	2,825.98		5,651.95		2,825.98	2,825.98	2,825.98	2,825.98	2,825.98	2,825.98	2,825.98	2,825.98	2,825.98	
Non Procedures Sub Total (Rs)				**Rs 0.00**	**Rs 21,018.20**	**Rs 4,592.21**	**Rs 2,825.98**	**Rs 11,480.53**	**Rs 11,480.53**	**Rs 11,480.53**	**Rs 11,480.53**	**Rs 11,480.53**	**Rs 11,480.53**	**Rs 11,480.53**	**Rs 11,480.53**	**Rs 0.00**
Overhead (all costs) 30%				**Rs 0.00**	**Rs 23,743.01**	**Rs 1,835.28**	**Rs 2,052.04**	**Rs 8,538.14**	**Rs 5,804.49**	**Rs 5,924.91**	**Rs 5,804.49**	**Rs 6,021.25**	**Rs 6,238.02**	**Rs 5,515.47**	**Rs 7,695.16**	**Rs 2,805.90**
Total Cost Per Visit with Overhead(INR)				**Rs 0.00**	**Rs 102,886.39**	**Rs 7,952.87**	**Rs 8,892.18**	**Rs 36,998.59**	**Rs 25,152.78**	**Rs 25,674.61**	**Rs 25,152.78**	**Rs 26,092.08**	**Rs 27,031.41**	**Rs 23,900.36**	**Rs 33,345.69**	**Rs 12,158.90**
Total Cost Per Patient (INR)				**Rs 355,238.64**												

Detailed Budget – Conditional Fees

Conditional Procedure	**Budget (INR)** (IOH Exclusive)
Informed consent	1,525.38
Local laboratory urine sample for albumin and creatinine	401.42
Optional postdose samples for AZD9977 and dapagliflozin	1,043.68
Optional RNA expression (blood) sample	321.13
Genomics Initiative optional, exploratory genetic sample	321.13
Genetic consent	1,043.68
Physician: Cardiology-Wearable device for assessment of activity, sleep and heart rate varaibles hand-out (optional)	4,094.45
Patient Reimbursement, Expenses, Patient Travel - Per Visit	1,204.25
Echocardiography	26,172.39
Interpretation and Report: Echocardiography	10,276.28
Local LH	2,569.07
Local FSH	3,211.34
Optional serum, plasma for exploratory assessment of biomarkers	321.13
Optional urine samples for exploratory assessment of biomarkers	722.55
SAEs	4,576.15
Local RT-PCR test for SARS CoV-2	3,612.75

Detailed Budget – Site Costs

Site Costs	**Budget (INR)** (IOH Exclusive)
Study Start-Up Fee/Site Set-Up Fee- Please refer to Exhibit A, point 4 for further details.	56,037.82
Document Storage, Archiving Total Cost- One time Fee, Upon Invoice for 15 years. Please refer to Exhibit A Point 4 for details	160,000.00

Exhibit B – Definitions

"**Affiliate**" means in relation to either party to this Agreement, any company, partnership or other entity which directly or indirectly controls, is controlled by, or is under common control with such party. For purposes of this definition, "control" means the beneficial ownership of more than fifty (50) per cent of the issued voting shares or the legal power to direct or cause the direction of the general management of the company, partnership or other entity in question, and "controlled" shall be construed accordingly.

"**Applicable Law**" means any international, national, federal, state, provincial, commonwealth, or local government law, statute, rule, requirement, code, regulation, or ordinance that applies to any party or to a Study, the Services, or this Agreement, as well as the current good clinical practices guidelines of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Topic E6: Guidelines on Good Clinical Practice, and applicable version(s) of the World Medical Association Declaration of Helsinki, and, where applicable, rules governing good manufacturing practice and good laboratory practice, and rules governing the collection and processing of Personal Data and the collection and storage of human tissue samples and the performance of DNA testing.

"**Completed Subject**" means any Subject who has completed the prescribed course of treatment for a subject in the Study in accordance with the Protocol.

"**Confidential Information**" means (i) the terms of this Agreement; and (ii) any business, employee, patient or customer information or data in any form which is disclosed or otherwise comes into possession of the Institution and/or Investigator, directly or indirectly, as a result of this Agreement and which is of a confidential or proprietary nature to the SPONSOR and CRO and/or their respective Affiliates (including, without limitation, the Study Documentation, any information relating to business affairs, operations, products, processes, methodologies, formulae, plans, intentions, projections, know-how, Intellectual Property, trade secrets, market opportunities, suppliers, customers, marketing activities, sales, software, computer and telecommunications systems, costs and prices, wage rates, records, finances and personnel).

"**Controller**" means the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data."

"**Data Security Breach**" means: (a) the loss or misuse (by any means) of Personal Data; (b) the inadvertent, unauthorized, and/or unlawful Processing, disclosure, access, alteration, corruption, transfer, or sale or rental, destruction, or use of Personal Data; or (c) any other act or omission that compromises the security, confidentiality, or integrity of Personal Data.

"**Designee**" means any person designated by the SPONSOR in writing who undertakes activities on behalf of the SPONSOR in relation to the Study, which may include an Affiliate or the CRO.

"**Developed Technology**" means any inventions, discoveries, improvements or developments made by the Institution or any Study Personnel (whether solely or jointly with others) in the course of or as a result of the Study and that are directly related to the Study Drug, or the use thereof.

"**eCRFs/CRFs**" (Electronic Case Report Forms or Case Report Forms) are paper or electronic questionnaires specifically used by Institution and Investigator pursuant to the Protocol for Subject data reporting.

"**Fully Cooperate**" means to assist in completing a specified end or purpose.

"**Intellectual Property** " means any and all rights in and to ideas, formulae, inventions, discoveries, know-how, data, databases, documentation, reports, Materials, writings, designs, computer software, processes, principles, methods, techniques and other information, including patents, trademarks, service marks, trade names, registered designs, design rights, copyrights and any rights or property similar to any of the foregoing in any part of the world, whether registered or not, together with the right to apply for the registration of any such rights.

"**Investigator**" is the individual named in preamble (4) of this Agreement, and is the person responsible for the conduct of the Study at Institution. If a Study is conducted by a team of individuals at an Institution, Investigator is the responsible leader of the team and may be called the principal investigator.

"**Investigator Request Form**" (IRF) shall mean the form containing the information that PAREXEL Finance Department requires from the payee prior to being able to process payments for said payee.

"**Materials**" means any equipment, materials (excluding Study Drug), documents, data, software and information supplied by or on behalf of, or purchased at the expense of, the SPONSOR, in connection with the Study, as described and set out in the Protocol and this Agreement.

"**Personal Data**" means any information relating to an identified or identifiable natural person ('Data Subject') ; an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number location data, an online identifier or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity of that natural person.

"**Personal Data Breach**" means a breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed."" "Process" means any operation or set of operations which is performed upon Personal Data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

"**Protocol**" means the clinical study protocol named in the front of this Agreement that has been approved by the relevant Ethics Committee/IRB, which describes the Study, including all amendments thereto as the parties and SPONSOR may from time to time agree in writing

"**Reports**" means any reports that are required by the applicable regulatory committee to close out the Study.

"**Resources**" refers to any facilities and equipment that are utilized for the conduct of the Study.

"**Services**" means the services to be provided by the Institution, the Investigator and/or the Study Personnel under the terms of this Agreement.

"**Study**" means the scientific research as defined in the Protocol.

"**Study Drug**" means the SPONSOR's investigational medicinal product(s), any placebo and any comparator drug(s) being studied or tested in the Study as set out in the Protocol.

"**Study Documentation**" means all records, accounts, notes, reports, data and ethics communications (submission, approval and progress reports), collected, generated or used in connection with the Study and/or Study Drug, whether in written, electronic, optical or other form, including all recorded original observations and notations of clinical activities such as (e)CRFs and all other reports and records necessary for the evaluation and reconstruction of the Study.

"**Study Instructions**" means any written document, other than the Protocol, issued by SPONSOR or CRO that specifically relates to and references the Study and which provides additional information and/or instructions on how the Institution and Investigator shall conduct the Study. Study Instructions may be transmitted from SPONSOR or CRO to Institution and/or Investigator by personal delivery, fax, e-mail, registered post, certified post or courier.

"**Study Personnel**" means any employees of Institution or Investigator, and/or contractors engaged by Institution or Investigator, who are involved in performing the Study, including Sub-Investigator(s), Study coordinator(s), and any other contractors, agents and employees of Institution or Investigator who assist Institution and Investigator with the Study.

"**Sub-Investigator**" is any individual member of the Study team designated and supervised by the Investigator at Institution to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).

"**Subject**" is a person participating in the Study and identified in the signed informed consent form.

ATTACHMENT C

EQUIPMENT USE, OWNERSHIP & DISPOSITION

C-1. Use. During the term of this Agreement, Institution and Principal Investigator may use Equipment only for purposes of this Trial.

C-2. Ownership. Until the termination of this Agreement, this Equipment remains the property of the respective Vendors that have provided the Equipment to Sponsor and must be returned either within a reasonable period of time upon request by Sponsor, not to exceed five (5) business days, or immediately upon termination of this Agreement. Institution and/or Principal Investigator agree to return the Equipment in the manner directed by Sponsor or Vendor in substantially the same condition as when received by Institution and/or Principal Investigator. Institution agrees to be financially responsible to cover any loss or destruction to Equipment while in Institution's and Principal Investigator's care, which exceeds ordinary wear and tear and/or lacks a reasonable causal relationship to proper performance of the Trial. Institution and Principal Investigator further agree that unless otherwise authorized in writing by the Sponsor of this Trial, Institution and Principal Investigator will not alter the Equipment in any way. Institution must not install any components or software, if applicable, without express approval of the Sponsor. Any software provided to Institution and/or Principal Investigator may not be duplicated. Institution and Principal Investigator are not permitted to use the Equipment for any other purpose than for the performance of this Trial in accordance with the Protocol. Neither Sponsor nor CRO has any liability for damages of any sort, including personal injury or property damage, resulting from the use of Equipment except to the extent that such damages were caused by the negligence or willful misconduct of Sponsor or CRO, as applicable, and except to the extent that a personal injury constitutes a compensable Trial Subject Injury to be paid by Sponsor as described in this Agreement.

C-3. Disposition. After completion of Trial conduct or at an earlier time specified by Sponsor, Institution will arrange for return of Equipment and Sponsor materials, at Sponsor's expense, to Sponsor, Vendor or a location designated by Sponsor. Alternatively the Institution and Principal Investigator may retain the Equipment at a mutually agreed amount equal to the depreciated value of the Equipment at the end of the Trial upon prior written Sponsor approval.

CLINICAL TRIAL SERVICE AGREEMENT

This Clinical Trial Service Agreement ("**Agreement**") is made on this 12th day of Apr 2022

Between

Glenmark Pharmaceuticals Limited, a company incorporated under the Companies Act, 1956 and having its registered office at B/2 Mahalaxmi Chambers, 22, Bhulabhai Desai Road, Mumbai - 400 026, India and its corporate office at Glenmark House, B. D. Sawant Marg, Chakala, Andheri (E), Mumbai – 400099, (hereinafter referred to as "**Glenmark**", which expression shall unless repugnant to the context or meaning thereof be deemed to mean and include its successors and permitted assigns) of the First Part;

And

Mahatma Gandhi Mission (MGM) Medical College & Hospital, an institution incorporated under the laws of India having its registered office at N-6, CIDCO, Aurangabad-431003, Maharashtra, India (hereinafter referred to as the "**Institution**" which expression shall unless repugnant to the context or meaning thereof shall be deemed to mean and include its successors and permitted assigns) of the **SECOND PART;**

And

Dr. Mohammad Hafiz Rajmohammad Deshmukh, aged around 43 years, Indian, residing at MGM Medical College & Hospital, N-6, CIDCO, Aurangabad-431003, Maharashtra, India (hereinafter referred to as the "**Investigator**" which expression shall unless repugnant to the context or meaning thereof shall be deemed to mean and include his heirs and legal representatives) of the **THIRD PART.**

And

Grapecity Research Solutions LLP, a Site management organization having address at Shree Prasad 4 Block No D-2, Prakash Housing Society, Kalewadi Phata, Thergaon Pune 411033, Maharashtra, India (hereinafter referred to as the "**SMO** " which expression shall unless repugnant to the context or meaning thereof shall be deemed to mean and include his heirs and legal representatives) of the **FOURTH PART.**

"Glenmark", "Institution", "SMO" and Investigator" are hereinafter collectively referred to as the "Parties" and severally as a "Party".

WHEREAS:

Glenmark is *interalia* engaged in the business of discovery, development, distribution and sales of pharmaceutical products;

The Institution is a private hospital and is *interalia* engaged in in carrying out clinical

trials;The Investigator is engaged in carrying out clinical research/studies/trials;

The SMO is a site management organization engaged in carrying out various activities during a clinical trial;

Glenmark has approached the Institution and the Investigator to provide the Services in accordance with the provisions herein below which the Institution and the Investigator are willing to provide on the terms and subject to the conditions of this Agreement;

Pursuant to the aforesaid, the Parties are desirous to spell out the terms and conditions in writing to give effect to the aforesaid understanding.

IN CONSIDERATION OF THE PAYMENTS AND MUTUAL PROMISES AND COVENANTS CONTAINED HEREIN AND WITH THE INTENT TO BE LEGALLY BOUND HEREBY, THE PARTIES HEREBY AGREE AS FOLLOWS:

1. GENERAL DEFINITIONS & INTERPRETATION

In this Agreement the following capitalised terms shall, unless the context requires otherwise, have the following meanings:

1.1. "**Adverse Event**" means any untoward medical occurrence in a patient or clinical investigation Subject administered a pharmaceutical product and which does not necessarily have a causal relationship with this treatment. An Adverse Event (AE) can therefore be any unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporarily associated with the use of a medicinal (investigational) product, whether or not related to the medicinal (investigational) Product;

1.2. "**Commencement Date**" means the date on which the Investigator commences its activities in accordance with this Agreement;

1.3. "**Confidential Information**" means the proprietary and/or confidential information of any Party, howsoever disclosed, which relates to the subject matter of this Agreement including without limitation technical information, business information, information relating to the conduct of the Trial, the Subjects of the Trial, Trial Material, Know-How, methodology, trade secrets, results, processes, sequences, structure and organization of the Trial, the Protocol, the Trial Materials and information relating to the Investigational Products etc. and information included within this definition by virtue of Sections 10 and 13;

1.4. "**Consent Form**" means the patient information sheet & consent form required to be voluntarily completed by every Subject/Patient participating in the Trial (and/or a relative or legal guardian of the Subject or any other person or authority required by law at each Site) after having been informed of all aspects of the Trial. The Consent Form shall be approved by Glenmark and Ethics Committee prior to use at the Site;

1.5. "**Co-investigator**" means one or more resident doctors / consultants with the Institution appointed by the Investigator at each Site as per the provisions of law and approved by Glenmark; who will lead, co-ordinate and run the Trial at the Site;

1.6. "**CRF**" means a printed, optical, or electronic document designed to record all of the Protocol required information to be reported to Glenmark on each Trial Subject/Patient;

1.7. "**Eligible Subject**" means a person who meets all the eligibility criteria as set out in the Protocol for enrolment of a subject/patient into the Trial at the time of selection;

1.8. "**Ethics Committee**" means the ethics committee/independent review board constituted according to GCP and local laws and regulations and having authority over the conduct of any clinical Trial at the Site and that is ultimately responsible for approving the conduct of the Trial and associated Protocol;

1.9. "**GCP**" means a standard for the design, conduct, performance, monitoring, auditing, recording, analyses, and reporting of clinical trials that provides assurance that the data and reported results are credible and accurate, and that the rights, integrity, and confidentiality of trial subjects are protected;

1.10. "**ICH**" means the International Conference on Harmonisation. The Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) specifies the unified standards to facilitate the mutual acceptance of clinical data by the regulatory authorities of Europe, Japan and North America together with such other good clinical practice requirements as are specified in Directive 2001/20/EC and Directive 2005/28/EC or the Code of Federal Regulations relating to medicinal products for human use and as may otherwise be applicable in the territory where the Site is located;

1.11. "**Ineligible Subject**" means a person who does not meet the eligibility criteria as set out in the Protocol for enrolment of a subject into the Trial;

1.12. "**Inspection(s)**" means the act by a Regulatory Authority of conducting an official review of documents, facilities, records, and any other resources that are deemed by the authority(ies) to be related to the clinical Trial and that may be located at the Site of the Trial, at Glenmark's facilities, or at other establishments deemed appropriate by the Regulatory Authority(ies);

1.13. "**Investigational Product**" means a pharmaceutical form of an active ingredient or placebo being tested or used as a reference in a clinical trial, including a product with a marketing authorisation when used or assembled (formulated or packaged) in a way different from the approved form, or when used for an unapproved indication, or when used to gain further information about an approved use;

1.14. "**Investigator**" shall have the same meaning as assigned herein above and who shall be responsible for the conduct of the clinical Trial at a trial Site;

1.15. "**Intellectual Property Rights**" means all intellectual property rights throughout the world (both present and future) including without limitation copyrights, trademarks, designs, patents, database rights, Know-How and all other rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them for their entire term and any applicable extensions;

1.16. "**Know-How**" means all technical and other information which is not in the public domain including but not limited to information comprising or relating to concepts, discoveries, data, designs, formulae, ideas, inventions, methods, models, procedures, designs for experiments and tests and results of experimentation and testing, processes, specifications and techniques, laboratory records, clinical data, manufacturing data and information contained in submissions to Regulatory Authorities;

1.17. "**Protocol**" means the document that describes the objective(s), design, methodology, statistical considerations, and organization of the Trial as more specifically laid down in **Annexure 1** hereto and shall include amendments (written description of a changes(s) to or a formal clarification of a Protocol) made by Glenmark at its sole discretion from time to time;

1.18. "**Regulatory Authority**" means any governmental or regulatory authority responsible for granting health approval, clinical trial authorisations and licences, import and/or export licences or any other relevant approval, permission or licence necessary for the conduct of a trial and those that conduct Inspections of sponsors, contract research organisations, Sites/Institutions/Investigators etc.;

1.19. "**SAE**" means any untoward medical occurrence that at any dose that: results in death, is life threatening (actual or hypothetical), requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, is a medically significant event;

1.20. "**Services**" means and includes the services to be performed according to the terms of this Agreement and the Protocol by the Investigator directly or through the Institution, Co-investigator etc. and conduct and performance of the Trial pursuant to ICH GCP and as more fully outlined in **Annexure 2** hereto;

1.21. **"Site"** means the location(s) where Trial related activities are actually conducted;

1.22. **"Site File"** means the file maintained by Investigator at each Site and the file maintained in-house by Glenmark containing the documentation specified in Section 8 of ICH GCP or as may otherwise be required by any other local rules, laws, regulations, directives or guidance;

1.23. **"Subject"** means a person who is enrolled in the Trial as an Eligible Subject and a recipient of the Investigational Product;

1.24. **"Termination Date"** means the date when the Parties have performed their respective obligations under the Agreement or if terminated earlier in accordance with the terms and conditions of this Agreement, then such earlier date;

1.25. **"Trial/Study"** means any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. The terms Trial and Study are synonymous;

1.26. **"Trial Materials"** means the Investigational Product, the Protocol, case report forms, Consent Forms, placebos, trial aids, and any other material that is used in, or arises out of, the conduct of the Trial;

1.27. Headings used or mentioned in this Agreement are for convenience only and do not affect the interpretation of the sections;

1.28. In this Agreement unless the context requires otherwise:

1.28.1. words importing the singular include the plural and vice versa and reference to one gender includes all genders;

1.28.2. reference to any individual or person includes a corporation, partnership, joint venture, association, authority, state or government and vice versa;

1.28.3. any phrase introduced or preceded by the terms "include", "including" and "in particular" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding these terms unless preceded by the term "explicitly".

1.29. Recitals and Annexures hereto constitute an integral part of this Agreement.

2. TERM

2.1. This Agreement shall come into force on the Commencement Date and shall remain valid until the Termination Date.

3. GENERAL OBLIGATIONS OF THE INSTITUTION & INVESTIGATOR

3.1. The Institution and the Investigator hereby represents and warrants that it has the expertise, facilities and all appropriate registrations, licenses, permits and authorisations necessary to provide the Services and more particularly to conduct the Services to the highest of the professional Standards mentioned **Annexure 3** and in accordance with this Agreement.

3.2. Throughout the Term the Institution and the Investigator shall:

3.2.1. provide the Services as per the terms of this Agreement and as more fully outlined in **Annexure 2** hereto;

3.2.2. appoint appropriate and professionally trained, experienced and qualified personnel at their sole responsibility, risk and cost to perform the Services under this Agreement;

3.2.3. use all reasonable endeavours to ensure the smooth running of the Services at all times as per the Standards mentioned in **Annexure 3** and Timelines mentioned in **Annexure 4;**

3.2.4. will ensure that all employees/study team perform the Services in accordance with the terms of this Agreement and the Standards mentioned in **Annexure 3** and Timelines mentioned in **Annexure 4;**

3.2.5. provide the data required by Glenmark pursuant to and in furtherance of the Services;

3.3. The Institution and the Investigator will at all times permit Glenmark and/or its nominees to conduct monitoring/audit at such intervals as required by Glenmark of all Services provided by the Institution and the Investigator under this Agreement including all records and documents relating to the Services, and any equipment or materials supplied and/or maintained by the Institution and the Investigator in connection therewith and the Institution and the Investigator will provide such assistance as reasonably requested by Glenmark in connection therewith.

3.4. The Institution and the Investigator will immediately notify Glenmark of any notified Inspections affecting or potentially affecting the Services provided to Glenmark.

4. GENERAL RESPONSIBILITIES

4.1. Glenmark shall assist and support the Institution and the Investigator in its performance of the Services as more particularly laid down in Annexure 2 hereto.

4.2. The Parties understand and agree that the Investigator may from time to time appoint the SMO to assist him in carrying out the Services (or any part thereof).

5. GENERAL OBLIGATIONS OF THE PARTIES

5.1. Parties understand, acknowledge and agree that they will work together and co-operate with the other in order to comply, as closely as possible, with the estimated Trial timeline annexed hereto as **Annexure 4**.

5.2. Parties further understand, acknowledge and agree that prior to or at any time during the course of the Trial, Glenmark may amend or vary the Services and/or the Protocol. In such an event:

5.2.1. The Investigator will co-operate with Glenmark to promptly incorporate and act upon such amendments in its performance of the Services going forward including undertaking further Site monitoring and audits, training of personnel at each Site, seeking approvals to the amendments as appropriate from the Ethics Committees;

5.2.2. Parties will negotiate in good faith any amendments do modifications in price and payment in **Annexure 5**, if applicable and required having regard to the impact of the changes in light of the previous scope of Services and the Protocol.

5.3. Should there be any inconsistency between the Protocol and the other terms of this Agreement, the terms of the Protocol shall prevail to the extent of such inconsistency.

6. PAYMENT

6.1. In consideration of the performance of the Services by the Institution and the Investigator pursuant to this Agreement, Institution and the Investigator shall submit to Glenmark for payment, pursuant to the following terms, an invoice for those sums identified in **Annexure 5** when the relevant event or time period set out in **Annexure 4** occurs

6.2. Glenmark will pay the Institution and the Investigator for all sums properly invoiced in accordance with Section 6.1 and **Annexure 5** within 30 days of receipt of such invoice.

6.3. Glenmark may suspend payment of an invoice if it raises a bona fide dispute as to the accuracy of any invoice submitted by the Institution and the Investigator. If the dispute cannot be resolved between the Parties, it will be referred to arbitration in accordance with Section 17.2.

7. **INDEMNIFICATION**

7.1. The Institution and the Investigator hereby jointly and severally undertakes to indemnify, defend and hold Glenmark, its successors and assigns, its officers, directors, employees harmless agents against all losses, damages, costs, expenses and other liabilities, including reasonable attorney's fees and court costs, incurred by it on its own account or any third party claim, action or proceeding to which Glenmark may be subject which arises out of or results from or may be payable by virtue of:

7.1.1. any failure of the Institution, Investigator, its affiliates, contractors or agents, Co-Investigator, to perform the Trial in accordance with the Protocol, ICH-GCP, local regulatory requirements; and/or

7.1.2. improper or negligent administration or use of the Investigational Product during the course of the Trial; and/or

7.1.3. any breach of Section 10 and/or 13 or other terms of this agreement; and/or

7.1.4. any negligence, misconduct, malpractice, material deviation, breach or non-compliance of any provisions of this Agreement by the Institution and/or the Investigator, its affiliates, contractors or agents, Co-Investigator, the project manager and the SMO; and/or

7.1.5. due to infringement of the Intellectual Property Rights of Glenmark or a breach of any warranty, representation, covenant or obligation.

7.2. Notwithstanding the above, Glenmark shall assume no liability for any case in which written informed consent and an authorization regarding personal data in accordance with applicable law was not given by the patient involved Protocol amendments (if any) were not approved by the Regulatory Authority.

7.3. Glenmark hereby undertakes to indemnify Institution, Investigator, its affiliates, contractors, agents or the Co-Investigator against all losses, damages, costs, expenses and other liabilities, including reasonable attorney's fees and court costs, arising out of, or in connection with, any injury to a person (including death) arising solely from the Investigational Product due to negligence of Glenmark, except to the extent the same is caused by the negligence, misconduct, malpractice or breach or non-compliance by the Institution and/or the Investigator, Co-Investigator or its officers, directors, employees or agents of the terms of the Protocol, the terms of this Agreement or any applicable laws, regulations, guidelines and generally accepted standards.

7.4. Any Party hereto seeking indemnification for itself or on behalf of those other parties specified hereunder ("**Indemnified Party**") shall notify the other Party ("**Indemnifying Party**") in writing reasonably promptly after the assertion against the Indemnified Party of any claim under the indemnity or allegation by a third party in respect of which the Indemnified Party intends to base a claim for indemnification hereunder ("**Claim**"), but the failure or delay so to notify the Indemnifying Party shall not relieve the Indemnifying Party of any obligation or liability that it may have to the Indemnified Party except to the extent that the Indemnifying Party demonstrates that its ability to defend or resolve such Claim is adversely affected by such unreasonable delay or failure.

7.5. The Indemnifying Party shall have the right, upon written notice given to the Indemnified Party within thirty (30) days after receipt of the notice from the Indemnified Party of any Claim to assume the

defence or handling of such Claim, at the Indemnifying Party's sole expense, in which case the provisions of Section 7.6 below shall govern.

7.6. The Indemnifying Party shall select external legal counsel reasonably proficient and experienced within the field of the dispute giving rise to the Claim in connection with conducting the defence or handling of such Claim, and the Indemnifying Party shall keep the Indemnified Party reasonably apprised of the status of such Claim. The Indemnifying Party shall not, without the prior written consent of the Indemnified Party, agree to a settlement of any Claim which leads to liability or creates any financial or other obligation on the part of the Indemnified Party for which the Indemnified Party is not entitled to full indemnification hereunder. The Indemnified Party shall fully cooperate with the Indemnifying Party and shall be entitled to appoint its own counsel to observe and report on but not participate in the Claim at its own expense. Notwithstanding the foregoing, in the event the Indemnifying Party fails to conduct the defence or handling of any Claim in good faith after having assumed such defence or handling, then the provisions of Section 7.8 below shall govern.

7.7. If the Indemnifying Party does not give written notice to the Indemnified Party, within thirty (30) days after receipt of the notice from the Indemnified Party of any Claim, of the Indemnifying Party's election to assume the defence or handling of such Claim, the provisions of Section 7.8 below shall govern.

7.8. Subject to Sections 7.5, 7.6 and 7.7, the Indemnified Party may, at the Indemnifying Party's expense, select external legal counsel reasonably proficient and experienced within the field of the dispute giving rise to the Claim in connection with conducting the defence or handling of such Claim and defend or handle such Claim in such manner as it may deem appropriate, provided, however, that the Indemnified Party shall keep the Indemnifying Party timely apprised of the status of such Claim and shall not settle such Claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld or delayed. If the Indemnified Party defends or handles such Claim, the Indemnifying Party shall fully cooperate with the Indemnified Party and shall be entitled to participate in the defence or handling of such Claim with its own counsel and at its own expense.

7.9. The Indemnified Party will only be entitled to claim under the indemnity for a Claim provided that it has not made any admission of liability or culpability without having first obtained the prior written consent of the Indemnifying Party.

8. LIMITATION OF LIABILITY

8.1. Save for the provisions of Section 8.2 below, notwithstanding any other provision in this Agreement, in no event shall either Party be liable, whether in contract, tort, under an indemnity, misrepresentation, negligence or otherwise, for any remote, indirect, incidental or consequential damages arising out of or in connection with this Agreement, or any performance, non-performance or breach of any provision hereof. However, it is understood and agreed that claims, actions, lawsuits or other proceedings made by third parties being the subject of the indemnification obligation under Section 7 shall not be considered as indirect, consequential, special or incidental damages.

8.2. Nothing in this Agreement will act as or seek to restrict, limit or exclude any liability for (i) death or personal injury caused by negligence; (ii) liability for fraud or fraudulent misrepresentation; (iii) negligence or misconduct; or (iv)any liability for breach of implied undertakings or conditions which cannot be excluded or limited by contract.

9. INSURANCE

9.1. Institution and the Investigator shall secure and maintain in full force and effect throughout the performance of the Trial insurance or self-insurance coverage for medical malpractice and general liability in amounts appropriate to the conduct of his/her business. Institution and the Investigator shall also require any subcontractor to secure and maintain such coverage for his/her/its activities related to the Trial. Certificates evidencing such insurance will be made available for examination upon request by Glenmark.

10. CONFIDENTIAL INFORMATION AND PUBLICITY

10.1. All data, documents and information whether written or orally supplied or disclosed by Glenmark to the Institution and/or the Investigator, including but not limited to Confidential Information and the Materials, Documents and all other data including that derived from the Services, in whatsoever form, shall be the exclusive property of Glenmark and shall be treated as strictly confidential and shall not be disclosed to any person except to the extent that any such disclosure is necessary to be disclosed to that person in connection with the proper performance of this Agreement. The Parties understand, acknowledge and agree that all results and data from the Services in whatever form are the exclusive property of Glenmark and cannot be:

10.1.1. used by the Institution and/or the Investigator or its Co-Investigators, agents, employees or consultants etc. other than pursuant to the performance of the Services; or,

10.1.2. disclosed by Institution and/or the Investigator or its Co-investigators or any of its employees, agents, personnel etc. to any person including directly or indirectly to any person other than Glenmark or to persons who are authorised, in writing by Glenmark in advance, to receive such information.

10.2. The Institution and/or the Investigator will take all precautionary measures to ensure compliance of this Section 10 by its employees, agents, consultants and personnel to whom Confidential Information is required to be disclosed under the terms of this Agreement. The Institution and/or the Investigator will ensure that all its employees, agents, consultants, and personnel are bound by obligations no less onerous than those contained herein before any disclosure of such Confidential Information to them.

10.3. A breach of this Section 10 by the Investigator or any of the Investigator's agents, employees or contractors shall constitute a material breach by the Investigator of this Agreement.

10.4. The restrictions and obligations under this Section 10 shall not apply to any information which:

10.4.1. at the time of disclosure, is freely and lawfully in the public domain or thereafter lawfully becomes part of the public domain;

10.4.2. is in the possession of the Institution and/or the Investigator prior to the first disclosure of such information by Glenmark or its agent and the Investigator and Institution are not under any obligation of confidence in respect of such information;

10.4.3. other than pursuant to the Services, is independently and without any reference (whether direct or indirect) to the Confidential Information generated by the Investigator and/or Institution as can be demonstrated by contemporaneous written documents without any obligation of confidence owed in respect of such new information;

10.5. In the event the Institution and/or the Investigator must disclose in order to comply with an applicable mandatory and enforceable legal obligation or to the extent ordered by a court of competent jurisdiction exercising its right of authority over the Institution and/or the Investigator (subject to entry of an appropriate protective order), provided that if the Institution and/or the Investigator is required by such law, regulation or order to make any such disclosure of Confidential Information, they shall give reasonable notice to Glenmark of such disclosure requirement and will use its best efforts to secure confidential treatment of such Confidential Information required to be disclosed.

10.6. Any inventions or improvements whether patentable or unpatentable which are conceived of, discovered, or developed by the Institution and/or the Investigator, its Affiliates or by any person claiming through them in any way derived from, related to, based on, or resulting from the use of the Confidential Information ("Derivative Intellectual Property") shall be promptly disclosed to Glenmark. Any such Derivative Intellectual Property shall be the sole property of Glenmark. The

Institution and/or the Investigator, its affiliates and any person claiming through them shall do all acts and things as shall be necessary to vest all right, title and interest therein in Glenmark. The Institution and/or the Investigator shall keep the said Derivative Intellectual Property confidential in accordance with this Agreement. The Institution and/or the Investigator therefore undertakes that they will not reverse engineer, decompile or dissemble the Confidential Information or make any variant out of the Confidential Information and strictly use or abide by the terms of this Agreement.

10.7. Notwithstanding the performance or the discharge for whatever reason including breach of this Agreement, the provisions of this Section 10 shall remain in full force and effect in perpetuity.

10.8. Institution and the Investigator will preserve all Confidential Information including periodic backup of computer files, to prevent the loss or alteration of Glenmark's study data, documentation, and correspondence. At Glenmark's request or on expiry or upon termination of this Agreement, the Investigator and Institution shall return all the Confidential Information received in pursuance to this Agreement including all information disclosed orally and shall also destroy or erase all the electronic files, copies, notes, memorandum, extracts, which contains, reflects or is derived from the Confidential Information of Glenmark.

11. REPRESENTATIONS AND WARRANTIES

11.1. Each Party represents, warrants and covenants for itself to the other that:

11.1.1. it has been duly incorporated or created and is validly subsisting and in good standing under the applicable laws of its incorporation mentioned elsewhere in this Agreement;

11.1.2. it has the power and authority to enter into and perform its obligations under this Agreement;

11.1.3. this Agreement has been duly authorised, executed and delivered by it and constitutes a valid and binding obligation enforceable against it in accordance with its terms;

11.1.4. neither the execution and delivery of this Agreement, nor the performance by such Party of its obligations hereunder nor compliance by such Party with the provisions hereof will violate, adversely effect, contravene or breach or create a default or accelerate any obligation under any other agreement, indenture, instrument, Memorandum or Articles of Association or charter or by-law provision, statute, regulation, judgment, ordinance, decree, writ, injunction or law applicable to such Party.

11.1.5. it will perform its obligations hereunder in accordance with all applicable federal, international, state or local law or regulation.

11.2. The Institution and Investigator represent and warrant that they will not enter into any other agreement(s) which would interfere or prevent performance of the obligations described herein.

11.3. The Institution and Investigator represents and warrants that they have the facilities, professional, technical and clerical staff, experience and expertise sufficient in quality and quantity to perform the Services and the Trial pursuant to the Protocol within the time frame set forth herein.

11.4. The Institution and the Investigator represents and warrants for itself and on behalf of its officers, directors, employees, affiliates, agents and representatives, that, in connection with the matters that are the subject of this Agreement, and the performance of its obligations hereunder it will comply with all applicable laws including the anti-bribery and anti-corruption laws, and will not take any action that will cause Sponsor or its affiliates to be in violation of any such laws.

11.5. Debarment Certification: the Investigator and Institution jointly and/or severally represent and warrant that the Investigator, its employees, the Co-Investigator and/or any agents, contractors, sub-

contractors etc. carrying out any of the Services have not been debarred under any law. In the event that the Institution, Investigator, its employees, the Co-Investigator and/or or any agent, contractor, sub-contractor (i) becomes debarred, suspended, excluded or otherwise sanctioned; or (ii) receives notice of an action or threat of an action with respect to such debarment, suspension, exclusion or sanction, the Investigator and Institution shall immediately notify the same to Glenmark. Upon receipt of such notice, or if Glenmark becomes aware of such actual or threatened debarment, suspension, exclusion or sanction, then Glenmark shall have a right to immediately cease all activities relating to this Agreement, and Glenmark shall have the right to immediately terminate this Agreement.

11.6. Compliance with Laws: the Institution and Investigator represent and warrant that all the Services performed and provided by the Institution and Investigator, the Co-Investigator and/or any agent, contractor, sub-contractor shall fully comply with all applicable central, state, and local laws, rules and/or regulations, as may be amended from time to time.

11.7. Inconsistent Obligations: the Institution and Investigator represent and warrant that the responsibilities and obligations assumed by the Institution and Investigator on behalf of Glenmark hereunder are not in conflict with any other obligations the Institution and Investigator may have.

11.8. Save for those express warranties set out herein, the Parties neither make nor give any other express or implied (whether by statute, custom or otherwise) warranties in relation to its obligations, duties or activities owed or performed under this Agreement and hereby excludes any other such express or implied warranty in respect of that subject matter.

12. DEFAULT AND TERMINATION

12.1. For the purpose of this Section 12 each of the following constitutes an event of default ("Default"):

12.1.1. If any Party breaches any of its obligations under this Agreement and fails to remedy the breach within 30 days of written notice being given by the other Party identifying and requiring that breach to be remedied;

12.1.2. if a Party becomes insolvent, is dissolved or makes a general assignment for the benefit of its creditors, has a receiver appointed for a substantial part of its assets or makes the requisites filings as a sick company before the relevant authorities;

12.1.3. if conducting the Services becomes prohibited by law, rule, regulation or any amendment thereof.

12.2. Either Party may immediately terminate this Agreement by notice in writing to the other Party if a default by that other Party occurs.

12.3. Without prejudice to any other rights Glenmark may have, Glenmark may terminate this Agreement immediately by written notice if, in the reasonable opinion of Glenmark, any of the following events occurs:

12.3.1. there is unsatisfactory progress of the Services and/or Trial;
12.3.2. if patient recruitment is not initiated within 60 days of Site initiation;

12.3.3. Any Co-Investigator ceases to be employed by or engaged in the performance of a Trial at any Site;

12.3.4. there is breach of Section 10 or 13 of this Agreement by the Institution and/or Investigator or any employee, director, agent, contractor, sub-agent, sub-contractor, the Co-Investigator or any other person appointed by or under control of or claiming through the Investigator;

12.3.5. there is an inability to recruit an adequate number of Subjects within the prescribed period as advised at the time of commencement;

12.3.6. there occur Adverse Events with the conduct of the Trial which in necessitate the discontinuance of the Trial;

12.4. Glenmark may terminate this Agreement upon 30 days' prior written notice without cause.

12.5. On termination or expiry of this Agreement for any reason whatsoever Institution and the Investigator:

12.5.1. will deliver to Glenmark all Investigational Product, Trial Materials within 14 days of the date of termination or expiry;

12.5.2. will return any sums paid for Services which have not been performed before the date of termination or expiry;

12.5.3. will co-operate with Glenmark and do everything necessary to bring about the orderly termination of all Services;

12.6. On termination or expiry of this Agreement for any reason, Glenmark will pay for all Services performed by the Institution and the Investigator to the satisfaction of Glenmark in compliance with this Agreement;

12.7. Each Party will be regarded as discharged from any further obligations under this Agreement except for those expressed to survive termination or expiry.

12.8. The termination of this Agreement pursuant to this Section 12 will not affect the rights of either Party in respect of any antecedent breach of this Agreement. Further, in the event of any termination of this Agreement on account of a Default under Section 12.2, the non-breaching Party shall have the right to recourse to such remedies that may be available to them at law or in equity.

13. **INTELLECTUAL PROPERTY**

13.1. Institution and the Investigator acknowledge and agree that Glenmark is the sole owner of all the Intellectual Property Rights as defined herein above and this Agreement does not grant, transfer or assign to the Institution and the Investigator any legal right or beneficial ownership in any Intellectual Property Rights of Glenmark.

13.2. Institution and the Investigator further acknowledge and agree that all rights to any discovery or invention conceived or reduced to practice in the direct performance of the Study conducted under this Agreement in accordance with the Protocol will belong to Glenmark. Institution and the Investigator agree to assign to Glenmark, at the request of Glenmark, the sole and exclusive ownership thereto, upon the payment of costs by Glenmark, if any, incurred by Institution and the Investigator in the filing, prosecution, or maintenance of any patent application or patent issuing thereon. Such application, if any, will be filed and prosecuted by Glenmark. Institution and the Investigator will promptly disclose to Glenmark any invention or discovery arising under this Agreement

13.3. All Intellectual Property and other data of Glenmark which the Institution and the Investigator may gain or have access to pursuant to this Agreement shall remain the property of Glenmark.

13.4. The Institution and the Investigator will not use Glenmark's name, trademark or brand in any publicity, advertising or news release without the prior written consent of Glenmark. For the avoidance of doubt, this restriction does not apply to the inclusion in documents of or use of Glenmark's name for the proper performance of the Services under this Agreement.

13.5. The Institution and the Investigator agrees that all Intellectual Property Rights and Know-How, arising from conduct of the Services belong to and vest in Glenmark and that the consideration payable hereunder shall be sufficient consideration towards the same.

13.6. The Institution and the Investigator hereby undertake to assign and to procure the assignment of all Intellectual Property Rights and to the extent possible in all Know-How, arising out of the performance of the Trial and Services to Glenmark to the extent the same are not automatically vested or assigned by virtue of this Agreement or require to be assigned by a person or entity other than Glenmark.

13.7. The Institution and the Investigator agree to co-operate regarding a reasonable request of Glenmark or to procure the assistance from another person or entity involved in the Services as may be required in any patent filings Glenmark deems necessary.

13.8. The Institution and the Investigator will not infringe the intellectual property rights of a third party or misappropriate any know-how or intellectual property rights of a third party in performing the Services.

13.9. Upon expiry or termination of this Agreement, the Institution and the Investigator shall stop using, return forthwith all the Intellectual Property Rights to Glenmark and restrain from using any Intellectual Property Rights.

14. PUBLICATION RIGHTS

Glenmark has the exclusive right to authorize any and all publications and/or communications relevant to the Trial/Study and Investigator undertakes to make no presentations or publications of the results of the Trial/Study without the prior written approval of the Glenmark with regard to the content and the timing of said presentations or publications. When permission for presentation or for publication is granted, Institution and Investigator agrees that, prior to submission of a manuscript or abstract to the publisher, Institution and or the Investigator shall forward a copy of said manuscript or abstract to the Glenmark for its written approval

15. RELATIONSHIP OF PARTIES

15.1. Glenmark, Institution and the Investigator have entered into this Agreement as independent contractors and nothing in this Agreement creates a relationship of employer and employee, principal and agent, joint venture or partnership between the Parties.

15.2. The Institution and the Investigator acknowledge and agree that the Institution and the Investigator are responsible for all the employees and all other personnel deputed by the Institution and the Investigator to conduct Services covered by this Agreement and a breach by any such person of the terms of this Agreement shall constitute a breach by the Institution and the Investigator of the same terms of this Agreement.

16. FORCE MAJEURE

16.1. A Party shall be excused from performing its obligations under this Agreement if its performance is delayed or prevented by any cause beyond such Party's reasonable control, including but not limited to, acts of God, fire, explosion, war, insurrection, civil strife, riots and government action which materially affects a Party's ability to perform its obligations under this Agreement. Performance shall be excused only to the extent of and during the reasonable continuance of such disability. Any deadline or time for performance specified in this Agreement which falls due during or subsequent to the occurrence of a Force Majeure occurrence, shall be automatically extended for a period of time equal to the period of such disability. The Investigator, Institutuion and SMO shall immediately notify Glenmark if, by reason of any of the disabilities referred to herein, the Institution and the Investigator is unable to meet any specified deadline or time for performance.

16.2. In the event that any part of the Services is rendered invalid as a result of such disability, the Institution and the Investigator shall, upon written request from Glenmark, repeat that part of the Services affected by the disability. Provided, however, that if a Force Majeure Event continues for more than 2 months, a Party may terminate this Agreement by giving at least 15 days' notice to the other Parties.

17. GOVERNING LAW / ARBITRATION

17.1. This Agreement shall be governed by and construed in accordance with the laws of India (without regard to its conflict of law principles).

17.2. Any and all disputes arising out of or in connection with this Agreement, including any question regarding its existence, validity or termination, which cannot be settled amicably between the Parties within a period of thirty (30) days from the date the dispute first arose, shall be referred to and finally resolved by arbitration in accordance with the Arbitration Rules of the Mumbai Centre for International Arbitration ("MCIA Rules") in force at the time of such arbitral proceeding, which rules are deemed to be incorporated by reference in this provision; by a sole arbitrator to be appointed under the said MCIA Rules. All proceedings of such arbitration including the award shall be in the English language and shall be kept confidential. The seat and venue of the arbitration shall be Mumbai.

17.3. The Parties may apply at all times to any competent judicial authority for interim or conservatory measures. The application of a Party to a judicial authority for such measures or the implementation of any such measures ordered by the arbitrator shall not be deemed to be an infringement or a waiver of the arbitration agreement.

18. NO WAIVER

18.1. Any waiver by any Party of any breach of, or failure to comply with or failure to enforce at any time, any of the provisions of this Agreement shall not be construed as or constitute a continuing waiver of such provision, or a waiver of any other breach of or failure to comply with, any other provision of this Agreement, nor shall it in any way affect the validity of this Agreement or any part thereof or the right of any party thereafter to enforce each and every provision of this Agreement.

19. SEVERABILITY

19.1. Should one or more provisions of this Agreement be or become invalid or unenforceable, the parties shall substitute such invalid provisions by valid provisions as close in meaning and effect as the original provisions. Should such substitution not be possible the invalidity or unenforceability of such provision shall not affect the validity of the Agreement as a whole.

20. ASSIGNMENT

20.1. Neither Party shall assign or sub-contract this Agreement or part or all of its obligations herein without the prior written consent of the other Parties. Any Party, which does sub-contract, as permitted with the other Parties consent will remain responsible for the acts and omissions of its sub-contractors as though they were its own.

21. AGREEMENT AND AMENDMENT

21.1. Any change in the terms of this Agreement shall be valid only if the change is made in writing, agreed and signed by the Parties.

21.2. This Agreement including its Annexures contains the entire understanding between the Parties and supersedes all other negotiations representations and undertakings whether written or oral of prior date between the Parties relating to the Services that are the subject of this Agreement.

22. This Agreement is made in English in more than one copy each of which shall be deemed to be an original and may have been translated to another language. All such copies are valid and in case of any discrepancy, English text will prevail over other languages.

23. **THIRD PARTY RIGHTS**

23.1. Nothing in this Agreement is intended to confer on any third party any right to enforce any term of this Agreement.

24. **SURVIVAL OF OBLIGATIONS**

24.1. The agreements, covenants and obligations set forth in Sections 6, 7, 8, 9, 10, 11, 12, 13, 14, 17 and 24 shall continue to be binding upon the Parties hereto and shall survive any termination or expiry of this Agreement. Any other terms of this Agreement which are either expressed so as to survive (or are capable of surviving) expiry, or termination of this Agreement or from their nature or context it is contemplated that they are to survive expiry or termination, shall remain in full force and effect notwithstanding any expiry or earlier termination of this Agreement.

25. **NOTICES**

25.1. All notices required or permitted under this Agreement shall be in writing and shall be deemed delivered when delivered in person or by fax or five (5) days after the date postmarked if sent by registered or certified mail or courier, return receipt requested, postage prepaid, addressed as follows:

If for Glenmark:
Glenmark House, B D Sawant Marg, Chakala, Andheri (E), Mumbai – 400099, India

If for the Institution:
MGM Medical College & Hospital, N-6, CIDCO, Aurangabad-431003, Maharashtra, India

If for the Investigator:
Dr. Mohammad Hafiz Rajmohammad Deshmukh, MGM Medical College & Hospital, N-6, CIDCO, Aurangabad-431003, Maharashtra, India

If for the SMO:
Grapecity Research Solutions LLP, Shree Prasad 4 Block No D-2, Prakash Housing Society, Kalewadi Phata, Thergaon Pune 411033, Maharashtra, India

25.2. A Party may change its address from time to time by providing written notice to the other Parties in the manner set forth above.

26. **COUNTERPART**

This Agreement may be executed in counterparts with the same effect as if Parties had signed the same document. All such counterparts shall be deemed an original, shall be construed together and shall constitute one and the same instrument. Signatures to this Agreement transmitted by email in "portable document format" (".pdf"), or by any other electronic means shall have the same effect as physical delivery of the paper document bearing original signature.

(Signature Page to follow)

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed.

For Glenmark Pharmaceuticals Limited

GLENMARK PHARMACEUTICALS LTD. MUMBAI 400 099

Name: Suyog Shetty
Title: Vice President – Legal

For the Institution

DEAN
MGM'S MEDICAL COLLEGE
AURANGABAD

Name: Dr. Rajendra Bohra
Title: Dean of MGM Medical college

For Head of Department

Professor & H.O.D.
Department of Pharmacolog
MGM's Medical College
Aurangabad.

Name: Dr.Deepak Bhosle

Title: HOD of Pharmacology department,
Clinical research center.

Investigator

Name: Dr. Mohammad Hafiz Rajmohammad Deshmukh

Dr. HAFIZ DESHMUKH
Assistant Professor
Dept. of Respiratory Medicine
MGM Medical College & Hospt.,Abad.
Reg. No. 2007/12/3956 MMC

For SMO

Name: Dr. Sunil Chaudhary
Title: Director of SMO

ANNEXURE 1

PROTOCOL

The Protocol title and protocol number are as follows:

Protocol Title: Ref:" A randomized, assessor-blind, placebo controlled, multi center, clinical endpoint bioequivalence study to compare the efficacy and safety of generic fluticasone propionate inhalation aerosol USP 44 mcg (Glenmark Pharmaceuticals Ltd) to Flovent HFA (fluticasone propionate inhalation aerosol) 44 mcg (GSK group of companies) in treatment of patients with bronchial asthma."

Sub: Clinical Trial Agreement

Protocol Number: GLK-2101

Clinical Trial Phase: Clinical Endpoint Bioequivalence Study

Protocol has already been provided to the Investigator separately and will form an integral part of this Agreement.

ANNEXURE 1

PROTOCOL

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Sub: Clinical Trial Agreement

Protocol Number: GLK-2101

Clinical Trial Phase: Clinical Endpoint Bioequivalence Study

Protocol has already been provided to the Investigator separately and will form an integral part of this Agreement.

ANNEXURE 2

Description of Responsibilities

1. OBLIGATIONS OF THE INSTITUTION AND THE INVESTIGATOR

The Institution and Investigator hereby represent and warrant that it has the expertise, facilities and all appropriate registrations, licenses, permits and authorisations necessary to provide the Services and more particularly to conduct Trial to the highest of the professional standards and in accordance with this Agreement, the Protocol, ICH GCP and all applicable standard operating procedures.

1.1 Throughout the Term the Investigator shall:

1.1.1 appoint appropriately and professionally trained, experienced and qualified personnel to perform the Services under this Agreement;

1.1.2 appoint the Co-investigators who meet the conditions stipulated in **Annexure 6**, time to time review eligibility of such Co-investigators and discontinue/remove those Co-investigators from further conducting the Trial who no longer meet those conditions;

1.1.3 use all reasonable endeavours to ensure the smooth running of the Trial at all times as per the Protocol and time lines mentioned in **Annexure 4** and will ensure that the Co-investigator performs the Trial in accordance with the terms of this Agreement, the Protocol and as per the provisions of all laws and practices applicable;

1.1.4 act professionally and responsibly as the necessary interface between the Co-investigator, Institution, Site and Glenmark;

1.1.5 collect all information and data required by Glenmark pursuant to and in furtherance of the Trial;

1.1.6 immediate reporting to Glenmark in accordance with the SAE reporting plan on becoming aware of any SAEs at the Sites;

1.1.7 fully co-operate with Glenmark throughout the Term and even thereafter in respect of the performance of the Services and compilation and use of information and data generated from the Trial and follow all directions and instructions relating to the Trial provided by Glenmark;

1.1.8 use all reasonable endeavours to ensure that the Trial is planned, performed and concluded within the estimated Trial timeline as per the projection.

1.1.9 Where required as explicitly informed by Glenmark, nominate for Glenmark's approval an appropriate number of Co-Investigators for the Trial and keep Glenmark and Institution and its personnel at the Site notified of the contact details of the respective Co-Investigator (including an emergency number) allocated responsibility for overseeing the Trial at such Site;

1.1.10 ensure that the Investigational Product supplied pursuant to Glenmark's obligations hereunder is not used for any purpose other than the Trial;

1.1.11 Investigator has not nor have his spouse nor any dependent children, enter into and will not enter into any financial arrangements with Glenmark to hold financial interests in Glenmark that are required to be disclosed pursuant to the US Code of Federal Regulations Title 21, Part 54, namely (i) any financial arrangement whereby the value of the compensation paid in respect of the performance of the Trial could be influenced by the outcome of the Trial (as defined in 21 CFR 54.2(a)), (ii) any proprietary interest in the product being tested (as defined in 21 CFR 54.2(c)), (iii) any significant equity interest in Glenmark (as defined in 21 CFR 54.2(b)) and (iv) any significant payments from Glenmark such as grants to fund ongoing research, compensation in the form of equipment, retainers for ongoing consultation or

honoraria (as defined in 21 CFR 54.2(f)). In the case of subparagraphs (iii) and (iv) the Investigator understands that such prohibitions relate to the period that the Investigator is carrying out the Trial and for 1 year following completion of the Trial.

1.2 Prior to the commencement of the Trial, the Investigator shall:

1.2.1 having regard to the scope of the Trial, eligibility criteria for Subjects, the Protocol and costs restraints investigate, select and prepare a list of suitable Sites and the Co-Investigators (subject to Section 1.1.9 above) for the Trial based upon the Investigator's assessment visits of such Sites, evaluation of the patient database at each Site as well as ensuring that each Site has the necessary manpower, facilities and infrastructure to conduct the Trial pursuant to ICH-GCP guidelines and Glenmark's requirements and to collect and track all essential documents including Consent Forms and the Trial Materials for each Site;

1.2.2 compile and prepare all documentation necessary for seeking Ethics Committee's approvals for conducting such Trial;

1.2.3 obtain all appropriate approvals and authorisations and make all necessary arrangements for:

1.2.3.1 initiation, continuation and performance of the Trial in all selected Sites;

1.2.3.2 storage and administration of the Investigational Products at every Site for use in the Trial and of any other Trial Materials as well as storage, processing of laboratory samples and data taken from Subjects in the Trial;

1.2.3.3 obtain the necessary approvals from the Ethics Committee at each Site for the conduct of the Trial and storage and use of the Investigational Product;

1.2.3.4 prepare all necessary documentation for the performance of the Trial including language translations of Consent Forms and patient diaries into local languages;

1.2.4 educate and train all Site personnel involved, directly or indirectly, in the conduct of the Trial at each Site regarding ICH GCP guidelines and in relation to creating and maintaining the necessary documentation required during conducting the Trial including the management and compilation of the Site File;

1.3 In preparation for and during the conduct and performance of the Trial, the Investigator shall:

1.3.1 at each Site ensure that the Trial is performed specifically in accordance with the Protocol and the obligations hereunder;

1.3.2 at each Site ensure that the Co-Investigator is monitoring the conduct of the Trial at the Site and has completed all CRFs throughout the performance of the Trial;

1.3.3 ensure that Site has adequate and appropriate processes established and operating to ensure:

1.3.3.1 patient randomisation in pursuance with the Protocol;

1.3.3.2 maintenance of all study related logs regarding screening of the Subjects and their enrolment including proper collection and storage of all Consent Forms;

1.3.3.3 proper accounting and storage of Investigational Product and Trial Materials whilst on Site;

1.3.3.4 all other relevant and applicable communications and information regarding the Subjects and the Trial are recorded and logged, including telephone logs of clinical questions, CRFs and questions relating to CRFs;

1.3.3.5 ensure the expiry date, shelf life or use by date (or equivalent) of any Trial Materials or Investigational Product are monitored to ensure efficient rotation of stocks and safe destruction (pursuant to Glenmark's instructions) or return to supplier of any such materials that have expired;

1.3.3.6 safe and effective return of any unused materials, including Trial Materials and the Investigational Product on conclusion of the Trial;

1.3.3.7 ensure that it has its own appropriate, effective and robust processes in place and operating for:

1.3.3.7.1 the effective ordering, despatch, delivery and tracking of all Trial Materials sent to each Site;

1.3.3.7.2 ensuring any Ineligible Subject is not enrolled or participate in the Trial;

1.3.3.8 ensure randomisation of Subjects in the agreed timeframe and ensure adequate process for scheduling Subject visits as specified in the Protocol to ensure the Trial is in compliance with the Protocol;

1.3.3.9 conduct a close out visit at the Site on termination or expiry of the Trial or this Agreement as the case may be, during which any Trial Material, unused Investigational Product or any other material exclusively procured for the Trial purposes shall be collected and submitted to Glenmark or to the Central Storage Facility or by the Co-Investigators at the Sites pursuant to the written guidelines of Glenmark;

1.3.4 The Institution and the Investigator will provide all necessary support to Glenmark in fulfilling its obligations relating to the Trial including all support and expertise required for Adverse Event and SAE follow-up, tracking and reporting to applicable Agencies, Institutions and Sites, and providing status reports to the applicable Agencies.

1.3.5 The Institution and the Investigator will at all times permit Glenmark and/or its nominees to conduct an audit at such intervals as required by Glenmark of all Services provided by the Investigator under this Agreement including all records and documents relating to the Protocol, Services and Trial, and any equipment or materials supplied and/or maintained by the Institution and the Investigator in connection therewith and will provide such assistance as reasonably requested by Glenmark in connection therewith and shall ensure that Glenmark can audit the Site and the records of the Institution of such Site (including the Investigator's records) applicable to the Trial and Services.

1.3.6 The Institution and the Investigator will promptly notify Glenmark if the Co-Investigator ceases to be employed or engaged in the performance of the Trial at a Site together with the reasons why such the Co-Investigator is no longer involved and the Investigator will use best efforts to find a replacement acceptable to Glenmark as soon as possible.

1.3.7 The Institution and the Investigator shall conduct the Study only at facilities that are listed on its Form 1572 reuquired by the U.S. Food and Drug Administration ("FDA") and determined to be adequate by Glenmark. Investigator and Institution shall ensure the facilities remain adequate for the duration of the Study (i.e. at a minimum, are safe, secure, hygenic, include adequately maintained, and claiberated equipment and provide for secure and accessible storage of Study materials and records).

1.4 The Institution and the Investigator warrant and represent that in entering into this Agreement it has not committed, any of the following acts:

1.4.1 providing or offering to provide to any person in the employment of the Institution and/or Site any gift or consideration other than that which is a reasonable financial arrangement either under this Agreement or by any other arrangement;

1.4.2 making payment or agreeing to make payment of any commission to any person in the employment of the Institution;

1.5 Institution and the Investigator will comply with all applicable laws and regulations in its/his/her performance of activities under this Agreement. Institution and Investigator will provide reasonable assistance to Glenmark so that Glenmark may comply with any applicable law or regulation in the performance of the activities under this Agreement.

1.6 Without limiting the generality of Section 1.5, Investigator will:

1.6.1 Take appropriate actions so that he/she will properly disclose protected or sensitive health information created or received by Investigator to Glenmark pursuant to any applicable Privacy Rule. Glenmark agrees to take appropriate measures to protect the privacy and confidentiality of the protected health information received in connection with the Trial.

1.6.2 Obtain a Glenmark approved written informed Consent Form from each Trial subject and will maintain a signed original of the written informed Consent Form in the Study subject's records.

2. Glenmark Responsibilities:

2.1 Glenmark agrees and acknowledges that it will ensure that the Investigational Product supplied for the Trial is manufactured and supplied to the Sites as per the Protocol and that it complies with the obligations of a clinical Trial sponsor as delegated under this Agreement in accordance with section 5 of ICH GCP.

2.1.1 Prior to commencement of the Trial, Glenmark shall:

2.1.1.1 prepare and finalize the Protocol, patient information sheet and Consent Form in English, Investigator brochure and provide the Trial Material to the Investigator for compiling the submissions for Ethics Committee approvals;

2.1.1.2 develop and finalise the monitoring and source data verification plan ("Monitoring and SDV Plan");

2.1.2 During the course of the Trials, Glenmark shall:

2.1.2.1 appoint a physician to act as a medical monitor to respond to Site questions regarding Subjects, their eligibility, dose modifications of the Investigational Product and to develop, authorise and maintain Protocol exceptions and/or deviations;

2.1.2.2 review Adverse Events and SAE reports as received from the Sites, along with the drug safety contact of the Investigator who will be primarily responsible for Adverse Event and SAE management;

2.1.2.3 establish and maintain the safety database for each Site;

2.1.2.4 notify all Sites, the Co-Investigators and Agencies of reported Adverse Events and SAEs as required by statutory bodies;

2.1.2.5 prepare periodic status reports for the study for the Agencies;

2.2 Glenmark shall assist the Institution and the Investigator in the performance of Services relating to seeking and obtaining approvals from the Ethics Committee, providing and maintaining on-site specific

training/support to the Investigator to enable it to provide appropriate training and support to each Site and archiving of Trial related documents.

RESPONBILITIES OF ALL PARTIES:

1. All Parties further understand, acknowledge and agree that prior to or at any time during the course of the Agreement, Glenmark may amend or vary the Services and/or the Protocol. In such an event:

   1.1. the Institution and the Investigator will co-operate with Glenmark to promptly incorporate and act upon such amendments in its performance of the Services going forward including undertaking further Site audits, training of personnel at each Site, seeking approvals to the amendments as appropriate from the Ethics Committees;

   1.2. All Parties will negotiate in good faith any amendments to modifications in price and payment in **Annexure 5**, if applicable and required having regard to the impact of the changes in light of the previous scope of Services and the Protocol.

ANNEXURE 3
Standards

The following Standards are applicable to the provision of the Services by the Investigator, Institution, SMO and Glenmark under this Agreement: -

- The Protocol annexed hereto as **Annexure 1** and any subsequent amendments
- ICH GCP
- New Drugs and Clinical Trial Rules, 2019
- U.S. Code of Federal Regulations (Form 1572, Financial Disclosures and Regulations as mentioned in the Protocol)
- Other local laws and regulations

ANNEXURE 4

FPI and CRF completion timelines

First Patient in (FPI)	Apr 2022
FPI to last Patient in (LPI)	May-2023
LPI to Last Patient Out (LPO)	Aug-2023

- CRF to be completed preferably within 7 days of patient visit.
- All DCFs should be resolved preferably within 7 days of issuance.
- All SAEs reporting to Glenmark, Ethics Committee and Regulatory Authorities to be done as per local regulatory requirements.
- All safety reports/updates from other sites provided by Glenmark to the Site shall be submitted by the Investigator to the Ethics Committee within 7 days of the receipt of the same or within such period as may be statutorily laid down.
- In case of no recruitment within 30 days of Site Initiation a joint decision would be taken by Sponsor and Investigators for continuation in the study.

ANNEXURE 5

Payment Schedule

GLK-2101 Site Budget

Site Budget	
Visit Details	**Per Subject**
Screening Visit (Visit 1)	**5000**
Run In Visit (Visit 2)	**3000**
Randomization (Visit 3, Day 1)	**6000**
Telephone contacts during 4-week treatment with IP Day 8 (+/- 1 day)	**1000**
Treatment Period (Visit 4, Day 15 +/- 1 day)	**5000**
Telephone contacts during 4-week treatment with IP Day 21 (+/- 1 day)	**1000**
Treatment Period (Visit 5, Day 28 +/- 1 day)	**6000**
Telephone Follow up Visit (Visit 6, Day 35 +/- 2 day)	**1000**
Per completed Subject	**28000**
Institutional Overhead (30%)	**8400**
Total completed Per Patient	**36400**

Site Budget for 55 Patients			
	Unit Amount	**No. of Subjects**	**Total**
Investigator Fees (Including PI, Sub-I, Phlebotomist, PFT technician & CRC)	28000	55	1540000
Institutional Overhead (30 %)	8400	55	462000
ECG (12 LED) @ 500 INR X 2	1000	55	55000
Chest X-Ray @ 650 INR X 1	650	55	35750
SARS-CoV-2 specific assessments (RT PCR) @ 1000- INR X 1 or On actual basis (If required)	1000	55	55000
Patient travelling (@1000 INR X 5 Visit)	5000	55	275000
Site Budget for 55 Patients			**2422750**

1. Patient travel reimbursement is upto maximum INR 1000/- per visit and as per actuals. The amount for patient travel reimbursement mentioned above would be paid on actuals based on invoice received.

2. X-ray charges and ECG would be paid upto maximum INR 650/- and INR 500/- per visit respectively and as per actuals. The amount for X-ray and ECG Charges mentioned above would be paid on actuals based on invoice received.
3. SARS-CoV-2 specific assessments (RT PCR) charges would be paid upto maximum INR 1000/- per visit and as per actuals. The amount for SARS-CoV-2 specific assessments (RT PCR) Charges mentioned above would be paid on actuals based on invoice received.
4. Local Laboratory and local test charges would be paid as per actual on case to case basis after confirmation from Sponsor.
5. All screen failed patients would be paid of the total randomized subjects an amount of Rs. 2000 as screening expenses and Rs 2000 for Run in failure only if screening/Run in procedures are conducted as per protocol at the end of the recruitment period.
6. As it is a competitive trial, the budget would be based on total number of patient enrolled on pro-rata basis for the grant mentioned above; for each completed patient
7. Request for payment would be made by letter stating the amount on Investigator's letter head/Institute letterhead and signed by Investigator/Hospital Authority after verified by the monitor per the completed visits and source data verified CRFs
8. The final payment would be released at the time of close out.
9. All payments made hereunder will be made in Indian Rupees.
10. Glenmark shall be entitled to deduct from any sums due hereunder any withholding taxes and other statutory duties which is mandatory to be deducted according to the applicable laws in force on the date of payment or invoice booking whichever is earlier.
11. The Institution and the Investigator shall issue a valid tax invoice / debit or credit note in the format prescribed under the relevant Good and Service Tax (GST) Act and rules framed thereunder ("GST Law") including (e-invoicing requirement). If the services provided by the Institution and/ or the Investigator are taxable under GST, the Institution and the Investigator shall ensure that the contents prescribed by the GST Law like GST number along with HSN code for services and QR code/IRN number (if applicable) are reflected on the face of the invoice. Further, the tax invoice / debit or credit note shall be uploaded on the GSTN portal within the prescribed timelines. The Institution and the Investigator shall incorporate the transaction with Glenmark under this Agreement in the periodical statutory returns filed by it within the prescribed time as required under the relevant and applicable GST Law and shall ensure that all taxes due as per the said return has been duly remitted in the manner prescribed under applicable law. Non – compliant invoices will be rejected with reasons and the Institution and the Investigator shall be required to send the revised invoice / debit or credit note. This is mandatory to ensure compliance with GST. If GST is exempted, necessary certificates and declaration is to be provided to Glenmark.
12. Any mismatches reported by GSTN portal if due to error by the Institution and the Investigator shall be reconciled and resolved by the Institution and the Investigator within the prescribed time. In all such cases where Glenmark is not able to avail input tax credit of GST amount paid or denied to Glenmark on account of mismatches on GSTN portal, non-payment of GST to government or non-filing of GST returns or non-uploading of invoice within due timelines or other reasons attributable to any failure on part including (e-invoicing requirement), then the Institution and the Investigator agrees that Glenmark shall have the right to set-off any such amounts (along with interest and penalty payable to government authorities) from any amounts that is already due or will become due and payable to the Institution and the Investigator under this Agreement or any other agreement. Further, Glenmark also reserves the right to recover the amount from the Institution and the Investigator for which the input tax credit of GST could not be availed and any interest and penalty so charged by government on Glenmark for such default of the Institution and the Investigator by raising a debit note, the Institution and the Investigator will be responsible to make payment against such debit note within seven (7) days from date of issuance of debit note.
13. The Institution and the Investigator agrees that if at any later date any error is found in the invoice, the same shall be rectified by the Institution and the Investigator by issuing debit/credit note as applicable.
14. The Institution and the Investigator shall further indemnify, hold harmless and defend at its costs and expense Glenmark, its directors, officers and employees, its affiliates in relation to:
    14.1.1 any claims from applicable tax authorities including interest/penalty or any amounts levied upon/paid by Glenmark due to the default, error or non-compliance of the Institution and the Investigator;

14.1.2 any loss/denial of input tax credit to Glenmark due to non-compliance of GST regulation by the Institution and the Investigator or due to late submission of invoices by the Institution and the Investigator;

14.1.3 any interest and/or penalty levied/paid by Glenmark to tax authorities in relation to loss/denial of input tax credit to Glenmark as mentioned in above point; and/or

14.1.4 non-compliance of obligations set out hereinabove in respect to GST Law and under other applicable laws.

15. Any interest so charged by the authorities on Glenmark for default of Principal Investigator/Institute, will also be recovered by Glenmark from Principal Investigator/Institute by way of raising a debit note on Principal Investigator/Institute.
16. Archival of study documents for 15 years after site close out will be done at sponsor's third party archival as agreed by Investigator.
17. Any equipment and/ or materials required for performing the Study procedures which are not maintained by Site will either be procured by Site or Sponsor will provide to the Site.
18. Sponsor provided equipment and/or materials shall be collected or retrieved from the Site after completion of the Study.

Payee Details:

Payee name	Grapecity Research Solutions LLP
PAN No.	AAPFG8186L
Name of the Bank, its Mailing address and Branch	ICICI Bank Shop no.: 2083/2, Ambience executive hotel, Wakad, Pune-41 10 5 7. Maharashtra, INDIA.
Branch	Wakad Branch, Pune- 411057
Bank Account No.	007305009846
IFSC code	ICIC0000073
GST No., if Applicable	27AAPFG8186LTZH

ANNEXURE 6

Conditions Applicable to each the Co-Investigator

Each Co-Investigator:

1. must be free to participate in the clinical Trial and there are no rights which may be exercised by or obligations owed to any third party which might prevent or restrict his performance of the obligations detailed in this Agreement.

2. must not be involved in any regulatory or misconduct litigation or investigation by the Food and Drug Administration, the Medicines Control Agency, the European Medicines Evaluation Agency, the General Medical Council or other regulatory Agencies. No data produced by the Co-Investigator in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.

3. must have considered, and is satisfied that, facilities appropriate to the Trial are available to him at the Site and that he/she is supported, and will continue to be supported, by medical and other staff of sufficient number and experience to enable the performance of the Trial efficiently and in accordance with the obligations under the Agreement and Protocol.

4. must during the Trial, not serve as the Co-Investigator or other significant participant in any clinical Trial for another sponsor if such activity might adversely affect his/her ability to perform his/her obligations under this Agreement.

5. has not nor have his spouse nor any dependent children, entered into and will not enter into any financial arrangements with Glenmark or the Investigator to hold financial interests in Glenmark or the Investigator that are required to be disclosed pursuant to the US Code of Federal Regulations Title 21, Part 54, namely (i) any financial arrangement whereby the value of the compensation paid in respect of the performance of the Trial could be influenced by the outcome of the Trial (as defined in 21 CFR 54.2(a)), (ii) any proprietary interest in the product being tested (as defined in 21 CFR 54.2(c)), (iii) any significant equity interest in Glenmark or the Investigator (as defined in 21 CFR 54.2(b)) and (iv) any significant payments from Glenmark or the Investigator such as grants to fund ongoing research, compensation in the form of equipment, retainers for ongoing consultation or honoraria (as defined in 21 CFR 54.2(f)). In the case of subparagraphs (iii) and (iv) the Co-Investigator understands that such prohibitions relate to the period that the Co-Investigator is carrying out the Trial and for 1 year following completion of the Trial.

CLINICAL TRIAL AGREEMENT
("Agreement")

THIS AGREEMENT is made by and between

(1) **Parexel International Clinical Research Private Limited,** CoWrks, Coworking Spaces Pvt. Ltd- RMZ Eco World, Ground floor, Bay Area- Adjacent to Building 6A, Outer Ring Road, Devarabeesanahalli Village, Bengaluru -560103, Karnataka, India

(hereinafter "CRO")

And

(2) **Mahatma Gandhi Mission's (MGM) Medical College & Hospital,** N-6 CIDCO, Aurangabad - 431003, Maharashtra, India.

(hereinafter "Institution")

And

(3) **Dr. Deshmukh Hafiz Mohd.,** Mahatma Gandhi Mission's (MGM) Medical College & Hospital, N-6 CIDCO, Aurangabad - 431003, Maharashtra, India.

(hereinafter "Investigator")

And

(4) **Grapecity Research Solutions LLP,** Shree Prasad, Block No D-2, Prakash Housing Society, Kalewadi Phata, Thergaon, Pune 411033, Maharashtra, India

(hereinafter "SMO")

together the "**Parties**" and each a "**Party**"

regarding

Protocol No: CRD/20 (hereinafter "Protocol")
A Multicenter, Randomized, Parallel-Group, 6-Week Treatment Clinical Study to Assess Bioequivalence of Budesonide 80 µg and Formoterol Fumarate Dihydrate 4.5 µg Inhalation Product (Cipla Ltd.) in comparison with the Reference Product, Symbicort® (Budesonide/Formoterol Fumarate Dihydrate, 80/4.5 µg per Actuation) Inhalation Aerosol (AstraZeneca, USA), in Adult Asthma Patients.
(hereinafter "Study")
Budesonide/Formoterol Fumarate Dihydrate, 80/4.5 µg(hereinafter "Study Drug")

of

SPONSOR: Cipla Ltd.
at Cipla House, Peninsula Business Park, Ganpatro Kadam Marg,
Lower Parel, Mumbai 400013, Maharashtra, India.
(hereinafter "SPONSOR")

WHEREAS, SPONSOR is the sponsor of the multi-center/multi-centre Study to clinically evaluate the Study Drug and CRO (or its Affiliate) has been retained by SPONSOR (under a separate written agreement) to act as SPONSOR's contractor and designee in managing the Study for SPONSOR; and

WHEREAS, Institution, SMO, and Investigator shall Fully Cooperate with CRO and shall permit CRO to perform any and all of the SPONSOR's Study obligations and to exercise any and all of SPONSOR's Study rights that lie with SPONSOR on the basis of Applicable Law and GCP regulations as though such rights were CRO's own rights, as has been delegated by SPONSOR to CRO; and

WHEREAS, Investigator is an employee of Institution; and

WHEREAS, Institution, SMO, and Investigator each desires to participate in the Study as described in this Agreement; and

WHEREAS, this Agreement explains the joint and several obligations and rights of Institution, SMO, and Investigator, and the obligations and rights of CRO with respect to the performance of the Study; and

WHEREAS, SMO is authorized to sign the Agreement as a party hereto, and has been engaged by Investigator and/or Institution to act as a payee for the financial aspects according to this Agreement and to coordinate with Investigator and Institution at the study site in accordance with the requirements of the Study and this Agreement on behalf of the Institution and Investigator. Notwithstanding, Institution and Investigator remain ultimate responsible for the performance of SMO. Institution and Investigator's responsibilities and obligations cited in this Agreement remain unchanged, with and/or without involvement of SMO; and
WHEREAS, under this Agreement CRO does not act, or purport to act, as SPONSOR's contractual agent, but rather as SPONSOR's appointed designee for managing the Study.

1. DEFINITIONS

Definitions for terms used in this Agreement are in Exhibit B.

2. CONDUCT OF THE STUDY

2.1 Institution agrees, and commits itself to CRO, to allow Investigator and other Study Personnel to conduct the Study at Institution, and warrants that Investigator and other Study Personnel are employed by Institution.

2.2 Investigator agrees, and commits itself to CRO, to conduct the Study at Institution and warrants that he/she is employed by Institution. Investigator shall personally supervise the conduct of the Study by the Study Personnel to the full extent contemplated by the Protocol and by Applicable Law.

2.3 Investigator, SMO, and Institution acknowledge that SPONSOR is the sponsor of the Study, and as such is an intended third-party beneficiary of this Agreement, whereas SPONSOR transfers any or all of the SPONSOR's Study-related functions to CRO in compliance with ICH-GCP, sec. 5.2.1. In addition to the foregoing, Investigator and Institution agree that CRO may disclose any and all Information and/or documents relating to this Agreement, and/or relating to Investigator's and Institution's participation in the Study (including without limitation any Reports or other documents or materials provided by Investigator or Institution to CRO hereunder), to SPONSOR. All references to SPONSOR herein (whether in the context of delivery of Information, submission of applications, financial terms, or anything else) derive from SPONSOR's status as such, as set out by Applicable Law and GCP regulations, and Investigator and Institution agree to all such instances. Investigator and Institution will Fully Cooperate with CRO's requests relating to SPONSOR.

2.4 Investigator and Institution acknowledge that CRO is the recipient of Services described in this Agreement and, for the avoidance of any doubt, that SPONSOR is not the recipient of Services described in this Agreement.

2.5 Institution, SMO, and Investigator specifically agree, and commit themselves to CRO, to (and warrant that Study Personnel will) conduct the Study in a diligent, efficient, and skilful manner, in strict compliance with the terms and conditions of this Agreement, the Protocol including subsequent amendments, any specific Study Instructions, Applicable Law, all requirements of the Institution or facility, and any other professional standards applicable to their professional industries and fields. Neither Institution nor Investigator nor any Study Personnel shall commit any negligent acts or any willful misconduct in connection with the Study. Neither Institution nor Investigator nor any Study Personnel shall make any unauthorized warranties to any person (including Subjects) concerning the product being tested in the Study. Institution and Investigator accept responsibility for the acts and omissions of all Study Personnel in the Study.

2.6 Investigator shall obtain the written approval of the appropriate Institutional Review Board (IRB) or Ethics Committee (EC) prior to commencement of the Study and will furnish CRO with the IRB/EC's letter of approval.

2.7 If required by Applicable Law, CRO shall make, or procure that SPONSOR makes, the necessary submissions or notifications to the regulatory authorities. The Study may not commence until the Investigator has been informed by CRO that such authorization has been granted.

2.8 Investigator shall, prior to a Subject's participation in the Study, obtain the Subject's written informed consent to participate in the Study. Each Subject's written informed consent shall be in a form that is in accordance with the Protocol.

2.9 Investigator shall enroll the number of duly qualified (according to the Protocol) Subjects for the Study as set forth in Exhibit A and shall do so according to the timetable set forth in Exhibit A. Notwithstanding the foregoing, Investigator agrees that SPONSOR or CRO may unilaterally revise the number of Subjects that Investigator shall enroll, and/or the timeframe for such enrollment, via Study Instructions at any time.

2.10 Institution, SMO, and Investigator shall (a) keep a detailed and written inventory of all clinical supplies, equipment and Study Drug provided by SPONSOR or CRO or its Affiliates and shall store such materials according to the Protocol or Study Instructions and (b) retain all necessary Subject records and/or documents whether electronic, paper, or in any other form relating to the Study for fifteen (15) years after the end or the premature termination of the Study. Institution and Investigator shall provide to CRO or its Affiliates all study data collected on case report forms as instructed by CRO.

2.11 Institution, SMO, and Investigator agree that they are not presently under any agreement or obligation which conflicts with the duties and obligations owed to CRO or SPONSOR under this Agreement, and further agree not to undertake any such obligation or agreement during the course of the Study. Investigator warrants that no Study Personnel are presently under any agreement or obligation which conflicts with the duties and obligations owed to SPONSOR or CRO under this Agreement, and shall ensure that no Study Personnel will undertake any such obligation or agreement during the course of the Study.

2.12 Institution, SMO, and Investigator hereby acknowledge and agree that each has received sufficient Information regarding their respective participation in the Study. In addition, Investigator further warrants (i) that he/she has distributed all relevant Information to the Study Personnel who have a need to know such Information in order to perform their assigned tasks on the Study, and (ii) that he/she, and all Study Personnel (as applicable), has read and understands such Information.

2.13 Institution and SMO shall, throughout the duration of the Study, provide, keep available to the Study Personnel and maintain all necessary Resources for the adequate performance of the Study. Investigator shall, throughout the duration of the Study, ensure that adequate Study Personnel are available to complete the Study. Institution, SMO, and Investigator shall inform CRO promptly in writing (including by email) about all changes impacting the Resources and/or the Study Personnel.

2.14 The Protocol, including any amendments thereto, constitutes an integral part of this Agreement by reference. In case of any inconsistency between this Agreement and the Protocol, the Protocol shall take precedence on matters of medicine, science and conduct of the Study; otherwise the terms of this Agreement shall prevail.

2.15 Institution and Investigator agree to compensate CRO and SPONSOR, as applicable, for all costs arising out of Institution's, SMO's, and/or Investigator's breach of this Agreement.

2.16 Institution, SMO, and Investigator agree that if any Study Personnel is a government employee, official and/or performing a governmental function, such relationship may be disclosed to the SPONSOR and any compensation that such individual receives with respect to the Study may be disclosed to the Institution and is hereby approved.

2.17 Institution, SMO, and Investigator warrant that neither they, nor any Study Personnel are officials, agents, or representatives of any government or political party or international organization where they may be in positions of authority to be able to improperly help CRO or SPONSOR obtain a business advantage. Institution, SMO, and Investigator further warrant that neither they nor any Study Personnel shall make any payment, either directly or indirectly, of any money or other consideration (hereinafter Payment), to government or political party officials, officials of international organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing (hereinafter collectively Officials) where such Payment would constitute violation of any law, including the U.S. Foreign Corrupt Practices Act. In no event shall Institution, Investigator, SMO, or any Study Personnel make any Payment either directly or indirectly to Officials if such Payment is for the purpose of influencing decisions or actions with respect to the subject matter of this Agreement or any other aspect of CRO's or SPONSOR's business. Institution, SMO, and Investigator shall report any violation of this warranty promptly to CRO and agree to respond to any CRO inquiries about any potential violations and make appropriate records available to CRO or SPONSOR upon request. At any time upon the request of CRO, Institution, SMO, and Investigator agree to promptly certify in writing their ongoing compliance (and the compliance of all other Study Personnel) with the warranties contained in this Section 2.17. Institution shall maintain records in compliance with 21 CRF Part 11.

2.18 If CRO or SPONSOR requests Institution and/or Investigator to source marketed/comparator drug, CRO will reimburse Institution and Investigator according to Exhibit A. Institution and Investigator warrant that they will only source drug products that comply with the specifications of the Protocol.

2.19 Investigator shall agree to keep the IMPs in Temperature controlled manner as specified in the protocol and temperature logger reading should be sent to Sponsor on a quarterly basis. If there is excursion in the temperature, CRO or Sponsor should be informed immediately.

3. REPORTS, MONITORING AND COOPERATION

3.1 Institution, SMO, and Investigator shall submit to CRO, and CRO has a right to claim under this Agreement, all completed eCRFs or CRFs resulting from the Study within ten (10) days and in accordance with any Study Instructions. Institution and Investigator warrant that all eCRFs or CRFs submitted to CRO are true, complete, correct and accurately reflect the results of the Study. Institution and Investigator shall promptly provide CRO with copies of all Reports, and any updates that are required by the EC/IRB.

3.2 Institution, SMO, and Investigator shall Fully Cooperate with CRO and will meet with representatives of CRO, or its designee, at mutually convenient times according to a schedule set forth in Study Instructions for monitoring visits, consultations and to allow direct inspection of all Study related records, including Subject medical files, as requested by CRO and for any other purposes relating to the Study as deemed necessary by CRO. Investigator shall ensure that all Study Personnel Fully Cooperates with CRO, including meeting with personnel of CRO, or its designee, as set forth in the preceding sentence.

3.3 Investigator shall agree on the resolution of queries in all trial related systems within 5-7 working days of receival of query.

4. AUDITS AND REGULATORY INSPECTIONS

4.1 Institution, SMO, and Investigator shall Fully Cooperate with audits or inspections, applicable to the Study, performed during or after completion of the Study, by SPONSOR or CRO. Institution, SMO, and Investigator shall allow SPONSOR, CRO and governmental or regulatory authorities, including but not limited to the U.S. Food and Drug Administration, access to Resources used to perform tasks related to the Study, shall make all requested documents available to them and shall provide them with any further Information as may be requested.

4.2 In the event the audit or regulatory inspection identifies a lack of compliance with this Agreement on the part of Institution or Investigator (or failure by any Study Personnel to act in accordance with the terms and conditions of this Agreement), CRO may terminate this Agreement in accordance with Section 16.1 (a).

4.3 Institution, SMO, and Investigator shall immediately notify CRO by telephone, email or fax if a governmental or regulatory authority, including but not limited to the Drugs Controller General of India (DCGI), requests to carry out an inspection of Institution's facilities, or does so. Institution and Investigator shall allow SPONSOR and CRO to be present during such inspection, and shall provide to SPONSOR and CRO copies of all materials, correspondence, statements, forms and records that Institution and Investigator receives, obtains or generates pursuant to or in connection with any such inspection.

5. FINANCIAL DISCLOSURE

5.1 During the conduct of the Study and for one (1) year after its completion, Investigator shall, and Institution shall cause the Sub-Investigator(s) if applicable, and Study Personnel, to, execute and update such forms, disclosures and certifications now or subsequently required by SPONSOR or any applicable regulatory bodies related to his/her financial interests in the SPONSOR and/or the Study Drug.

6. CONFIDENTIAL INFORMATION

6.1 Institution, SMO, and Investigator agree that any and all Confidential Information that they receive from CRO, SPONSOR or otherwise in connection with this Agreement shall be received and maintained by them in strict confidence and not disclosed to any third party (other than SPONSOR) during the conduct of the Study and for fifteen (15) years thereafter. Furthermore, Institution, SMO, and Investigator agree to use the Confidential Information only for the purposes of this Agreement except as otherwise specifically provided for herein.

6.2 Institution and Investigator may disclose Confidential Information only to (a) Study Personnel, or other employees or staff who require access thereto for the purposes of this Agreement provided, however, that prior to making any such disclosures Institution and/or Investigator bind such Study Personnel, employees or staff in writing to the same obligations as are contained herein to maintain Confidential Information in confidence and not to use such Confidential Information for any purpose other than in accordance with the terms of this Agreement, and (b) to the appropriate EC or IRB having jurisdiction over the performance of the Study at Institution.

6.3 The terms of this Agreement, including but not limited to the financial terms, are the Confidential Information of SPONSOR and CRO, and shall be maintained in confidence by Institution, SMO, and Investigator in accordance with Section 6.1 above. If, however, Institution or Investigator is required by Applicable Law to disclose such Confidential Information, they may do so without breaching their obligations under this Section provided, in advance of disclosure, they notify CRO of the Confidential Information to be disclosed, the reason for disclosure, and the date of disclosure.

6.4 Nothing contained herein will in any way restrict or impair any party's right to use, disclose, or otherwise deal with any Confidential Information which at the time of its receipt:

(a) is generally available in the public domain or becomes available to the public through no act of the party receiving said Confidential Information; or

(b) is independently known by the party receiving the Confidential Information, prior to receipt thereof, which said party can demonstrate by documented proof; or

(c) is lawfully given to the receiving party by a third party who is not bound by any obligation to preserve it as confidential.

7. RIGHTS TO INFORMATION AND INVESTIGATIONAL PRODUCT

7.1 All Information and Investigational Product(s) provided to Institution or Investigator for purposes of the Study are and will remain SPONSOR's property. Institution, Investigator, SMO, (and Study Personnel) shall not acquire any rights of any kind whatsoever with respect to the Investigational Product(s) or such Information as a result of performance under this Agreement or otherwise.

7.2 Institution and Investigator shall deliver all Information, unused Investigational Product(s) and clinical specimens to SPONSOR, CRO or their respective designee(s) in a timely manner throughout the performance of the Study, as provided in the Protocol or Study Instructions, and in no event later than ten (10) business days after (i) the date of termination of this Agreement or (ii) the date on which SPONSOR or CRO otherwise requests delivery of Information, unused Investigational Product(s) and clinical specimens.

7.3 The Information and Study Results (including publication) may be used by SPONSOR in any manner it deems appropriate to comply with its business interests, both during, and following termination of, this Agreement.

8. PUBLICITY

No party to this Agreement shall use the name, symbols, trademarks or image of any other party hereto, or SPONSOR's name, symbols, trademarks or image, in connection with any advertising or promotion of any product or service without the prior written consent of such party or SPONSOR, as appropriate.

9. PUBLICATION

9.1 Institution, SMO, and Investigator may publish the Study Results only in accordance with this Section 9. Before publication or presentation of Study Results, Institution shall provide Sponsor, for its review, a copy of manuscript, any poster presentation, abstract or any other written or oral material which describes or discloses the Study Results, in form and manner to be published or presented by the Institution. Upon written consent of Sponsor, Institution may publish or present such manuscripts, posters, etc. relating to the Study Results.

9.2 SPONSOR reserves the right to remove all Confidential Information from any publications or presentations. In the event that SPONSOR deems that such removal would not sufficiently protect its Intellectual Property Rights, then SPONSOR may require that Institution and/or Investigator does not publish such publication or presentation, and Investigator and Institution shall not publish any such publication or presentation in any such case.

9.3 Institution and Investigator agree that because the Study is part of a multi-center/multi-centre Study, any publication by Institution or Investigator of the Study Results shall not be made before the first multi-center/multi-centre publication.

10. INTELLECTUAL PROPERTY

10.1 Any and all Study Results and Information, material or assets relating to the Study Drug, the Protocol or the Study, including any and all existing or future rights therein (hereinafter collectively referred to as Assets), whether patentable or not, conceived by Institution or Investigator or SMO or Study Personnel, solely or jointly with others as a result of work performed under this Agreement, shall be, and remain, at all times the sole and exclusive property of SPONSOR and SPONSOR shall own, to the widest extent possible under Applicable Law, any and all Intellectual Property Rights thereto (subject to the rights expressly reserved for CRO under Section 10.3). To the extent required for SPONSOR to obtain, secure and perfect said rights and legal positions under Applicable Law, the Assets shall automatically vest in SPONSOR and to the extent required, Institution and Investigator hereby assign all rights, title and interests in any and all Assets to SPONSOR, and shall perform any and all other acts necessary to assist SPONSOR in obtaining, securing and perfecting the rights to said Assets. If necessary, Institution and Investigator shall obligate Study Personnel to perform any and all acts required to enable SPONSOR to obtain, secure and perfect said rights. In the event that SPONSOR, according to Applicable Law, cannot obtain or secure ownership of any of said Assets, Institution and Investigator hereby grant SPONSOR and obligate SMO and the Study Personnel to grant SPONSOR, as applicable, worldwide, exclusive, unlimited and royalty-free rights of use, exploitation and utilization and/or licenses regarding said Assets. Institution and Investigator warrant by the execution of this Agreement, that neither they nor any Study Personnel have entered, and that none of them will enter, into any contractual agreement or relationship which would in any way conflict with or compromise SPONSOR's proprietary interest in, or rights to, any Assets existing at the time of the execution of this Agreement or arising out of or related to its performance thereunder.

10.2 Institution, SMO, and Investigator shall disclose to CRO (who will disclose to SPONSOR) all Study Results, Information and in particular all inventions, findings, discoveries and other creative ideas and developments (hereinafter referred to as Inventions) conceived or reduced to practice as a direct result of the Study. Such disclosure shall/must be made fully and promptly in writing to an authorized/authorised representative of CRO (who will disclose to SPONSOR).

10.3 All parties to this Agreement and SPONSOR shall retain all right, title and interest in any Intellectual Property that was owned by such party or SPONSOR prior to or apart from the commencement of this Agreement. No license grant or assignment, express or implied, by estoppel or otherwise, is intended by, or shall be inferred from, this Agreement except to the extent necessary for each party to fulfill its obligations under this Agreement or otherwise give effect to this Agreement.

11. DATA PROTECTION & PRIVACY

11.1 Institution and/or Investigator hereby represent and warrant that they shall obtain all necessary consents in writing from:

(a) all Subjects as per the informed consent form; and

(b) the key members of Study Personnel and Investigator participating in the Study for administrative / study management and any other purpose required by law

so that such Subjects' Study Personnel's and Investigator's Personal Data can be Processed by (including transferred to) CRO, any of its Affiliates, and SPONSOR or any of its Affiliates and regulatory authorities in each case within or outside the country where such data originates.

11.2 Institution, SMO, and Investigator shall notify CRO immediately in writing (but in no event later than five (5) days from the date) of any Data Security Breach related to the Study.

11.3 If requested by CRO in order to enable CRO to comply with any Applicable Law and to Process any Personal Data, Institution, SMO, and Investigator will work with CRO in good faith to address any issue relating to the Processing of Personal Data.

12. INDEMNIFICATION

12.1 Institution and Investigator shall immediately notify CRO in writing of any claim of illness or injury that is claimed to be due to an adverse reaction to the Study Drug or any of the clinical intervention or procedures that are provided for or required by the Protocol to which the Subjects would not have been exposed but for their participation in the Study. Institution and Investigator shall allow SPONSOR to handle such claim (including, if applicable, settlement negotiations), and shall cooperate fully with SPONSOR in its handling of the claim.

12.2 Subject to Section 12.3 below, any indemnification of the Institution and Investigator by SPONSOR shall be through a separate written agreement (or letter) between Institution, Investigator and SPONSOR directly. CRO shall act as the intermediary to coordinate the provision of any such agreement or letter of indemnity by SPONSOR, and shall have no other obligation in connection therewith. Requests for such letters should be made in writing to the address below

Investigator Contracts
Attention Parexel Project No. 256954
Parexel International Clinical Research Private Limited,
CoWrks, Coworking Spaces Pvt.Ltd-RMZ Eco World,
Ground floor, Bay Area- Adjacent to Building 6A,
Outer Ring Road, Devarabeesanahalli Village,
Bengaluru -560103, Karnataka, India

Such requests must include the full legal names and addresses of all parties who are requested to be indemnified by SPONSOR.

12.3 Institution and Investigator acknowledge that SPONSOR has no obligation to indemnify or be responsible for any loss, claim, cost (including reasonable attorney fees) or demand if and to the extent such losses, claims or demands arise from any injuries or damages resulting from Institution's, Investigator's or the Study Personnel's negligence, breach of this Agreement, failure to adhere to the Protocol, failure to obtain signed informed consent forms, failure to follow Applicable Law, misuse of the Study Drug, unauthorized warranties, or willful misconduct. This indemnification obligation is without prejudice to the precedence of insurance coverage from compulsory clinical trial insurance.

12.4 Neither CRO nor SPONSOR will be responsible for, and Institution shall defend, indemnify and hold CRO, its Affiliates, and SPONSOR (and their respective directors, officers and employees) harmless from, any loss, claim, or demand arising from, but not limited to any (a) injuries or damages incurred if they are the result of or are alleged to be the result of negligence or wilful misconduct on the part of the Institution, Investigator or Study Personnel; (b) activities contrary to the Protocol, any Study Instructions, this Agreement, or Applicable Law; (c) unauthorized warranties made by the Institution, Investigator or Study Personnel concerning the product being tested; or (d) case in which written informed consent was not obtained in accordance with the Protocol for the Subject involved in such case.

12.5 Institution and Investigator shall be liable under this Agreement for damages resulting from negligence or wilful misconduct in the execution of the Study.

12.6 CRO shall be liable under this Agreement for damages resulting from its negligence or wilful misconduct in the execution of its obligation hereunder.

13. INSURANCE

13.1 Institution warrants that it has in place, and shall maintain in full force and effect throughout the duration of the Study, Liability Insurance in amounts appropriate to cover its liability for any damage which may be caused as a result of fault or negligence of Institution, Investigator or Study Personnel involved in the performance of the Study, Institution shall promptly provide evidence of its insurance upon request by CRO. Institution shall secure and maintain in full force and effect throughout the performance of study and services, cyber insurance coverage from a reputed A rated insurance company to cover its service obligation and any liability or obligation towards data privacy. Copy of institute insurance certificate shall be handed over to CRO prior to commencement of the study.

13.2 Investigator warrants that he/she has in place, and shall maintain in full force and effect throughout the duration of the Study, and for a period of 3 (three) years from completion of the Study, Liability Insurance in amounts appropriate to cover his/her liability for any damage which may be caused as a result of fault or negligence of Investigator or Study Personnel involved in the performance of the Study, but at least $5 (five) million per occurrence. Investigator shall promptly provide evidence of his/her insurance upon request by CRO.

13.3 CRO procures that SPONSOR shall, to the extent required by law, maintain in full force and effect throughout the performance of the Study clinical trials liability insurance in accordance with local regulations.

14. DEBARMENT

14.1 Institution and Investigator hereby certify that neither Institution, Investigator, SMO, nor any person employed by Institution or Investigator to work on the Study (including any subcontractor permitted pursuant to Section 17.2) has been:

(a) debarred by any relevant authorities, pursuant to any Applicable Law, including but not limited to Section 306(a) and (b) of the US Federal Food, Drug and Cosmetic Act, or disqualified as a clinical investigator under Applicable Law;

(b) threatened to be debarred or indicted for a crime or otherwise engaged in conduct for which a person can be debarred under Applicable Law;

(c) disciplined by and/or banned by a relevant authority from carrying out clinical trials.

For purposes of this Section, any of the foregoing shall be deemed to constitute being "debarred".

In addition, Institution and Investigator agree that no debarred person will in the future be employed or otherwise engaged (including on a contract basis) by Institution, SMO, or Investigator to work on the Study. If during the course of the Study, Institution, SMO, or Investigator becomes debarred or learns that any person connected with the Study is debarred, or that there is a threat of debarment of any such person, then Institution, SMO, and Investigator must immediately notify SPONSOR and CRO. CRO may immediately terminate this Agreement in the event any of the foregoing occurs.

15. PAYMENT TERMS AND CONDITIONS

15.1 In full consideration for the Services of Institution, Investigator and Study Personnel rendered in compliance with the Protocol, CRO agrees to pay the fees and expenses set forth in Exhibit A. Such fees and expenses will be paid solely to the Payee. The parties agree that Exhibit A – Payment Schedule is part of this Agreement clarifying the schedule of payments associated with this Agreement and that the fees and expenses set forth in Exhibit A represent the fair market value for the Services provided by Institution and Investigator. Payments shall be made in accordance with the provisions set forth in Exhibit A, with the last payment being made after Institution, SMO, and Investigator complete all of their obligations under this Agreement and any Exhibits thereto. Institution, SMO, and Investigator shall not seek reimbursement for any medical services or Investigational Product from any third party payers if such costs are already covered by payments made under this Agreement.

15.2 Institution, SMO, and Investigator shall comply with all obligations with respect to taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement including, without limitation, those that relate to any payments made hereunder to Payee or, as the case may be, those that relate to any payments made by Payee to Institution, Investigator and Study Personnel. All fees and expenses payable to the Payee, Institution and Investigator are inclusive of all taxes and social security contributions applicable, other than GST.

15.3 Institution and Investigator acknowledge and agree that its, his or her judgment with respect to its, his or her advice to and care of each Subject is not and shall not be affected by the compensation Institution and/or Investigator receive in accordance with the Study.

15.4 Institution, SMO, and Investigator agree that SPONSOR and CRO may disclose the fees and expenses payable or paid under this Agreement to any governmental authorities according to Applicable Law.

16. TERMINATION

16.1 This Agreement will become effective upon the date it is fully executed by all parties and shall continue in effect for the full duration of the Study according to the Protocol unless sooner terminated in accordance with the provisions of this Section. CRO may terminate this Agreement immediately upon written notice to Institution and Investigator for any reasons, including without limitation upon any of the following occurrences:

(a) Institution, SMO, or Investigator has failed to cure a breach to this Agreement within thirty (30) days of receipt of written notice specifying such breach; or

(b) Investigator becomes personally unavailable to conduct the Study and a CRO- approved replacement has not been identified by Institution and Investigator; or

(c) two months after shipment of the Investigational Product, Investigator has failed to meet the enrolment target for Subjects set forth in Exhibit A, or has recruited such a low number of Subjects that it can be reasonably assumed by CRO that the agreed number of Subjects will not be reached in accordance with the schedule set forth in Exhibit A; or

(d) the authorization/authorisation and approval to perform the Study is withdrawn by the regulatory authority governing Institution; or

(e) the audit or regulatory inspection identifies a serious breach or lack of compliance with this Agreement; or

(f) if any of the circumstances permitting termination pursuant to Section 14.1 occur.

16.2 This Agreement may be terminated by Institution or Investigator, upon sixty (60) days' prior written notice, for breach of contract by CRO if the breach is not cured within thirty (30) days of notification.

16.3 If this Agreement is terminated prematurely in accordance with Section 16.1 or 16.2, Institution, SMO, and Investigator shall/must use its, his or her best efforts to:

(a) minimize further costs while maintaining good medical care of the Subjects; and;

(b) ensure that all Subjects shall complete the Study according to the Protocol unless dictated otherwise by Study Instructions.

16.4 Should Investigator conclude that continuation of the Study is no longer medically justifiable, due to (i) unexpected results, (ii) the severity or prevalence of serious adverse events or (iii) the efficacy of the treatment with Study Drug appears to be insufficient; then he/she will promptly notify CRO and the EC/IRB in writing, and may suspend treatment of Subjects until such time as CRO (based on consultations with SPONSOR) and Investigator reach agreement as to the best course of action.

16.5 Termination of this Agreement by any party shall not affect the rights and obligations of the parties accrued prior to the effective date of termination of this Agreement. Any provision of this Agreement that should survive expiration or termination of this Agreement in order to give proper effect to its intent, shall survive expiration or termination of this Agreement.

17. INDEPENDENT CONTRACTOR

17.1 The relationship of Institution and Investigator to CRO is that of independent contractor. Institution and Investigator commit themselves to perform the Services only as independent contractor and nothing contained herein shall be construed to be inconsistent with that relationship or status. Institution, Investigator, and Study Personnel, shall not be considered employees or agents of CRO and, as such, shall not be entitled to any benefits available to employees of CRO.

17.2 Institution and Investigator shall not retain any subcontractor to perform any of its obligations under this Agreement without the prior written consent of CRO. Any such consent shall not relieve Institution and Investigator of its obligations hereunder, and Institution and Investigator shall remain fully liable for all acts and omissions of any such subcontractor. CRO shall be permitted to assign in whole or in part the discharge of obligations it assumed under this Agreement to any of its Affiliates (or adequately qualified third party subcontractors), without releasing CRO from its responsibility for the appropriate performance of such assigned obligations towards Institution.

17.3 This Agreement shall not constitute, create or in any way be interpreted as, a joint venture, partnership, or business organization of any kind.

18. CONTRACTUAL

18.1 Titles to the Sections of this Agreement are solely for convenience and do not constitute a substantive part of this Agreement.

18.2 If any provision of this Agreement is held illegal, invalid or unenforceable by a court of law, the remainder of this Agreement shall not be affected thereby.

18.3 Failure to insist upon compliance with any of the terms and conditions of this Agreement shall not constitute a general waiver or relinquishment of any such terms or conditions, and the same shall remain at all times in full force and effect.

18.4 Institution and Investigator understand and agree that, as set forth in Section 2.3, SPONSOR is an intended third-party beneficiary of this Agreement.

18.5 The respective signatories of the parties to this Agreement represent and warrant that they have the authority and ability to enter into the terms, provisions and conditions of this Agreement on behalf of their respective parties.

18.6 Neither party shall be responsible for any default under this Agreement by reason of strikes, riots, hostilities, wars, fire, acts of terrorism, acts of God, death of Investigator, or any other cause beyond its reasonable control.

18.7 This Agreement may not be assigned by Institution or Investigator without the prior written consent of CRO.

18.8 CRO may assign this Agreement to any of its subsidiaries, Affiliates or to any third party.

18.9 This Agreement constitutes the entire agreement and final understanding of the parties with respect to the subject matter hereof and supersedes and terminates all prior and/or contemporaneous understandings and/or discussions between the parties, whether written or verbal, express or implied, relating in any way to the subject matter hereof. This Agreement may not be altered, amended, modified or otherwise changed in any way except by a written agreement, signed by all parties.

18.10 All notices necessary or appropriate to be given pursuant to this Agreement shall be effective when delivered to the appropriate party at the address below:

To CRO:
Parexel International Clinical Research Private Limited
CoWrks, Coworking Spaces Pvt.Ltd-RMZ Eco World,
Ground floor, Bay Area- Adjacent to Building 6A,
Outer Ring Road, Devarabeesanahalli Village,
Bengaluru -560103, Karnataka, India
Attn: notices@parexel.com

To Investigator:
Mahatma Gandhi Mission's (MGM) Medical College & Hospital,
Hospital N-6 CIDCO, Aurangabad - 431003,
Maharashtra, India.
Attn: Dr. Deshmukh Hafiz Mohd., Assistant Professor
Phone: +91-8390628800
Email: hafizdeshmukh.mgmhospital@gmail.com

To Institution:
Mahatma Gandhi Mission's (MGM) Medical College & Hospital,
Hospital N-6 CIDCO, Aurangabad - 431003,
Maharashtra, India.
Attn: Dr.Rajendra Brijmophan Bohra, Dean and HOD of ENT Department
Phone: +91-9225304660
Email: rajbohra@msn.com

To SMO:
Grapecity Research Solutions LLP,
Shree Prasad, Block No D-2, Prakash Housing Society,
Kalewadi Phata, Thergaon, Pune 411033,
Maharashtra, India
Attn: Dr. Sunil Chaudhary, Director
Phone: +91-9890840086
Email: drsunilchaudhary07@gmail.com

18.11 Any party may change its address or number for notice by giving notice in accordance with Section 18.10 and 18.12.

18.12 Any delivery that is called for under this Agreement shall be complete when made by personal delivery, fax, email, registered post, certified post or courier, in each case with confirmation of delivery/receipt.

18.13 The parties agree that this Agreement shall be governed by the laws of India, without regard to the conflicts of law provisions thereof. In case a dispute is brought before a court of law, the courts of Mumbai will have sole jurisdiction over the litigation.

IN WITNESS WHEREOF, the parties hereto have set their hands in triplicate with the intention that this is a binding agreement as provided herein.

(1) **Parexel International Clinical Research Private Limited:**

DocuSigned by:
Sanjay Vyas
Signer Name: Sanjay Vyas
Signing Reason: I approve this document
CA8FD795E38E490C94EE2D32BEBCC18A

(Signature of Authorized Official)

Sanjay Vyas, EVP, India Country Head and MD

(Name of Authorized Official)

31st May 2022

Date

(2) **Mahatma Gandhi Mission's (MGM) Medical College & Hospital:**

(Signature of Authorized Official)

Dr. Rajendra Brijmophan Bohra, Dean and HOD of ENT Department

(Name of Authorized Official)

07-JUN-2022.

Date

(3) **Mahatma Gandhi Mission's (MGM) Medical College & Hospital:**

DocuSigned by:
Deepak Bhosle
Signer Name: Deepak Bhosle
Signing Reason: I approve this document
Signing Time: 6/3/2022 [illegible]
[illegible]

(Signature of Authorized Official)

Dr. Deepak Bhosle, HOD- Clinical Research Centre, Pharmacology Department

(Name of Authorized Official)

3 /5/2022

Date

(4) **Investigator:**

DocuSigned by:
Deshmukh Hafiz Mohd
Signer Name: Deshmukh Hafiz Mohd
Signing Reason: I approve this document
Signing Time: 6/3/2022 [illegible]
[illegible]

(Signature of Investigator)

Dr. Deshmukh Hafiz Mohd., Assistant Professor

(Name of Investigator)

04/06/2-22

Date

(5) **SMO:**

DocuSigned by:
Sunil Chaudhary
Signer Name: Sunil Chaudhary
Signing Reason: I have reviewed this document
Signing Time: 5/31/2022 | 5:22:46 AM PDT
[illegible]

(Signature of Authorized Official)

Dr. Sunil Chaudhary, Director

(Name of Authorized Official)

31-May-2022

Date

Exhibit A – Enrolment and Payment Schedule

Protocol Number: CRD/20

Protocol Title: A Multicenter, Randomized, Parallel-Group, 6-Week Treatment Clinical Study to Assess Bioequivalence of Budesonide 80 µg and Formoterol Fumarate Dihydrate 4.5 µg Inhalation Product (Cipla Ltd.) in comparison with the Reference Product, Symbicort® (Budesonide/Formoterol Fumarate Dihydrate, 80/4.5 µg per Actuation) Inhalation Aerosol (AstraZeneca, USA), in Adult Asthma Patients.

1. **Payee Details**

Payee	Payee Details
Protocol Number	CRD 20
Site Number	156
Payee Name	Grapecity Research Solutions LLP
Payee Address	Grapecity Research Solutions LLP, Shree Prasad, Block No D-2,
Address Line 2	Prakash Housing Society, Kalewadi Phata,
Address Line 3	Thergaon, Pune 411033, Maharashtra, India
Province/State/Country	Maharashtra
City	Pune
Postal Code	411033
Country	India
Payee Contact	Dr Sunil Chaudhary
Payee Contact Phone Number	+91-9890840086
Remittance E-mail Address	drsunilchaudhary07@gmail.com
General Finance contract e-mail address if different from above	N/A
NPI	N/A
Tax ID (VAT/GST Registration/TIN/SSN)	GST Registration: 27AAPFG8186L1ZH
Bank Account Holder Name	GRAPECITY RESEARCH SOLUTIONS LLP
Bank Account Number	007305009846
IBAN (International Bank Account Number)	NA
Bank Name	ICICI Bank
Bank Number	3363
Bank Branch Number	3363
Bank Identification Code	ICIC0003363
Bank Type	CURRENT ACCOUNT

Institution and payee "Payee" is obliged to inform CRO, in writing, of any changes or required updates of payment instructions and/or bank details to the following email address: InvestigatorPaymentHelpdesk@parexel.com. To the extent that such written notice is provided, the Parties agree that no amendments to this Agreement shall be required in the event that any of the above listed Payee details are modified during the course of the Study.

The Payee warrants that it shall allocate the following agreed proportions of the total payment to the Institution, Investigator and Study Personnel according to its own internal guidelines. CRO shall not be responsible for ensuring that payee makes any payments to the Institution, Investigator, Study Personnel and its internal departments.

CRO and Sponsor accept no liability for incorrect Payee details provided by any other Payee hereunder

2. **Enrolment**

This Study is designed to evaluate patients in accordance with the Protocol. The Investigator on behalf of the Institution will use best efforts to enrol patients as contemplated under this Agreement. When enrolment is complete for the study, the Institution will be notified in writing and will dis-continue enrolling.

3. **Fee Per Completed Subject:**

3.1. A more detailed budget breakdown of the Study Budget can be found in Attachment 1

3.2. All fees and expenses in this Schedule are exclusive of GST, if applicable.

4. **Other Payments:**

SUBJECT MEALS &TRAVEL: A maximum of INR 700.00 per visit will be paid for Subject travel reimbursement. This amount needs to be reflected in the informed consent form as it will be provided to the Subject. The reimbursement will be paid against the receipt of the invoice and corresponding support documentation.

SCREENING FAILURE: Screening failures will be paid per procedure performed and up to the maximum amount of INR 32,390.00 per Screen Failure, provided that the number of Screen Failures paid hereunder will be capped at a ratio of 1:3 (meaning the Institution will be paid a maximum of (1) one Screen Failure Subject per (3) three Enrolled Subject) Any payments for screening failures over (1:3 ratio) will be only at SPONSOR's discretion. A screening failure is considered a Subject who signs the informed consent form and completes screening but fails under inclusion/exclusion criteria and will not be randomized to the maintenance phase. Payment to Institution will be made upon receipt of the corresponding invoice.

UNSCHEDULED VISIT: An Unscheduled Visit means a subject visit that is not expressly set forth in the Protocol but is otherwise required for the Study. Unscheduled Visits will be reimbursed on a per procedure basis in accordance with the rates set forth in the Budget up to a maximum of INR 8,140 per Unscheduled Visit. In the event a medically necessary procedure is not included in the Budget, Institution must receive prior written approval before such procedure is performed. The amount of compensation payable for a procedure not included in the Budget will be approved at the time written approval is provided

START UP FEES: A non-refundable payment of INR 22,570.00 for start-up related activities (e.g. initial pharmacy fees, preparation of regulatory documents, preparation, administration and submission of protocol and related documents to the IRB/EC, etc.) will be made upon execution of the Agreement. This payment is considered full and final compensation for all activities associated with Study initiation. Payment to Institution will be made upon receipt of the corresponding invoice.

RETENTION SAMPLES: Payee will receive a onetime payment of INR 25,000.00 for retention samples to be stored under appropriate conditions at the site as per Protocol. The payment will be paid against the receipt of the invoice and corresponding supporting documentation as pass through cost.

HOSPITALIZATION COST: A onetime maximum payment of INR 1,000.00 on Visit 4 will be paid for stay of patients at site/clinical facility as per protocol. The reimbursement will be paid against the receipt of the invoice and corresponding support documentation.

5. **Pro-Rata Payments:**

5.1 Payment for Subjects who do not complete the Study may be made to Payee on a pro rata basis. Payment will include only those Subjects who were enrolled before the premature termination of the Study or the date that notice is received of such premature termination, whichever is later.

5.2 Should CRO terminate the Study prior to completion, pro-rated expenses and fees shall be paid as set forth in Section 2.1 for each Subject visit performed before the premature termination of the Study or the date notice is received of such premature termination, whichever is later.

5.3 If other non-cancelable costs are incurred by Institution in accordance with Section 16.3, of the main Agreement, written justification must be provided to CRO for review and approval, and payment of such costs is subject to SPONSOR's approval.

6. **Protocol Violators**

Payments for Study Subjects who are deemed to have been in violation of the Protocol may be paid up to the point that the violation occurred at the discretion of SPONSOR and/or CRO.

7. Payment Conditions

7.1 Payee

The payee under this Exhibit A is defined in Section 1 Payee Details.

7.2 Periodic Payments

Institution or Investigator shall submit invoices for Services performed and expenses incurred on a monthly basis. Payments will be made by electronic wire to the bank account stated in the Investigator Request Form. CRO shall provide Institution with the information necessary to determine the amount of remuneration due to Institution. Institution shall issue its invoice based on this information. Payments shall only be made when the following criteria have been met:

(a) Subject meets the inclusion and exclusion criteria as defined in the Protocol; and
(b) Study procedures have been conducted in full compliance with the Protocol; and
(c) Completed CRFs for the month have been delivered to and/or received by CRO according to any stipulated points in time and the data contained therein can be verified by reference to the Study Subject's medical files and is complete and correct.

All payments are subject to withholding taxes required under the applicable jurisdictions.

7.3 Final Payment

Notwithstanding the criteria defined in Section 7.2 above, the final payment shall be contingent upon the following additional conditions:

(a) all required Subject visits have been completed; and
(b) CRO has received all Subject data in a form suitable for analysis; and
(c) all data clarification queries have been resolved to CRO's satisfaction; and
(d) CRO has verified that all required regulatory documentation is complete, and
(e) Institution, SMO, and Investigator has returned all required equipment, drugs and other material to SPONSOR or CRO or its Affiliates; and
(f) the Study close-out visit has been completed; and
(g) Institution has provided final invoices within 30 days of close out visit.

Payee shall have 60 days from the receipt of the final payment under this Agreement to identify discrepancies and resolve any payment disputes with CRO.

8. Investigator Request Form and Payment Instructions

8.1 CRO shall send, via e-mail transmission, an electronic version of the Investigator Request Form to the Institution. This e-mail will also contain details of where to return the completed version of the electronic format.

8.2 The Institution shall complete the electronic version of the Investigator Request Form and return it to CRO via e-mail transmission, at the email address specified in the e-mail referred to in Section 8.1 above.

8.3 Payments shall be made by CRO and shall be paid within sixty (60) days of receipt, review and approval of an invoice.

8.4 Please send invoices to the following postal address:

Parexel International Clinical Research Private Limited,
CoWrks, Coworking Spaces Pvt.Ltd-RMZ Eco World,
Ground floor, Bay Area- Adjacent to Building 6A,
Outer Ring Road, Devarabeesanahalli Village,
Bengaluru -560103, Karnataka, India
Attention: Investigator Payment Office

To expedite faster payment turnaround, please electronically e-mail invoices to CRO at the following e-mail address: PIILPayablesInvoices@parexel.com

Please note that invoices must contain the following information:

(a) Protocol Number; and
(b) Invoice Number; and
(c) Invoice Date; and
(d) Place, Date & Description of Services Provided; and
(e) CRO Project Number; and
(f) Total amount payable; and
(g) Exchange rate used (where applicable); and
(h) Investigator Name; and
(i) Site Number; and
(j) Payee Name and Address (per this Agreement); and
(k) CRO Address listed above; and
(l) Date of Supply

Invoices and associated documentation should be de-identified of patient personal information (e.g. name, date of birth, initials, etc.) prior to being submitted to CRO.

Where the payee is GST registered then payment will not be made by CRO without receipt of a valid GST invoice. In addition to the above invoice requirements, GST registered payees must also include the following information:

(a) GST registration number of the supplier (payee), prefixed with their country code (if applicable); and
(b) Name, address and GST registration number of the customer (CRO);and
(c) GST, Net & Gross Amount (if applicable); and
(d) GST Rate (if applicable)

Attachment 1

Detailed Study Budget Matrix Table(s)

Per Patient Cost

Procedure	Qty	OH	Budget	SV	D15_OS	D-1_TELE	D1_OS	D7_TELE	D21_OS	D35_TELE	D42_OS	D49_TELE
Informed consent signed prior to any assessment	1	✔	1,200.00	1,200.00								
Demographics	1	✔	600.00		600.00							
Medical history and baseline conditions, including asthma/atopy	1	✔	2,000.00	2,000.00								
Inclusion/exclusion criteria, Randomization criteria check	3	✔	1,100.00	1,100.00	1,100.00		1,100.00					
Physical examination, including oropharyngeal examination	5	✔	1,000.00	1,000.00	1,000.00		1,000.00		1,000.00		1,000.00	
Vital signs (at screening and prior to PFT)	5	✔	800.00	800.00	800.00		800.00		800.00		800.00	
Blood draw for Hematology, Biochemistry, liver function test, Serum Beta HCG (for WOCBP)	1	✔	140.00	140.00								
Urine sample for cotinine	1	✔	290.00	290.00								
Urine pregnancy test (for WOCBP)	1	✔	400.00				200.00				200.00	
Electrocardiogram	1	✔	1,100.00	1,100.00								
Pulmonary function tests (PFTs) – Spirometry	15	✔	1,100.00		1,100.00		12,100.00		2,200.00		1,100.00	
Interpretation and Repor for Pulmonary function tests (PFTs) – Spirometry	15	✔	350.00		350.00		3,850.00		700.00		350.00	
Reversibility testing	1	✔	2,146.00		2,146.00							
Interpretation and Report for Reversibility testing	1	✔	350.00		350.00							
Concomitant therapy check, Concomitant medication changes	9	✔	600.00	600.00	600.00	600.00	600.00	600.00	600.00	600.00	600.00	600.00
Adverse event monitoring, AE check	9	✔	600.00	600.00	600.00	600.00	600.00	600.00	600.00	600.00	600.00	600.00
Telephonic call	4	✔	500.00			500.00		500.00		500.00		500.00
Preparation of sample for Shipping	1	✔	300.00	300.00								
Procedures Sub Total (INR)				**₹ 9,130.00**	**₹ 8,646.00**	**₹ 1,700.00**	**₹ 20,250.00**	**₹ 1,700.00**	**₹ 5,900.00**	**₹ 1,700.00**	**₹ 4,650.00**	**₹ 1,700.00**

Non Procedure	Qty	OH	Budget	SV	D15_OS	D-1_TELE	D1_OS	D7_TELE	D21_OS	D35_TELE	D42_OS	D49_TELE
Study Coordinator, Simple-Instruct subjects on washout of prohibited medications and restrictions, Maintain source documentation, Data entry	8	✔	2,300.00	4,600.00	2,300.00	1,150.00	2,300.00	1,150.00	2,300.00	1,150.00	2,300.00	1,150.00
Study Coordinator-Registration on IWRS	4	✔	900.00	900.00	900.00		900.00		900.00			
Study nurse	6	✔	1,000.00	2,000.00	1,000.00		1,000.00		1,000.00		1,000.00	
PI time	6	✔	3,500.00	7,000.00	3,500.00		3,500.00		3,500.00		3,500.00	
Patient Reimbursement, Expenses, Patient Travel - Per Visit	5	✔	700.00	700.00	700.00		700.00		700.00		700.00	
Pharmacy, Simple-Dispense rescue medicine inhaler (albuterol), Collect study treatment medication, Dispense placebo inhaler for 2-weeks run-in period, Collect eDiary with PEF-meter, Study treatment medication administration at site/clinical facility, Inhaler device training to pt.	4	✔	550.00	550.00	550.00		550.00		550.00			
Training on eDiary with PEF-meter, Issue eDiary with PEF-meter, eDiary compliance check	7	✔	550.00		550.00	550.00	550.00	550.00	550.00	550.00	550.00	
Physician: Pulmonary Medicine - Review rescue medication use, Check for asthma exacerbation and record severity, Medication washout check	6.4	✔	2,500.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	
Daily Bed Charges - Per Day	1	✔	1,000.00		1,000.00							
Spirometry Technician	1.4	✔	1,500.00		525.00		525.00		525.00		525.00	
Non Procedures Sub Total (INR)				**₹ 17,750.00**	**₹ 13,025.00**	**₹ 3,700.00**	**₹ 12,025.00**	**₹ 3,700.00**	**₹ 12,025.00**	**₹ 3,700.00**	**₹ 10,575.00**	**₹ 1,150.00**
Overhead (all costs)	30%			**₹ 8,064.00**	**₹ 6,501.30**	**₹ 1,620.00**	**₹ 9,682.50**	**₹ 1,620.00**	**₹ 5,377.50**	**₹ 1,620.00**	**₹ 4,567.50**	**₹ 855.00**
Total Cost Per Visit with Overhead(INR)				**₹ 34,944.00**	**₹ 28,172.30**	**₹ 7,020.00**	**₹ 41,957.50**	**₹ 7,020.00**	**₹ 23,302.50**	**₹ 7,020.00**	**₹ 19,792.50**	**₹ 3,705.00**
Total Cost Per Patient (INR)		**₹**	**172,933.80**									

Conditional Cost

Conditional Procedure (Inclusive of IOH)	Budget (INR)
Physical examination, including oropharyngeal examination	814.00
Vital signs (at screening and prior to PFT)	444.00
Electrocardiogram	592.00
Serious adverse events (SAE)	999.00
Concomitant therapy check, Concomitant medication changes	333.00
Urine pregnancy test (for WOCBP)	222.00
Blood draw for Hematology, Biochemistry, liver function test, Serum Beta HCG (for WOCBP)	74.00
Preparation of sample for Shipping	185.00
Swab collection	148.00
PCR for covid	740.00
Pulmonary function tests (PFTs) – Spirometry	592.00
Interpretation and Repor for Pulmonary function tests (PFTs) – Spirometry	185.00
Reversibility testing	1,073.00
Study Coordinator, Simple-Instruct subjects on washout of prohibited medications and restrictions, Maintain source documentation, Data entry	740.00
Study nurse	370.00
PI time	555.00
Patient Reimbursement, Expenses, Patient Travel - Per Visit	700.00
Interpretation and Report for Reversibility testing	185.00
Pharmacy, Simple-Dispense rescue medicine inhaler (albuterol), Collect study treatment medication, Dispense placebo inhaler for 2-weeks run-in period, Collect eDiary with PEF-meter	185.00
Training on eDiary with PEF-meter, Issue eDiary with PEF-meter, eDiary compliance check	185.00
Physician: Pulmonary Medicine - Review rescue medication use, Check for asthma exacerbation and record severity, Medication washout check	814.00

Site Cost

Site Costs (Inclusive of IOH)	Description	Budget (INR)
Study Start-Up Fee/Site Set-Up Fee	One time fee- Please refer to Point 4 of Exhibit A- Enrolment and Payment Schedule for further details.	22,570.00
Document Storage, Archiving Total Cost	One time Fee for 15 years, upon Invoice, will be paid after close-out visit to cover costs associated with archiving the study records for 15 years after the end or premature termination of the study.	75,000.00
Pharmacy: Store study drug, per shelf per year,total cost for 5years	One time Fee for 05 years, upon Invoice, will be paid after close-out visit to cover costs associated with archiving the retention samples for 05 years after the end or premature termination of the study. Please refer to point 4 of Exhibit A- Enrolment and Payment	25,000.00

Exhibit B – Definitions

"Affiliate" means in relation to either party to this Agreement, any company, partnership or other entity which directly or indirectly controls, is controlled by, or is under common control with such party. For purposes of this definition, "control" means the beneficial ownership of more than fifty (50) per cent of the issued voting shares or the legal power to direct or cause the direction of the general management of the company, partnership or other entity in question, and "controlled" shall be construed accordingly.

"Applicable Law" means any international, national, federal, state, provincial, commonwealth, or local government law, statute, rule, requirement, code, regulation, or ordinance that applies to any party or to a Study, the Services, or this Agreement, as well as the current good clinical practices guidelines of the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Topic E6: Guidelines on Good Clinical Practice, and applicable version(s) of the World Medical Association Declaration of Helsinki, and, where applicable, rules governing good manufacturing practice and good laboratory practice, and rules governing the collection and processing of Personal Data and the collection and storage of human tissue samples and the performance of DNA testing.

"Completed Subject" means any Subject who has completed the prescribed course of treatment for a subject in the Study in accordance with the Protocol.

"Confidential Information" refers to any and all Information belonging to SPONSOR, CRO and/or their respective Affiliates including, but not limited to, Information that SPONSOR, CRO and/or their respective Affiliates consider to be trade secrets and / or the release of which could prejudice legal, commercial or other interests of SPONSOR, CRO and/or their respective Affiliates and which are (i) provided, disclosed or submitted to Institution or Investigator or (ii) which are otherwise obtained by Institution and Investigator.

"Data Security Breach" means: (a) the loss or misuse (by any means) of Personal Data; (b) the inadvertent, unauthorized, and/or unlawful Processing, disclosure, access, alteration, corruption, transfer, or sale or rental, destruction, or use of Personal Data; or (c) any other act or omission that compromises the security, confidentiality, or integrity of Personal Data.

"eCRFs/CRFs" (Electronic Case Report Forms or Case Report Forms) are paper or electronic questionnaires specifically used by Institution and Investigator pursuant to the Protocol for Subject data reporting.

"Fully Cooperate" means to assist in completing a specified end or purpose.

"Information" refers to any and all oral, written (including all other tangible forms) and other information, material and assets of any nature, whether or not protected by Intellectual Property Rights or any applications for such rights, such as, but not limited to, data, data information, data and Reports on the Study and the Study Drug, (e)CRFs (whether completed or not), final Reports, all other clinical data, manufacturing data, the Protocol, the Investigator Brochure, laboratory records, information contained in submissions to regulatory authorities, unpublished data and Reports, any and all other Study documentation, technical information, findings, samples, interim results and results, Intellectual Property Rights and any other information and assets potentially subject to any kind of intellectual property rights, whether protectable or not, and any existing or future rights therein; Subjects' medical files and documents facilitating identification of the Study Subjects.

"Intellectual Property Rights" refers to existing and / or future patents, patent applications, trade marks, trade names, service marks, domain names, copyrights, moral rights, rights in and to databases (including rights to prevent the extraction or reutilization/reutilisation of Information from a database), design rights, topography rights, know-how, trade secrets and all rights or forms of protection of a similar nature or having equivalent or the similar effect to any of them which may subsist anywhere in the world, whether or not any of them are registered and including applications for registration of any of them; furthermore rights of use, rights of exploitation, rights of utilization and licenses, whether royalty-free or otherwise.

"Investigational Product" refers to SPONSOR's investigational product(s) including the Study Drug and / or investigational device and to placebo, comparator drug / device or any other control material as defined in the Protocol.

"Investigator" is the individual named in item (3) in the introduction to this Agreement, and is the person responsible for the conduct of the Study at Institution. If a Study is conducted by a team of individuals at an Institution, Investigator is the responsible leader of the team and may be called the principal investigator.

"Investigator Request Form" (IRF) shall mean the form containing the information that PAREXEL Finance Department requires from the payee prior to being able to process payments for said payee.

"Liability Insurance" is insurance that provides coverage against liabilities for claims made by an entity or individual as a result of fault, negligence, malpractice or any other inappropriate action committed by Institution, Investigator and/or Study Personnel in their provision of professional services for the Study.

"Personal Data" means any information relating to an identified or identifiable natural person; an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.

"Process" means any operation or set of operations which is performed upon Personal Data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

"Reports" means any reports that are required by the applicable regulatory committee to close out the Study.

"Resources" refers to any facilities and equipment that are utilized for the conduct of the Study.

"Services" means the services to be provided by the Institution, the Investigator and/or the Study Personnel under the terms of this Agreement.

"Study" means the scientific research as defined in the Protocol.

"Study Instructions" means any written document, other than the Protocol, issued by SPONSOR or CRO that specifically relates to and references the Study and which provides additional information and/or instructions on how the Institution and Investigator shall conduct the Study. Study Instructions may be transmitted from SPONSOR or CRO to Institution and/or Investigator by personal delivery, fax, e-mail, registered post, certified post or courier.

"Study Personnel" means any employees of Institution or Investigator, and/or contractors engaged by Institution or Investigator, who are involved in performing the Study, including Sub-Investigator(s), Study coordinator(s), and any other contractors, agents and employees of Institution or Investigator who assist Institution and Investigator with the Study.

"Study Results" refers to any and all Information and any other material and results directly or indirectly arising from or in connection with the Study, regardless of whether the Study was aimed at yielding the relevant Study Results or whether they are ancillary in connection with the Study.

"Sub-Investigator" is any individual member of the Study team designated and supervised by the Investigator at Institution to perform critical trial-related procedures and/or to make important trial-related decisions (e.g., associates, residents, research fellows).

"Subject" is a person participating in the Study and identified in the signed informed consent form.

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4.4.2022

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I. PACKIA AROCKIA MARY
STAMP VENDOR L.NO. 109 / B4 / 88
HIGH COURT CAMPUS
CHENNAI

Icon clinical Research India Pvt Ltd.

CLINICAL STUDY AGREEMENT
among
ICON Clinical Research India Private Limited
and
Dr. Ashish Ramchandrarao Deshmukh
and
Mahatma Gandhi Mission (MGM) Medical College & Hospital
and
Aurangabad Health Care & Research LLP

Pfizer Protocol # B7451094

This Clinical Study Agreement ("**Agreement**") among

ICON Clinical Research India Private Limited, with a place of business at **Chennai ONE IT Park, North Block – 4th Floor, Pallavaram – Thoraipakkam 200 Feet Road, Thoraipakkam, Chennai – 600097, Tamil Nadu, India** ("**CRO**")

and

Dr. Ashish Ramchandrarao Deshmukh, with a place of business at **Mahatma Gandhi Mission (MGM) Medical College & Hospital, N-6, CIDCO, Aurangabad - 431003, Maharashtra, India** ("**Principal Investigator**").

and

Mahatma Gandhi Mission (MGM) Medical College & Hospital, with a place of business at **N-6, CIDCO, Aurangabad - 431003, Maharashtra, India** ("**Institution**"),

and

Aurangabad Health Care & Research LLP, with a place of business at **Shop No.126, CTS No.12482/1 Chetan Trade Centre, Opp. S. F School, Jalna Road, Aurangabad - 431001, Maharashtra, India** ("**SMO**"),

when signed by all parties, is effective as of **17-Jun-2022**.

Pfizer Inc.("**Pfizer**") wishes to sponsor a clinical study trial/entitled "A Randomized, Open-Label, Parallel-Group Study To Evaluate The Safety And Efficacy Of Abrocitinib 100 mg And 200 mg Tablets In Participants Aged 12 Years And Older With Moderate To Severe Atopic Dermatitis In India" ("**Study**") to be conducted by Principal Investigator at Institution under the Pfizer protocol identified above ("**Protocol**"). Pfizer has delegated responsibility for management of this Study, including contracting and Study monitoring, to CRO, and has authorized CRO to bind Pfizer to all commitments within this Agreement identified as belonging to Pfizer.

The Principal Investigator as a signatory/confirming party to this Agreement acknowledges the liabilities and obligations as an 'investigator' under the provisions of the New Drugs and Clinical Trials Rules, 2019 ("**Rules**").

The Institution has designated the SMO to receive payments for the work carried out by the Institution on behalf of the Institution. The Institution also engages the SMO to provide study coordinator services. The Institution shall oversee and be responsible for the activities of the SMO and shall ensure that the SMO is in compliance with all applicable laws. The Institution warrants and represents that payments to the SMO do not contravene any Institutional policy, contract of employment, law and/or regulation including but not limited to any medical ethics regulation.

The parties agree as follows:

1. Responsibilities

1.1 Investigators and Research Staff. The Study will be conducted by Principal Investigator, namely **Dr. Ashish Ramchandrarao Deshmukh** ("**Principal Investigator**") at a facility that is identified as a 'clinical trial site' under the Rules. Principal Investigator is an employee of Institution. Principal Investigator is authorized by Institution to conduct the Study at Institution under a separate agreement between Principal Investigator and Institution. Principal Investigator will ensure that only individuals who are appropriately trained, experienced and qualified assist in the conduct of the Study as investigators, sub-investigators or research staff. The Principal Investigator shall sign an undertaking in the form prescribed in **Table 4** of the **Third Schedule** of the Rules.

1.2 Compliance Obligations. Principal Investigator and Institution are responsible to CRO and Pfizer for compliance by all Study personnel with the terms of this Agreement, the Protocol, the applicable provisions of the Drugs and Cosmetics Act, 1940 ("**Act**"), the Rules, and International Conference on Harmonization Good Clinical Practice ("**ICH GCP**") guidelines, ethical guidelines for Biomedical Research on Human Participants issued by the Indian Council of Medical Research, as well as applicable law, regulations, and governmental guidance, including without limitation, the laws of the Republic of India. The Institution and CRO shall be jointly responsible for obtaining requisite permissions and approvals for the conduct of the Study in terms of applicable laws, including permission from the Central Licensing Authority. The Institution also undertakes to abide by and comply with any statutory modifications/ amendments to the Rules, as may be effective from time to time. Institution is responsible for compliance by all personnel who are employees or contractors of Institution, and Principal Investigator is responsible for compliance by any personnel not employed or contracted by Institution.

1.3 Pfizer GCP Training. Prior to enrollment of any Study Subjects (as defined in Section 4, Subject Enrollment), Principal Investigator and any sub-investigators will either complete or provide a valid certificate of the Pfizer-provided Good Clinical Practice training course ("**Pfizer GCP Training**"). Any investigators who later join the Study, in compliance with applicable laws including the Rules, will complete the Pfizer GCP Training or provide a valid certificate before performing Study-related duties.

1.4 Compliance with Global Trade Controls. The parties agree that activities under this Agreement may be subject to applicable import, export, and economic sanctions laws and regulations ("Global Trade Control Laws"). Institution and CRO will comply with all applicable Global Trade Control Laws.

a. The parties confirm that none of the activities under this Agreement will (i) take place in a Restricted Market; (ii) involve individuals ordinarily resident in a Restricted Market; and (iii) involve companies, organizations, or Governmental Entities from a Restricted Market. "Restricted Market" shall mean the Crimean Peninsula, Cuba, the Donbass Region, Iran, North Korea, Sudan, and Syria.

b. Each party represents and warrants that (i) it is not on any Restricted Party Lists (defined below); (ii) it is not owned or controlled by any individual or entity on any Restricted Party Lists; and (iii) that it will not involve any individual or entity on any Restricted Party Lists in the activities under this Agreement. In the event that an individual or entity on a Restricted Party List is included in activities under this Agreement, the party connected with such individual or entity will immediately notify the other party and suspend the relevant affected activities, including any and all affected payments, until the parties agree to go forward.

c. With respect to this Agreement, Restricted Party Lists include the Consolidated Screening List (https://www.export.gov/consolidated_screening_list); the Excluded Parties List System (https://www.sam.gov); and the Consolidated List of Persons, Groups, and Entities Subject to E.U. Financial Sanctions https://eeas.europa.eu/headquarters/headquarters-homepage/8442/consolidated-list-sanctions_en

1.5 The Institution shall ensure that the Principal Investigator shall conduct Study/clinical trials only with the permission of the IRB/IEC after the examination of the risk and complexity involved in the trials proposed to be conducted and shall not in any instance conduct any higher number of Study/clinical trial not permitted by the IRB/IEC. The Institution shall indemnify the CRO and Pfizer, their respective employees and agents against any and all claims and proceedings (to include any settlements or reasonable legal and expert cost and expenses) arising out of or in connection with the Principal Investigator's failure to adhere to provisions of this Clause.

2. Funding. CRO will provide funding in support of this Study to Institution as delineated in Attachment A, Study Budget and Payment Terms, and subject to the terms specified in that Attachment. For the avoidance of doubt all payments made to the Institution will be made to the SMO which is the designated recipient of all fees payable to the Institution for work performed in terms of this Agreement as indicated in Attachment A.

2.1 Payee. Other than stated above the SMO shall have no further obligations or responsibilities in respect of this Agreement. CRO's only payment obligation under this Agreement is to pay the SMO. Allocation of funds between Institution and Principal Investigator and SMO is governed by a separate agreement between those

parties. Principal Investigator/Institution releases CRO and Pfizer from any obligation or liability related to the disbursement of funds by SMO.

2.2 Investigator Meetings. If Principal Investigator or other Study personnel are required to attend investigator meetings for this Study, CRO will arrange and pay directly for travel and accommodation and will cover the reasonable costs of meals in connection with those meetings, but does not provide compensation for such attendance.

2.3 Disclosure by Pfizer. In the interest of transparency relating to its relationships with investigators and Study sites or to ensure compliance with applicable local laws, Pfizer may publicly disclose the support it provides under this Agreement. Such a disclosure by Pfizer may identify both the Institution and the Principal Investigator, but will clearly differentiate between payments or other transfers of value to institutions and those made to individuals.

3. Protocol. Principal Investigator will conduct the Study and Study-related activities in accordance with the Protocol, including, but not limited to, the requirements relating to approval of the IRB/IEC (as laid out in Clause (B) of **Table 1** of **Third Schedule** under the Rules)and the Licensing Authority under the Rules as also related to reporting/ adverse event reporting in terms of the applicable laws.

3.1 Amendments. The Protocol may be modified only by a written amendment, approved by Pfizer, the CRO, the responsible IRB/IEC and the Central Licensing Authority ("**Amendment**") except, as described in the Protocol, for emergency changes necessary to eliminate immediate hazards and/or protect the safety of the Study Subjects (as defined in Section 4, Subject Enrollment). The Amendment(s) of the Protocol, if any, to eliminate immediate hazards and protect the safety of the Study Subject shall be immediately notified to the responsible IRB/IEC, provided that any administrative and/or logistic changes in the Protocol shall be notified to the Licensing Authority within 30 days in accordance with applicable laws.

3.2 No Additional Research. No additional research may be conducted on Study Subjects (as defined in Section 4, Subject Enrollment) during the conduct of the Study or on biological samples collected during the conduct of the Study unless it is approved by Pfizer and documented as an Amendment to the Protocol in compliance with applicable laws.

4. Subject Enrollment. Principal Investigator has agreed to enroll in the Study a minimum of 10 but no more than 30 qualified Study participants by 10-Jun-2023, unless CRO, upon Pfizer's prior instructions, modifies this enrollment period by written notice. A qualified participant is one who meets all Protocol criteria for inclusion in the Study ("**Study Subject**").

4.1 Multi-Center Studies. CRO, upon Pfizer's prior instructions, may end Study Subject enrollment early by written notice if the total enrollment needed for a multi-center study has been achieved before the end of the enrollment period for this Study or before Principal Investigator has enrolled the minimum number of Study Subjects.

5. Study Conduct

5.1 Charging Study Subjects. Neither Principal Investigator nor Institution will charge a Study Subject or third-party payer for Investigational Drug (see Section 8, Investigational Drug) or for any services reimbursed by CRO under this Agreement.

5.2 Safety Measures and Serious Protocol or ICH GCP Breaches. Principal Investigator will inform CRO immediately of any urgent safety measures taken by Principal Investigator to protect Study Subjects against immediate hazard. Principal Investigator and Institution will inform CRO immediately of any deviations or serious breaches of the Protocol, the Act, the Rules, the GCP Guidelines or of ICH GCP guidelines of which Principal Investigator or Institution becomes aware, adverse drug reactions / adverse events / serious adverse events reportable in accordance with the applicable laws, and new information that may adversely affect safety of the Study Subjects or the conduct of the Study.

5.3 The Institution shall ensure that adequate information in relation with the Study is provided to the Study Subject by the Principal Investigator in compliance with the Rules and applicable laws. The Principal Investigator shall document the standard operating procedures for the Study and shall also strictly comply with all the requirements prescribed under the Rules and the GCP Guidelines.

6. Data Protection and FDA Financial Disclosure

6.1 Personal Data. Personal data is any information from which it is possible to identify an individual. Personal data that concerns health information, including physical, physiological and mental health condition, biometric information and medical records and history, is sensitive personal data. Personal data collected in association with the Study will include personal data relating to the Principal Investigator, sub-investigators, research staff, third parties, and Study Subjects (which could include sensitive personal data) (collectively "**Personal Data**"). Such Personal Data may be subject to specific legislation relating to its processing, storage, transfer and use. Principal Investigator and Institution will comply with all relevant laws relating to the protection and use of Personal Data and data privacy in their conduct and reporting of the Study and shall ensure that the provider of Personal Data has given his consent and has the knowledge of the fact of collection, purpose of usage, intended recipients and storage of the information. Principal Investigator and Institution will take all appropriate technical and organizational measures to prevent damage to, or disclosure, unauthorized or unlawful processing.

or accidental loss or destruction of such Personal Data. CRO and Pfizer will take appropriate measures to protect the confidentiality and security of all Personal Data that they receive in connection with the Study.

6.2 Use by CRO and Pfizer. Personal Data will be processed and used for the purposes of administration of this Agreement and in connection with the Study. Information relating to the Principal Investigator, sub-investigators, and research staff will be held on one or more databases for the purpose of determining their involvement in future research and in order to comply with any regulatory requirements.

6.3 Financial Disclosure. Where the Study is deemed by Pfizer to be a "covered study" for the purpose of the United States Food and Drug Administration regulation entitled "*Financial Disclosure by Clinical Investigators*" (the "**FDA Regulation**"), Principal Investigator agrees, and Principal Investigator or Institution, as appropriate, will ensure that any sub-investigator engaged in the Study agrees, to disclose to CRO and Pfizer all relevant financial and other information (including details of equity interests in Pfizer or any of its affiliates) relating to the Principal Investigator or sub-investigators, as the case may be (and, where relevant, spouse and dependents of Principal Investigator or sub-investigator) as required by CRO to enable Pfizer to comply with the FDA Regulation.

6.4 Disclosure and Transfer. Some of the Personal Data discussed in this Section 6 may be disclosed or transferred to other members of the CRO or Pfizer group of companies, to representatives and contractors working on behalf of the CRO or Pfizer group, and to regulatory authorities across the world. The Institution will ensure that all necessary consents are in place to comply with the provisions of this Section 6 with respect to any affected employees and contractors of Institution. Principal Investigator will ensure such consent for any individuals working under Principal Investigator's direction and control who are not employees or contractors of Institution.

7. Informed Consent and Subject Recruitment.

7.1 Informed Consent. The Institution/Principal Investigator shall be responsible to provide information, including the information on the right to claim compensation in case of trial related injury or death, to the Study Subject through the informed consent process as set out in the Rules. The Institution and Principal Investigator will ensure that informed consent is obtained from each Study Subject (and if applicable, from any legally authorized representative) in the Informed Consent Form prescribed under **Table 3** of the **Third Schedule** of the Rules, as approved by the IRD/IEC, along with an audio visual recording of the informed consent in accordance with the applicable laws. Any recording will be taken and preserved in accordance with applicable data privacy laws and regulations. This obligation of taking and preserving the written consent and the audio- visual recording will also apply to any re-consent process required during the course of the Study.Principal Investigator will provide CRO and/or Pfizer an opportunity to review and approve

the content of the informed consent document (including any revisions made during the course of the Study) before it is used. Principal Investigator must not make any changes to this document without the prior written approval of the CRO or Pfizer (including any revisions made during the course of the Study or required by IRB/IEC), and such approval is to be obtained before the revised informed consent document is used in respect of the Study.

7.2 Subject Recruitment. Principal Investigator will ensure that all Study-specific subject recruitment methods, procedures and materials have prior IRB/IEC written approval and comply with all applicable law, regulations and governmental guidance.

8. Investigational Drug. CRO will arrange for Institution to receive, at no charge, sufficient quantities of the Pfizer product that is being studied ("**Pfizer Drug**") to allow Principal Investigator to conduct the Study. The CRO is *inter alia* obligated to apply for and obtain a license for import from the Central Licensing Authority in prescribed form under the Rules.Unless otherwise indicated in Attachment A (Study Budget and Payment Terms), CRO will also arrange for Institution to receive at no charge, or will cover the costs of, any other Protocol-required drugs (e.g., placebo, comparator drug, concomitant drug). Any other Protocol-required drug that CRO or Pfizer provides or covers the cost of is, together with the Pfizer Drug, considered "**Investigational New Drug**".

8.1 Custody and Dispensing. Principal Investigator will maintain appropriate control of supplies of Investigational New Drug and will not administer or dispense it to anyone who is not a Study Subject, or provide access to it to anyone except Study personnel.

8.2 Use. Principal Investigator will use Investigational New Drug only as specified in the Protocol. Any other use of Investigational New Drug by Principal Investigator or Institution or permitted by Principal Investigator or Institution constitutes a material breach of this Agreement.

8.3 Ownership of Pfizer Drug. Pfizer Drug is and remains the property of Pfizer. Except for, and limited to, the use specified in the Protocol, Pfizer grants neither Principal Investigator nor Institution any express or implied intellectual property rights in the Pfizer Drug or in any methods of making or using the Pfizer Drug. The CRO agrees and acknowledges that it does not have the right to manufacture for sale or for distribution of the Investigational New Drug.

9. Equipment or Materials. CRO or Pfizer may provide, or arrange for a vendor to provide, certain equipment ("**Equipment**") or proprietary materials for use by Principal Investigator or Institution during the conduct of Study. Such proprietary materials may include computer software, methodologies, rating scales and other instruments that are owned or licensed for use by CRO or Pfizer (collectively, "**Materials**"). Equipment or Materials to be provided for the Study and any requirements relating to them are described in

Attachment C, Equipment and Materials which is incorporated into this Agreement by reference.

10. Confidential Information. During the course of the Study, Principal Investigator and the Institution and / or the Principal Investigator may receive or generate information that is confidential to CRO, Pfizer, or a Pfizer affiliate.

10.1 Definition. Except as specified in Section 10.2, Exclusions, below, "**Confidential Information**" includes

a. the Protocol,
b. the Investigator Brochure,
c. Study Data (as defined in Section 11, Study Data, Biological Samples, and Study Records below),
d. Biological Sample Analysis Data (as defined in Section 11, Study Data, Biological Samples, and Study Records, below),
e. Attachment A (Study Budget and Payment Terms) to this Agreement, and
f. any other information related to the Study, the Pfizer Drug, or CRO, Pfizer, or Pfizer affiliate technology, research, or business plans that CRO, Pfizer, or a Pfizer affiliate provides to Institution/Principal Investigator or Institution in writing or other tangible form and marks as CONFIDENTIAL or initially discloses orally and then summarizes and confirms in writing as CONFIDENTIAL within 30 days after the date of oral disclosure. Information of the type described in this Section 10.1.f. that is disclosed orally will also be considered Confidential Information even if not later confirmed in writing if the confidential nature of the disclosure is reasonably apparent to the other party.

10.2 Exclusions. Confidential Information does not include information that

a. is in the public domain at the time of disclosure or during the term of this confidentiality obligation by means other than breach of this Agreement by Principal Investigator or Institution,
b. is already known to Principal Investigator or Institution at the time of disclosure and is free of any obligations of confidentiality,
c. is obtained by Principal Investigator or Institution, free of any obligations of confidentiality, from a third party who has a lawful right to disclose it, or
d. is independently developed, as documented by written records, by individuals within Institution who had no access to Confidential Information.

10.3 Obligations of Confidentiality. Unless CRO or Pfizer provides prior written consent, Principal Investigator and Institution may not use Confidential Information for any purpose other than that authorized in this Agreement, nor may they disclose Confidential Information to any third party except as authorized in this Agreement or as required by law, including applicable regulations.

a. CRO and Pfizer specifically authorize any required disclosure of Confidential Information to IRB/IEC or regulatory authority representatives.

b. Permitted uses of Study Data and Biological Sample Analysis Data are described in Section 15 (Publications) of this Agreement and use of Personal Data is discussed in Section 6 (Data Protection and FDA Financial Disclosure) and 12.2 (Pfizer Representative Personal Data).

10.4 Disclosure Required by Law. If disclosure of Confidential Information beyond that expressly authorized in this Agreement is required by law, that disclosure does not constitute a breach of this Agreement so long as the party disclosing the information

a. notifies CRO in writing as far as possible in advance of the disclosure so as to allow CRO or Pfizer to take legal action to protect its Confidential Information,
b. discloses only that Confidential Information required to comply with the legal requirement, and
c. continues to maintain the confidentiality of this Confidential Information with respect to all other third parties.

10.5 Survival of Obligations. For Confidential Information other than Study Data and Biological Sample Analysis Data (as defined in Section 11, Study Data, Biological Samples, and Study Records), these obligations of nonuse and nondisclosure survive termination of this Agreement and continue for a period of five years after termination. Confidentiality obligations for Study Data and Biological Sample Analysis Data survive for as long as the party retains this information, subject to the permitted uses described in Section 15 (Publications) of this Agreement.

10.6 Return of Confidential Information. If requested by CRO and/or Pfizer in writing, Principal Investigator and / or Institution will return all Confidential Information except that required to be retained at the Study site or by Principal Investigator by applicable regulation. However, Principal Investigator and Institution may each retain a single archival copy of the Confidential Information to determine the scope of obligations incurred under this Agreement.

11. Study Data, Biological Samples, and Study Records

11.1 Study Data. During the course of the Study, Principal Investigator will collect certain data, as specified in the Protocol, and submit it to CRO, Pfizer or Pfizer's agent ("**Study Data**"). Principal Investigator will ensure accurate and timely collection, recording, and submission of Study Data, including adhering to timelines for data entry set out in the *CRF Completion Requirements* document provided to Principal Investigator by CRO or Pfizer.

a. Ownership of Study Data. Subject to Principal Investigator's right to use Study Data to publish the results of the Study (see Section 15, Publications), Pfizer is the exclusive owner of all Study Data.

b. Medical Records. Study Subject-related medical records that are not submitted to CRO or Pfizer may include some of the same information as is included in Study Data; however, neither CRO nor Pfizer makes any claim of ownership to those documents or the information they contain.

c. Data Review by CRO. CRO and/or Pfizer will review the Study Data it receives on an ongoing basis. CRO and/or Pfizer will comply with applicable regulations requiring notification of participating investigators of new safety information about the Pfizer Drug (as defined in Section 8 of this Agreement). CRO and/or Pfizer further commits to promptly notify Institution/ Principal Investigator of any other new information of which CRO and/or Pfizer becomes aware that could affect the safety of the Study Subjects or influence the conduct of the Study.

d. Study Results. After analysis of Study Data from all sites is complete, CRO or Pfizer will provide Institution/Principal Investigator with a summary of the overall results of the Study. CRO and Pfizer encourage Institution/Principal Investigator to communicate the results, as appropriate, to the Study Subjects. If within two years after Study completion Pfizer identifies results that could affect Study Subject safety, CRO or Pfizer, in consultation with the IRB/IEC as appropriate, will cooperate with Principal Investigator or Institution to ensure that those results are appropriately communicated to the Study Subjects by Principal Investigator or Institution.

11.2 Biological Samples. If so specified in the Protocol and the informed consent document, Principal Investigator may collect and provide to CRO, Pfizer or their designee biological samples obtained from Study Subjects (e.g., blood, urine, tissue, saliva, etc) for testing that is not directly related to Study Subject care or safety monitoring, such as pharmacokinetic, pharmacogenomic, or biomarker testing ("**Biological Samples**").

a. Use. Neither Principal Investigator nor Institution will use Biological Samples collected under the Protocol in any manner or for any purpose other than that described in the Protocol. CRO and Pfizer will use Biological Samples only in ways permitted by the informed consent under which they were obtained.

b. Analysis Data. CRO, Pfizer, or their designees will test Biological Samples as described in the Protocol. Unless otherwise specified in the Protocol, neither CRO nor Pfizer plan to provide the results of these tests ("**Biological Sample Analysis Data**") to Principal Investigator or Study Subject. If CRO or Pfizer does provide Biological Sample Analysis Data to Principal

Investigator, that data will be subject to the provisions of Section 11.1 (Study Data) of this Agreement.

c. Ownership. Pfizer is the exclusive owner of all Biological Samples and Biological Sample Analysis Data.

11.3 Study Records. On behalf of Principal Investigator and itself, Institution will retain each Study Subject's Study records, which include the Principal Investigator's copies of all Study Data as well as relevant source documents (collectively, "**Study Records**"), under storage conditions conducive to their stability and protection, for a period of 15 years after termination of the Study. Institution agrees to contact Pfizer at InvestigatorRecords@Pfizer.com prior to destroying any Study Records and Principal Investigator and Institution further agree to permit Pfizer to ensure that the Study Records are retained for a longer period if necessary, at Pfizer's expense, under an arrangement that protects the confidentiality of the records (e.g., secure off-site storage).

12. Monitoring, Inspections, and Audits

12.1 Monitoring. CRO intends to monitor Study conduct. Pfizer, or an external service provider acting on its behalf, has the right, but not the obligation, to co-monitor the Study. Upon reasonable notice and during regular business hours, Principal Investigator and Institution will permit CRO or Pfizer representatives access to the premises, facilities, Study Records, sub-investigators, and research staff as required to monitor Study conduct. Upon request from CRO or Pfizer, Institution will permit remote electronic access to Study Records when available and permitted under applicable law. CRO or Pfizer will promptly notify Principal Investigator of any monitoring findings that could affect the safety of Study Subjects or influence the conduct of the Study. Principal Investigator will inform Study Subjects of such findings as appropriate.

12.2 Pfizer Representative Personal Data. If in the support of a clinical trial, Pfizer representatives are required to submit to Institution and Principal Investigator any Personal Data, including but not limited to, name, address, phone number, government identifier, or birthdate ("**Pfizer Representative Personal Data**"), Institution and Principal Investigator will:

a. protect the confidentiality of Pfizer Representative Personal Data using the same or similar standards Institution uses for its own employees;

b. not sell or disclose Pfizer Representative Personal Data to any third party except as required by law;

c. impose similar confidentiality and security obligations, by contract, on any contracted service providers with whom Institution may share Pfizer Representative Personal Data;

d. take appropriate measures to protect against any unauthorized use or disclosure of Pfizer Representative Personal Data and will promptly notify Pfizer of any breach of this provision.

12.3 Inspections and Audits. Principal Investigator and Institution acknowledge that the Study is subject to inspection by regulatory authorities worldwide, including the United States FDA, and that such inspections may occur prior to commencement, during or after completion of the Study and may include auditing of Study Records. CRO or Pfizer may also audit Study Records during or after the Study as part of its monitoring of Study conduct.

a. Notification. Principal Investigator will notify CRO as soon as reasonably possible if the Study or site is inspected or scheduled to be inspected by a regulatory authority in relation to the Study.

b. Right to be Present. If not prohibited by law, Pfizer or CRO will have the right to be present during, and participate in, any such inspection, audit, investigation, or regulatory action.

c. Cooperation. Principal Investigator and Institution will cooperate with regulatory authority and CRO or Pfizer representatives in the conduct of inspections and audits and will ensure that Study Records are maintained in a way that facilitates such activities.

d. Resolution of Discrepancies. Principal Investigator will promptly resolve any discrepancies that are identified between the Study Data and the Study Subject's medical records.

e. Inspection Findings and Responses. Principal Investigator and Institution will promptly forward to CRO and Pfizer copies of any inspection findings that either receives from a regulatory authority in relation to the Study. Whenever feasible and permitted by law, Principal Investigator and Institution will also provide CRO and Pfizer with an opportunity to prospectively review and comment on any responses to regulatory authority inspections in regard to the Study.

12.4 Study Conduct Evaluations. CRO, Pfizer or Pfizer's external service providers may document and evaluate the performance of Institution and Principal Investigator in the conduct of the Study. CRO and Pfizer will use these evaluations solely for internal purposes.

13. Remedies for Breach of Certain Study Obligations. In the event Principal Investigator or Institution fails to comply with any of its obligations set out in Sections 3 (Protocol), 7 (Informed Consent and Subject Recruitment), 11 (Study Data, Biological Samples, and Study Records) and 12 (Monitoring, Inspections, and Audits) of this Agreement, or the requirements of the Protocol relating to adverse event reporting, ethical conduct of the Study, and IRB/IEC review, in addition to its right to terminate the Study immediately under Section 18.1.c(2), CRO will have recourse to either or both of the following alternative remedies:

a. Suspension of Study Subject enrollment, if the Study is not yet fully enrolled, and
b. Suspension of all payments by CRO

Any suspension of enrollment or payment will continue until Principal Investigator and Institution return to compliance with their Study obligations, as determined by CRO. Use of either or both of the above remedies does not preclude CRO or Pfizer from exercising its right to immediately terminate the Study if Principal Investigator and Institution do not become compliant.

14. Inventions

14.1 Notification. If the conduct of Study results in any invention or discovery whether patentable or not ("**Invention**"), Principal Investigator will promptly inform CRO and Pfizer.

14.2 Assignment. Principal Investigator or Institution, as applicable, will assign, or ensure that inventors assign, all interest in any such Invention to Pfizer, free of any obligation or consideration beyond that provided for in this Agreement.

14.3 Assistance. Principal Investigator and Institution will provide reasonable assistance to Pfizer in filing and prosecuting any patent applications relating to Invention, at Pfizer's expense.

15. Publications. Pfizer supports the exercise of academic freedom and has no objection to publication by Principal Investigator of the results of the Study based on information collected or generated by Principal Investigator, whether or not the results are favorable to the Pfizer Drug, subject to the Principal Investigator maintaining the privacy and confidentiality of the Study Subjects in compliance with applicable laws.

15.1 Prepublication Review. Principal Investigator will provide Pfizer an opportunity to review any proposed publication or any other type of disclosure of the results of the Study (collectively, "**Publication**") before it is submitted or otherwise disclosed. Pfizer will review for unprotected Inventions (see Section 14, Inventions) and may also provide comments on content. Principal Investigator will

consider any such comments in good faith but is under no obligation to incorporate any Pfizer suggestions.

a. Submission to Pfizer. Principal Investigator will provide any Publication to Pfizer at least 30 days before it is submitted for publication or otherwise disclosed. If any patent action is required to protect intellectual property rights, Principal Investigator agrees to delay the disclosure for a period not to exceed an additional 60 days.

b. Redaction of Confidential Information. Principal Investigator will, on request, remove any previously undisclosed Confidential Information before disclosure, except for any Study- or Pfizer Drug-related information necessary to the appropriate scientific presentation or understanding of the Study results.

15.2 Multi-Center Studies. If Study is part of a multi-center trial, Principal Investigator and Institution agree that the first Publication is to be a joint Publication covering all Study sites, and that any subsequent Publications by Principal Investigator will reference that primary Publication. However, if a joint manuscript has not been submitted for publication within 12 months of completion or termination of Study at all participating sites, Principal Investigator is free to publish separately, subject to the other requirements of this Section 15.

15.3 Standards. For all Publications relating to the Study, Principal Investigator will comply with the authorship guidelines in the *Recommendations for the Conduct, Reporting, Editing, and Publication of Scholarly Work in Medical Journals* (http://www.icmje.org/icmje-recommendations.pdf) provided by the International Committee of Medical Journal Editors.

15.4 Disclosure of Support. Principal Investigator will disclose Pfizer sponsorship and financial support of the Study in any publication of Study results. The Institution will at all times ensure that such Publications are made in strict compliance with laws prevalent in India.

15.5 Study Registration by Pfizer. Pfizer commits to register, on the National Institutes of Health Clinical Trials Data Bank (www.clinicaltrials.gov), all Pfizer-sponsored Phase 1 through 4 interventional and non-interventional studies that involve the use of a Pfizer product and evaluate the safety or efficacy of that product. Pfizer will also register Pfizer-sponsored studies on other listings of ongoing studies maintained by competent regulatory authorities where there is a regulatory requirement to do so. Pfizer also commits to register on Indian Council for Medical Research's Clinical Trial Registry before the enrollment of the first Study Subject.

16. Indemnification and Research Injury. CRO does not provide any indemnification under this Agreement. The Pfizer Indemnification and Research Injury Policy applicable to this Study is appended to this Agreement as Attachment B.

17. Assignment and Delegation

17.1 By Principal Investigator or Institution. Neither Principal Investigator nor Institution shall assign his/her/its rights or delegate or subcontract any duties under this Agreement without written permission from CRO and Pfizer. If CRO and Pfizer authorize delegation or subcontracting, the party that delegated or subcontracted its duties remains responsible to CRO for the performance of those duties.

17.2 By CRO. CRO may freely assign any or all of its rights and delegate any or all of its duties under this Agreement to Pfizer (subject to the prior written consent of Pfizer). If CRO assigns all rights and delegates all duties to Pfizer, CRO or Pfizer will notify Principal Investigator and Institution in writing. Any other assignment of rights and obligations of the CRO under this Agreement shall be mutually agreed between the CRO and Pfizer and notified to the Institution.

18. Termination

18.1 Termination Events. Termination of this Agreement will be triggered by the earlier of any of the following events.

a. Disapproval by IRB/IEC. If the Study cannot be initiated because of IRB/IEC disapproval, this Agreement will terminate.

b. Study Completion. This Agreement will terminate when the Study is complete, which means the conclusion of all Protocol-required activities for all enrolled Study Subjects.

c. Early Termination of Study. This Agreement will terminate if the Study is terminated early as described below.

(1) Termination of Study Upon Notice. CRO or Pfizer may terminate the Study for any reason upon 30 days' written notice to Principal Investigator and Institution.

(2) Immediate Termination of Study by CRO or Pfizer. CRO or Pfizer may terminate the Study immediately upon written notice to Principal Investigator and Institution for causes that include failure to enroll Study Subjects at a rate sufficient to achieve Study performance goals; material unauthorized deviations from the Protocol or reporting requirements; circumstances that in CRO's or

Pfizer's opinion pose risks to the health or well-being of Study Subjects; regulatory authority actions relating to the Study or the Investigational New Drug; or any non-compliance by the Principal Investigator or Institution with applicable laws, ICH GCP, or the terms of Section 20 (Anti-Corruption) of this Agreement.

(3) Immediate Termination of Study by Principal Investigator or Institution. Principal Investigator or Institution may terminate the Study immediately upon notification to CRO if requested to do so by the responsible IRB/IEC or if such termination is required to protect the health of Study Subjects.

(4) CRO or Pfizer shall have the right but not the obligation to terminate the Agreement, without further obligation to the Institution and/or Principal Investigator in the event that the Principal Investigator fails to declare to the IRB/IEC the number of clinical trials being conducted by the Principal Investigator and/or conducts clinical trial above such number as may have been decided by the IRB/IEC.

18.2 Effective Date of Agreement Termination. If termination of the Agreement is triggered by any of the events described in Section 18.1, above, the termination will be effective after receipt by CRO or Pfizer of all Protocol-required Study Data and Biological Samples generated up until termination; receipt of all payments due to any party; and completion by all parties of any remaining applicable Agreement obligations.

18.3 Payment upon Early Termination of Study. Except as otherwise indicated in this subsection, if the Study is terminated early, CRO will pay for work already performed, in accordance with Attachment A, less payments already made for such work. CRO will also cover any non-cancelable expenses, other than future personnel costs, so long as they were properly incurred and prospectively approved by CRO and only to the extent they cannot reasonably be mitigated. If the Study cannot be initiated because of disapproval by the IRB/IEC and through no fault of Principal Investigator or Institution, CRO will reimburse Principal Investigator or Institution, as applicable, for IRB/IEC fees and any other expenses that were prospectively approved, in writing, by CRO.

a. Non-Compliance with Anti-Corruption Provision. If CRO or Pfizer terminates the Study because of Principal Investigator's or Institution's non-compliance with the terms of Section 20, Anti-Corruption, CRO and Pfizer will not provide any further payment under this Agreement, regardless of any activities that Principal Investigator or Institution has undertaken or third-party agreements that Principal Investigator or Institution has entered into before termination.

18.4 Institution's duty on Early Termination. The Institution should promptly inform the Study Subjects, the IRB/IEC as well as the Central Licensing Authority of such termination. The Institution should also ensure appropriate therapy and follow-up for the Study Subjects at no cost to Pfizer or CRO.

18.5 Return of Materials. Unless CRO instructs otherwise in writing, upon termination of the Agreement, Principal Investigator and Institution will promptly return all materials supplied by CRO or Pfizer for Study conduct, including unused Investigational New Drug, unused Case Report Forms, and any CRO or Pfizer-supplied Equipment and Materials.

18.6 Survival of Obligations. Obligations relating to Funding, Confidential Information, Study Records, Inventions, Publications, Indemnification and Research Injury, Suitability, and Anti-Corruption survive termination of this Agreement, as does any other provision in this Agreement, including Attachments, that by its nature and intent remains valid after the term of the Agreement.

19. Other Terms

19.1 Suitability. Principal Investigator and Institution each certify that he/she/it is licensed, registered, or otherwise qualified and suitable under applicable law, regulations, policies, or administrative requirements to conduct the Study and required Study-related activities or act as Study site, as applicable. Principal Investigator and Institution also each certify that he/she/it is not debarred under subsections 306(a) or (b) of the United States Federal Food, Drug, and Cosmetic Act and any applicable law, that there are no applicable regulations or other obligations, that there are no applicable regulations or other obligations that prohibit either party from conducting the Study and entering into this Agreement and that they will not use in any capacity the services of any person debarred under such law with respect to services to be performed under this Agreement. During the term of this Agreement and for three years after its termination, Institution and Principal Investigator will notify CRO promptly if any of these certifications need to be amended in light of new information.

19.2 Investigations, Inquiries, Warnings, or Enforcement Actions Related to Conduct of Clinical Research. Principal Investigator and Institution each certify that he/she/it is not the subject of any past or pending governmental or regulatory investigation, inquiry, warning, or enforcement action (collectively, "**Agency Action**") related to its conduct of clinical research or the practice of medicine that has not been disclosed to CRO or Pfizer. Principal Investigator or Institution will notify CRO promptly if he/she/it receives notice of or becomes the subject of any Agency Action regarding compliance with ethical, scientific, or regulatory standards for the conduct of clinical research or the practice of medicine if the Agency Action relates to events or activities that occurred prior to or during the period in which the Study was conducted.

19.3 Use of Name. CRO and Pfizer reserve the right to identify the Principal Investigator and Institution in association with a listing of the Protocol in the United States National Institutes of Health (NIH) Clinical Trials Data Bank, the Indian Council for Medical Research's Clinical Trial Registry and other publicly available listings of ongoing clinical trials, or other Study Subject recruitment services or mechanisms. Neither CRO nor Pfizer will otherwise use the name of Principal Investigator, Institution, or any of Institution's employees or contractors, and neither Principal Investigator nor Institution will use the name of CRO, Pfizer, or any of their respective employees or contractors, for promotional or advertising purposes without written permission from the party whose name will be used.

19.4 Relationship of the Parties. The relationship of Principal Investigator and Institution to CRO and Pfizer is one of an independent contractor and not one of partnership, agents and principal, employees and employer, joint venture, or otherwise.

19.5 Modification. Any modification to this Agreement shall be in writing, signed by the parties, and identified as an Amendment, except for certain mutually agreeable changes in the Study budget as identified in Attachment A.

19.6 No Waiver. Failure to assert a right under this Agreement does not constitute a waiver of that right in the future. No waiver of any right is effective unless in writing and signed by the party who waives the right.

19.7 Conflict with Attachments. If there is any conflict between this Agreement and any Attachments to it, the terms of this Agreement control. If there is any conflict between this Agreement and the Protocol, the Protocol will control as to any issue regarding treatment of Study Subjects, and the Agreement will control as to all other issues.

19.8 Affiliates. As used in this Agreement, the term "**affiliate**" means any entity that directly or indirectly controls, is controlled by, or is under common control with the named party.

19.9 Successors and Assigns. This Agreement will bind and inure to the benefit of the successors and permitted assigns of each party.

19.10 Third Party Beneficiary. Pfizer is an intended third-party beneficiary to this Agreement and is entitled to enforce directly any and all of its rights under it. If a third party acquires rights in the Pfizer Drug and Pfizer transfers sponsorship of the Study to the third party Pfizer may freely transfer any or all of its rights and obligations under this Agreement to the new sponsor.

19.11 Disclaimer of Warranties by CRO. THE PARTIES ACKNOWLEDGE THAT PFIZER HAS ENGAGED CRO TO PROVIDE SERVICES IN REGARD TO THIS PFIZER-SPONSORED CLINICAL STUDY. CRO HAS NOT

PERFORMED ANY INDEPENDENT RESEARCH OR ANALYSIS REGARDING THE SAFETY OR EFFICACY OF ANY INVESTIGATIONAL NEW DRUG OR OTHER MATERIALS OR TREATMENT PROCEDURES TO BE USED IN THIS STUDY AND THEREFORE CRO MAKES NO WARRANTIES, EXPRESSED OR IMPLIED, CONCERNING THOSE DRUGS, MATERIALS, OR TREATMENT PROCEDURES, THE RESULTS TO BE OBTAINED BY ADMINISTERING THEM PURSUANT TO THE PROTOCOL, OR TO THEIR FITNESS FOR ANY PARTICULAR PURPOSE, OR TO ANY OTHER PFIZER OBLIGATION UNDER THE PROTOCOL OR THIS AGREEMENT.

19.12 Entire Agreement. This Agreement, including Attachments, represents the entire understanding between the parties relating to this subject matter. This Agreement supersedes all previous agreements between the parties (oral and written) relating to this Study, except for any obligations that, by their terms, survive independent of this Agreement.

19.13 Notices. Any notice required to be given hereunder shall be in writing and deemed to have been sufficiently given, (i) when delivered in person, (ii) on the next business day after mailing by overnight courier service, or, where overnight courier service is unavailable, by other expedited delivery provided by a recognized express courier, or (iii) when delivered via e-mail, provided the original is delivered via one of the preceding methods on or prior to the fifth (5th) business day after transmission of the e-mail, to the addresses specified below. Each notice shall specify the name and date of and parties to this Agreement.

CRO:

ICON Clinical Research India Private Limited,
Chennai ONE IT Park, North Block – 4th Floor,
Pallavaram-Thoraipakkam,
200 Feet Road, Thoraipakkam,
Chennai – 600097, Tamil Nadu, India
Attention: John Luke
Dir, Clinical Trial Management
Telephone: 080 - 40394063
Email: john.luke@iconplc.com

Principal Investigator:

Dr. Ashish Ramchandrarao Deshmukh
Mahatma Gandhi Mission (MGM) Medical College & Hospital
N-6, CIDCO, Aurangabad - 431003, Maharashtra, India
Telephone: +919422213292
Email: ashish7557@gmail.com

Institution:

Mahatma Gandhi Mission (MGM) Medical College & Hospital
N-6, CIDCO, Aurangabad - 431003, Maharashtra, India
Attention: Dr. Rajendra Bohra
Dean
Telephone: 0240-6601100
Email: mgmmca@themgmgroup.com

Institute Witness:
Attention: Dr. Deepak Bhosle
Professor & Head, Department of Pharmacology
Telephone: +917770087870
Email: mgmmcha@gmail.com

SMO:

Aurangabad Health Care & Research LLP,
Shop No.126, CTS No.12482/1, Chetan Trade Centre,
Opp. S. F. School, Jalna Road,
Aurangabad - 431001, Maharashtra, India
Attention: Dr. Ujwala Kulkarni
Telephone: +918830049295
Email: druskulkarni@gmail.com

Pfizer:

For Submission of Publications Only:

Dr. Seema Pai (MBBS, MD, PGDCR)
Global Site & Study Operations Clinical Development & Operations
GPD Pfizer Limited
The Capital, 1802 Plot No. C-70, G Block Bandra Kurla Complex,
Bandra (E) Mumbai - 400051, Maharashtra, India
Telephone: +91 2266332442, Mobile: +91-8826422322
Email: seema.pai@pfizer.com

19.14 Counterparts and Signature. This Agreement may be executed in two or more counterparts, each of which will be deemed to be an original, and all of which will together constitute one and the same agreement. The Agreement will be deemed to be fully executed when signed by each of the parties through written signature, Portable Document Format (PDF), validated digital signature, or other reliable electronic means, and delivered to the parties.

20. Anti-Corruption

20.1 Definitions

a. Government. As used in this Agreement, "**Government**" includes all levels and subdivisions of governments (ie, local, regional, and national; administrative, legislative, and executive).

b. Government Official. As used in this Agreement, "**Government Official**" includes (1) any elected or appointed non-US Government official (eg, a legislator or a member of a non-US Government ministry), (2) any employee or individual acting for or on behalf of a non-US Government official, non-US Government agency, or enterprise performing a function of, or owned or controlled by, a non-US Government (eg, a healthcare professional employed by a non-US Government hospital or researcher employed by a non-US Government university), (3) any non-US political party officer, candidate for non-US public office, or employee or individual acting for or on behalf of a non-US political party or candidate for public office, (4) any employee or individual acting for or on behalf of a public international organization, and (5) any member of a royal family or member of a non-US military.

20.2 Anti-Bribery and Anti-Corruption Principles. Principal Investigator, Institution and SMO have each received a copy of Pfizer's International Anti-Bribery and Anti-Corruption Principles as an Attachment to this Agreement. Principal Investigator, Institution and SMO will ensure that they and any of their agents or subcontractors conducting Pfizer work will comply with the Anti-Bribery and Anti-Corruption Principles.

20.3 Warranties. Principal Investigator, Institution and SMO warrant to CRO and Pfizer the following:

a. Any information that Principal Investigator or Institution or SMO provided to CRO or Pfizer as part of CRO's or Pfizer's anti-corruption due-diligence process is complete and accurate.

b. If any response that Principal Investigator or Institution or SMO provided on the CRO or Pfizer due-diligence questionnaire in regard to Principal Investigator or Institutionor SMO, any individuals identified in the questionnaire, or the Family Relatives (as defined in the questionnaire) of those individuals changes during the term of this Agreement. Principal Investigator or Institution or SMO will notify CRO.

c. The funding provided by CRO or Pfizer under this Agreement will not cause Principal Investigator or Institution or SMO to do anything that would result in CRO or Pfizer improperly obtaining or retaining business or gaining any improper business advantage.

d. Principal Investigator, Institution or SMO have not and will not accept any payment or anything of value that would result in CRO or Pfizer improperly

obtaining or retaining business or gaining any improper business advantage.

e. Principal Investigator, Institution or SMO have not and will not in the future directly or indirectly offer or pay, or authorize the offer or payment of, any money or anything of value in an effort to influence any Government Official or any other person.

20.4 Funding Requirements. CRO will make no payment in addition to the funding set out in Attachment A (Study Budget and Payment Terms) in connection with this Agreement unless CRO has prospectively approved that expenditure in writing. All invoices and any supplemental documents that Principal Investigator, Institution and SMO submit to CRO or Pfizer under this Agreement must be truthful and show in reasonable detail what the requested payment is for. Principal Investigator, Institution and SMO will maintain true, accurate, and complete records (eg, invoices, reports, statements, and books) relating to the funding and expenditures for this Study.

20.5 Right to Audit. Pfizer has the right to take all reasonable steps and actions to ensure that each payment made by CRO on behalf of Pfizer is properly and legitimately used. To this end, Principal Investigator, Institution and SMO will permit, during the term of the Agreement and for three years after the final payment has been made under the Agreement, Pfizer's internal and external auditors access to any relevant books, documents, papers, and records of the Principal Investigator, Institution and SMO involving transactions related to the Agreement. Because this Agreement relates to a clinical study, there will be acceptable safeguards employed in such an audit to ensure confidentiality and protect the privacy of the Study Subjects.

20.6 Failure to Comply. If CRO or Pfizer terminates the Study or this Agreement because of Principal Investigator's or Institution's or SMO's breach of any of the provisions in this Anti-Corruption section, Principal Investigator, Institution and SMO will be liable to Pfizer for damages or remedies as provided by law. Further, Principal Investigator, Institution and SMO will indemnify CRO and Pfizer against any third-party claim, fine, or penalty against CRO or Pfizer that results from such a breach by Principal Investigator or Institution or SMO.

Agreed to and Accepted by:

ICON Clinical Research India Private Limited

John Luke
Printed Name
Dir. Clinical Trial Management, Clinical Project Mg
Title
Date: 17/Jun/2022

Dr. Ashish Ramchandrarao Deshmukh

Principal Investigator
Title 22 Jun 2022

Date:

Dr. A. R. Deshmukh
M.D. D.N.B.
Professor & HOD
Dept. of DVL
M Medical College & Hosp.A'bad.
Reg. No.85220

Mahatma Gandhi Mission (MGM) Medical College & Hospital

Dr. Rajendra Bohra
Printed Name
Dean
Title
Date: 22/6/2022

DEAN
MGM'S MEDICAL COLLEGE
AURANGABAD

Institute Witness:

Dr. Deepak Bhosle
Printed Name
Professor & Head, Dept. of Pharmacology
Title
Date: 22/6/22

Professor & H.O.D.
Department of Pharmacology
MGM's Medical College
Aurangabad.

Aurangabad Health Care & Research LLP (SMO)

Dr. Ujwala Kulkarni
Printed Name
Director
Title
Date: 22 Jun 2022

Aurangabad Health Care & Research LLP
Shop No. 126, CTS No. 1248211, Chetan
Trade Centre Opp. S.F. School, Jalna Road,
Aurangabad MH India.

Attachments

Attachment A	Study Budget and Payment Terms
Attachment B	Indemnification and Research Injury Policy
Attachment C	Equipment and Materials
Attachment D	Pfizer International Anti-Bribery and Anti-Corruption Principles

Attachment A
Study Budget and Payment Terms
Pfizer Protocol # B7451094

1. **Payee Name and Address**: Payment of the sums due under this Agreement will be made payable to:

PI Name:	Dr. Ashish Ramchandrarao Deshmukh
Pfizer assigned Site ID:	1012
Payee:	Aurangabad Health Care & Research LLP

The SMO must provide CRO, in writing, full payment instructions for the payee listed above, including completion of applicable payment processing forms, before any payments can be made under the Agreement. The SMO is obligated to inform CRO, in writing, of any changes or required updates of payment instructions and/or bank details.

No other payments will be made to the SMO until the following are completed: (1) execution of the Agreement, (2) submission of all regulatory documents to CRO, and (3) IRB approval.

If the Agreement is terminated before all payments are earned, the remainder must be returned to CRO immediately in accordance with **Section 13 (Refunds)** below. If SMO fails to do so, Pfizer, in its sole discretion, may apply such unearned sums to payments otherwise due in connection with SMO participation in another Pfizer study or may pursue other available remedies.

2. **Per Subject Cost**: The Per-Subject Cost as defined in Exhibit 1 is based upon completion of all visits and procedures in accordance with the Study specifications set forth in the Protocol. Payments will be calculated based on Study Data entered into EDC system and will be paid as long as the site is in compliance with the Protocol and the terms of the Agreement including the submission of an invoice where required. CRO will make payments on a quarterly basis within forty-five (45) days of completion of each activity period based upon the services completed during the previous three (3) months. The initial activity period will begin on the first day of the month in which the first patient is screened.

3. **Additional TreatmentRelated Costs:** In addition to the Per-Subject Costs, CRO will pay SMO for the other Additional Treatment Related Costs as set forth in Exhibit 1. SMO shall submit requests for payment for Additional Treatment Related Costs in accordance with **Section 12 (Invoices & Payments)**, including submission of any back-up documentation or receipts for pass-through expenses. Any costs designated as invoiceable in Exhibit 1 should be invoiced at the visits or time points specified therein and not submitted to third party insurance payors.

4. **Other Study-Level Costs:** In addition to costs covered in the other two sections of Exhibit 1, CRO will pay SMO for the other Study-Level Costs as set forth in Exhibit 1. SMO shall submit requests for payment for other Study-Level Costs in accordance with **Section 12 (Invoices & Payments)**, including submission of any back-up documentation or receipts for pass-through expenses. Any non-procedural pass-through expenses will be paid only in the amount actually incurred, up to the maximum amounts shown in Exhibit 1, with no mark-up in cost. Any costs designated as invoiceable in Exhibit 1 should be submitted for payment or invoiced, where applicable, at the visits or time points specified therein and not submitted to third party insurance payors.

5. **Final Payment:** The final payment will be paid upon final review and acceptance of all Study Data for Study Subjects by CRO, completion of all required administrative matters by the Principal Investigator and/or Institution, including, but not limited to, resolution of all outstanding queries, and the return of any Pfizer/CRO or Vendor-provided Equipment requested by Pfizer.

6. **No Payment**. SMO will not be paid for any Study Subjects whose enrollment in the Study deviates from the Protocol's eligibility criteria or from whom Study Data cannot be analyzed because of Protocol deviations, lack of proper records or incomplete, uncorrected or unverifiable CRFs.

7. **Investigational Drug:** Per Section 8 of this Agreement, CRO will provide the Pfizer Drug. The following additional Protocol-required drugs will be provided at no charge or Pfizer will cover the costs of as indicated below:
    - None

8. **Standard of Care:** Compensation for all Protocol-required activities to be performed by SMO is included in the budget as documented in Exhibit 1.

9. **Screen Failures:** A "Screen Failure" is a consented subject who fails to meet the screening visit criteria and is thus not eligible for enrollment into the Study. Screen Failures will be reimbursed as outlined in Exhibit 1. To receive payment for Screen Failures, the Screening CRFs must be completed. SMO shall request payment for each Screen Failure in accordance with **Section 12 (Invoices & Payments)**, specifying the candidate's screening number (or other unique identifier) and the date of the Screen Failure.

10. **Patient Travel Expenses:** CRO will reimburse reasonable travel expenses per patient visit during the Study at the rate set out in the Budget (Exhibit 1). Travel reimbursement will be issued directly by SMO to the Study Subjects.

11. **Additional Testing, Treatment or Procedures**: The Parties agree that the Exhibit 1 includes all Trial-related costs, as referenced in the Protocol. SMO will not be reimbursed for any additional testing, treatment, or procedures not required by the Protocol or specified in the Agreement or this Attachment A, unless such additional testing, treatment or procedures are pre-approved by Pfizer or CRO.

12. Invoices & Payments:

CRO will make payments within forty-five (45) days of receipt and approval of invoice.

For any costs not in Exhibit 1, requests for payment or reimbursement or invoices must not be submitted by SMO until a contract amendment or a budget modification letter has been executed.

To expedite payment, such invoices can be accompanied by a copy of the amendment.

Invoices must be in the name of ICON Clinical Research India Private Limited and submitted in English. Where hard copy invoices are required they should be submitted and addressed to:

ICON Clinical Research India Private Limited,
Chennai ONE IT Park, North Block – 4th Floor,
Pallavaram-Thoraipakkam,
200 Feet Road, Thoraipakkam,
Chennai – 600097, Tamil Nadu, India

Invoices will be submitted to:**IPG-PSBUpayments@iconplc.com**

The following information shall be provided when submitting an invoice:

- Invoice number
- Invoice date
- Invoice amount
- Date and description of service provided as described in Exhibit 1
- Principal Investigator Name
- Institution/Center or Site Name and Address
- Pfizer assigned Site Id (as listed above)
- Protocol Identifier or Number
- Tax/VAT Registration Number
- Any Tax/VAT charge, relevant Tax/VAT percentage or indication of a 'reverse charge' as appropriate
- CRO Project Number
- CRO Address (listed above)

In the following limited circumstances Goods & Service Tax (GST) shall be added to any sums stated in this Attachment A:

where GST arises in accordance with GST legislation and the same is correctly charged in the invoice raised;

where the SMO has listed its/his/her GST number below;

where the SMO submits a valid invoice duly signed by the Authorized Signatory containing all particulars including but not limited to disclosing the following details:

1. Complete bill from address (Site's)
2. Complete bill to address (ICON's)
3. Invoice Date
4. Invoice Number (Unique)
5. Principal Investigator Name
6. Institution Name
7. Protocol Number/CRO Study Number (as shown above)
8. Nature of Services provided
9. PAN of the Supplier / Site / Investigator
10. GST Registration number of Supplier / Site / Investigator
11. GST Registration number of ICON Clinical Research India Private Limited
12. Appropriate SAC/HSN Codes of product/services being provided
13. 0% IGST - (subject to LUT, since ICON Chennai office is an SEZ unit)
14. IGST Rate % - (if not eligible for LUT for zero rate IGST)
15. IGST amount - (if not eligible for LUT for zero rate IGST)
16. If site is unregistered with GST, a confirmation (email /letter) required on the same stating the clause under which they have not registered with GST
17. Bank Details
    a.) Beneficiary name as per bank
    b.) Account number
    c.) IFSC (11 digit)
    d.) Bank Name
    e.) Branch
18. Email ID of the Site / Supplier for sharing the remittance advice, TDS certificates etc.

All other taxes are included in the sums stated in this Attachment A.

SMO GST Number: 27ABRFA2186R1ZJ

Failure to include required information on all requests for payment or reimbursement or invoices will result in delayed payment.

13. **Refunds**: To confirm process for return of refunds, SMO shall contact CRO at ICON Clinical Research India Private Limited, Chennai ONE IT Park, North Block – 4th Floor, Pallavaram-Thoraipakkam, 200 Feet Road, Thoraipakkam, Chennai – 600097, Tamil Nadu, India or at such other contact as may be communicated from time to time.

14. **Amendments**: The following Study budget changes may be documented by a modification letter signed by Pfizer or its authorized agent: (1) increases in the total Study budget, with or without modification of the payment schedule, or (2) modification of the payment schedule with no change in total Study budget.

15. **Inquiries**: All inquiries regarding the reasons for any denial of, or failure to approve, a request for payment or reimbursement or invoice must be directed to the CRO PM for B7451094 at ICON Clinical Research India Private Limited, Chennai ONE IT Park, North Block – 4th Floor, Pallavaram – Thoraipakkam, 200 Feet Road, Thoraipakkam, Chennai – 600097, Tamil Nadu, India or such other contact as may be communicated to Institution from time to time.

16. **Research Injury Treatment**: Pursuant to the Indemnification and Research Injury policy, SMO will promptly notify CRO of any Research Injury. Institution will submit all invoices for Research Injury treatment in accordance with **Section 12 (Invoices & Payments)** above.

    Invoices for Research Injury treatments must be separate from invoices submitted for any other protocol required treatments or services and be clearly identified as being for a Research Injury treatment. The following information shall be provided when submitting the invoice:

    - Invoice number
    - Invoice date
    - Invoice amount associated with each AE/SAE
    - Principal Investigator Name
    - Institution/Center or Site Name and Address
    - Protocol Identifier or Number
    - Subproject Number (if Pfizer supplied)
    - Subject Identifier (i.e. as reported on the CRF)
    - Date of AE/SAE Onset (i.e. as reported on the CRF)
    - AE/SAE treatment(s) associated with each AE/SAE
    - Date of treatment(s)
    - AE/SAE end date (if not ongoing at the time of invoicing and if consistent with the CRF)
    - AE/SAE event term

    AE/SAE term(s) and treatment(s) specified in the invoice must match Study Data reported on Case Report Forms and AE/SAE forms to avoid delay in payment.

Exhibit 1 to Attachment A
STUDY BUDGET

COMPOUND :	**PF-04965842**	**AMENDMENT :**	**PA1**	**INVESTIGATOR:**	**Dr. Ashish Ramchandrarao Deshmukh**
STUDY NUMBER :	**B7451094**	**ARM/COHORT :**		**INSTITUTION:**	**Mahatma Gandhi Mission (MGM) Medical College & Hospital**
TITLE :	**A RANDOMIZED, OPEN-LABEL, PARALLEL-GROUP STUDY TO EVALUATE THE SAFETY AND EFFICACY OF ABROCITINIB 100 MG AND 200 MG TABLETS IN PARTICIPANTS AGED 12 YEARS AND OLDER WITH MODERATE TO SEVERE ATOPIC DERMATITIS IN INDIA**			**CCID:**	1012
COUNTRY/Currency :	India - INR				
OVERHEAD	30.00%				

	DESCRIPTION OF COST	Comments		Frequency of Procedure		VISIT 1		VISIT 2		VISIT 3		VISIT 4		VISIT 5	
			COST	Total Number of times a procedure occurs based on PSC Structure	Total PSC	f	Day -28 Screening	f	Day 1 Baseline	f	Week 2	f	Week 4	f	Week 8
Per Subject Cost	Informed Consent		1,465.00	1.0	1465	1.00	1,465.00		0.00		0.00		0.00		0.00
	Medical History	includes Demographics	3,164.00	1.0	3164	1.00	3,164.00		0.00		0.00		0.00		0.00
	Complete Physical Examination		4,716.00	3.0	14148	1.00	4,716.00		0.00		0.00		0.00		0.00
	Brief Physical Examination		1,994.00	1.0	1994		0.00	1.00	1,994.00		0.00		0.00		0.00
	Vital Signs	includes Height & Weight if applicable	1,038.00	11.0	11418	1.00	1,038.00	1.00	1,038.00	1.00	1,038.00	1.00	1,038.00	1.00	1,038.00
	ECG		1,000.00	3.0	3000	1.00	1,000.00		0.00		0.00		0.00		0.00
	Hematology	hemoglobin, WBC, neutrophils (%, absolute), lymphocytes (%, absolute)	653.00	6.0	3918	1.00	653.00		0.00		0.00	1.00	653.00		0.00
	Clinical Chemistry	urea, sCr, sCysC (at Screening only), estimated creatinine clearance, AST, ALT, TBili, alkaline phosphatase	1,928.00	6.0	11568	1.00	1,928.00		0.00		0.00	1.00	1,928.00		0.00
	Coagulation Panel	APTT, PT/INR	1,867.00	6.0	11202	1.00	1,867.00		0.00		0.00	1.00	1,867.00		0.00
	Lipid Profile	total cholesterol, LDL, VLDL, HDL, and triglycerides	2,696.00	6.0	16176	1.00	2,696.00		0.00		0.00	1.00	2,696.00		0.00
	HIV, HBsAg, HCV		2,676.00	1.0	2676	1.00	2,676.00		0.00		0.00		0.00		0.00
	IGA		1,000.00	6.0	6000	1.00	1,000.00	1.00	1,000.00	1.00	1,000.00	1.00	1,000.00	1.00	1,000.00
	EASI		920.00	6.0	5520	1.00	920.00	1.00	920.00	1.00	920.00	1.00	920.00	1.00	920.00
	SCORAD		700.00	6.0	4200	1.00	700.00	1.00	700.00	1.00	700.00	1.00	700.00	1.00	700.00
	Photography for AD lesion		1,000.00	5.0	5000		0.00	1.00	1,000.00		0.00		0.00		0.00
	PROs	includes POEM, ADCT, PP-NRS, HSS Pedi-FABS (1 month recall); HSS Pedi-FABS (1 year recall) as applicable	1,750.00	8.0	14000	1.00	1,750.00	1.00	1,750.00	1.00	1,750.00	1.00	1,750.00	1.00	1,750.00
	Dispense Investigational Product	oral	800.00	6.0	4800		0.00	1.00	800.00	1.00	800.00	1.00	800.00	1.00	800.00
	C-SSRS		2,196.00	7.0	15372	1.00	2,196.00	1.00	2,196.00	1.00	2,196.00	1.00	2,196.00	1.00	2,196.00
	Study Coordinator Fee (hourly rate)	includes Inclusion/Exclusion Criteria, estimated creatinine clearance, Randomization, Investigational Product Accountability; Contraception Check, AEs, SAEs and Concomitant Medication Monitoring, support for monitoring visits (remote / on-site), scheduling/patient outreach, and facilities scheduling	2,854.00	30.6	87332.4	3.35	9,560.90	3.45	9,846.30	3.20	9,132.80	3.20	9,132.80	3.20	9,132.80
	DE/Admin Fee (hourly rate)		1,756.00	12.0	21072	2.00	3,512.00	1.00	1,756.00	1.00	1,756.00	1.00	1,756.00	1.00	1,756.00
			PSC Subtotal w/out Overhead		244,025.40		40,841.90		23,000.30		19,292.80		26,436.80		19,292.80
			PSC Subtotal with Overhead		317,233.02		53,094.47		29,900.39		25,080.64		34,367.84		25,080.64

	DESCRIPTION OF COST	Comments		Frequency of Procedure		VISIT 6		VISIT 7		VISIT 8		VISIT 9		VISIT 10		VISIT 11
			COST	Total Number of times a procedure occurs based on PSC Structure	Total PSC	f	Week 12 (Main Study EOT)	f	EOS, 4 weeks post EOT (Main Study Participants only)	f	Week 24 (Substudy Participants Only)	f	Week 36 (Substudy Participants Only)	f	Early Termination /End of Treatment Visit (Substudy Participants Only)	f	Follow-up Visit (Substudy Participants only)
Per Subject Cost	Informed Consent		1,465.00	1.0	1465		0.00		0.00		0.00		0.00		0.00		0.00
	Medical History	includes Demographics	3,164.00	1.0	3164		0.00		0.00		0.00		0.00		0.00		0.00
	Complete Physical Examination		4,716.00	3.0	14148	1.00	4,716.00		0.00		0.00		0.00	1.00	4,716.00		0.00
	Brief Physical Examination		1,994.00	1.0	1994		0.00		0.00		0.00		0.00		0.00		0.00
	Vital Signs	includes Height & Weight if applicable	1,038.00	11.0	11418	1.00	1,038.00	1.00	1,038.00	1.00	1,038.00	1.00	1,038.00	1.00	1,038.00	1.00	1,038.00
	ECG		1,000.00	3.0	3000	1.00	1,000.00		0.00		0.00		0.00	1.00	1,000.00		0.00
	Hematology	hemoglobin, WBC, neutrophils (%, absolute), lymphocytes (%, absolute)	653.00	6.0	3918	1.00	653.00		0.00	1.00	653.00	1.00	653.00	1.00	653.00		0.00
	Clinical Chemistry	urea, sCr, sCysC (at Screening only), estimated creatinine clearance, AST, ALT, TBili, alkaline phosphatase	1,928.00	6.0	11568	1.00	1,928.00		0.00	1.00	1,928.00	1.00	1,928.00	1.00	1,928.00		0.00
	Coagulation Panel	APTT, PT/INR	1,867.00	6.0	11202	1.00	1,867.00		0.00	1.00	1,867.00	1.00	1,867.00	1.00	1,867.00		0.00
	Lipid Profile	total cholesterol, LDL, VLDL, HDL, and triglycerides	2,696.00	6.0	16176	1.00	2,696.00		0.00	1.00	2,696.00	1.00	2,696.00	1.00	2,696.00		0.00
	HIV, HBsAg, HCV		2,676.00	1.0	2676		0.00		0.00		0.00		0.00		0.00		0.00
	IGA		1,000.00	6.0	6000	1.00	1,000.00		0.00		0.00		0.00		0.00		0.00
	EASI		920.00	6.0	5520	1.00	920.00		0.00		0.00		0.00		0.00		0.00
	SCORAD		700.00	6.0	4200	1.00	700.00		0.00		0.00		0.00		0.00		0.00
	Photography for AD lesion		1,000.00	5.0	5000	1.00	1,000.00	1.00	1,000.00		0.00		0.00	1.00	1,000.00	1.00	1,000.00
	PROs	includes POEM, ADCT, PP-NRS, HSS Pedi-FABS (1 month recall); HSS Pedi-FABS (1 year recall) as applicable	1,750.00	8.0	14000	1.00	1,750.00		0.00		0.00		0.00	1.00	1,750.00	1.00	1,750.00
	Dispense Investigational Product	oral	800.00	6.0	4800		0.00		0.00	1.00	800.00	1.00	800.00		0.00		0.00
	C-SSRS		2,196.00	7.0	15372	1.00	2,196.00	1.00	2,196.00		0.00		0.00		0.00		0.00
	Study Coordinator Fee (hourly rate)	includes Inclusion/Exclusion Criteria, estimated creatinine clearance, Randomization, Investigational Product Accountability; Contraception Check, AEs, SAEs and Concomitant Medication Monitoring, support for monitoring visits (remote / on-site), scheduling/patient outreach, and facilities scheduling	2,854.00	30.6	87332.4	3.20	9,132.80	2.10	5,993.40	2.30	6,564.20	2.30	6,564.20	2.20	6,278.80	2.10	5,993.40
	DE/Admin Fee (hourly rate)		1,756.00	12.0	21072	1.00	1,756.00	1.00	1,756.00	1.00	1,756.00	1.00	1,756.00	1.00	1,756.00	1.00	1,756.00
			PSC Subtotal w/out Overhead		244,025.40		32,352.80		11,983.40		17,302.20		17,302.20		24,682.80		11,537.40
			PSC Subtotal with Overhead		317,233.02		42,058.64		15,578.42		22,492.86		22,492.86		32,087.64		14,998.62

	Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	Day -28 Screening	f	Day 1 Baseline	f	Week 2	f	Week 4	f	Week 8
Additional Treatment Related Costs TO BE INVOICED	TB test - Quantiferon	if applicable per site standards	2,097.00	1.0	2097	1.00	2,097.00		0.00		0.00		0.00		0.00
	TB test - Mantoux	if applicable per site standards	542.00	1.0	542	1.00	542.00		0.00		0.00		0.00		0.00
	Serum Pregnancy test	WOCBP	2,210.00	1.0	2210	1.00	2,210.00		0.00		0.00		0.00		0.00
	Urine Pregnancy test	WOCBP	1,255.00	10.0	12550		0.00	1.00	1,255.00	1.00	1,255.00	1.00	1,255.00	1.00	1,255.00
	Chest X-ray - includes interpretation and report	if performed at Screening	2,674.00	1.0	2674	1.00	2,674.00		0.00		0.00		0.00		0.00
	CT Chest - includes interpretation and report	if performed at Screening	10,000.00	1.0	10000	1.00	10,000.00		0.00		0.00		0.00		0.00
	MRI Chest - includes interpretation and report	if performed at Screening	10,000.00	1.0	10000	1.00	10,000.00		0.00		0.00		0.00		0.00
	Participant Assent	Substudy Participants only	1,033.00	1.0	1033	1.00	1,033.00		0.00		0.00		0.00		0.00
	Knee MRI - includes interpretation and report	Substudy Participants only per protocol	20,000.00	2.0	40000	1.00	20,000.00		0.00		0.00		0.00		0.00
	Additional Study Coordinator Fee - Substudy	Assess knees of participant for relevant history; Monitor if any discontinuation criteria for substudy have been met or not; Applicable from Screening through Week 12	2,854.00	2.0	5708	0.75	2,140.50	0.25	713.50	0.25	713.50	0.25	713.50	0.25	713.50
	DE/Admin Fee - Substudy	Substudy PRO data entry HSS Pedi-FABS (1 month recall); HSS Pedi-FABS (1 year recall)	1,756.00	1.0	1756	0.50	878.00	0.50	878.00		0.00		0.00		0.00
	Dispense Investigational Product - Week 12	Substudy participants only	800.00	1.0	800		0.00		0.00		0.00		0.00		0.00
Summary Costs	Per Subject Cost Subtotal				244,025.40		40,841.90		23,000.30		19,292.80		26,436.80		19,292.80
	Additional Cost Subtotal				89,370.00		51,574.50		2,846.50		1,968.50		1,968.50		1,966.50
	Subtotal				333,395.40		92,416.40		25,846.80		21,261.30		28,405.30		21,261.30
	Overhead				100,018.62		27,724.92		7,754.04		6,378.39		8,521.59		6,378.39
	INVESTIGATOR COST PER SUBJECT with Overhead				**433,414.02**		**120,141.32**		**33,600.84**		**27,639.69**		**36,926.89**		**27,639.69**

	Additional Procedures that may not apply to all Patients		COST	Total Number of times a procedure may occur	Total Potential PSC	f	Week 12 (Main Study EOT)	f	EOS, 4 weeks post EOT (Main Study Participants only)	f	Week 24 (Substudy Participants Only)	f	Week 36 (Substudy Participants Only)	f	Early Termination /End of Treatment Visit (Substudy Participants Only)	f	Follow-up Visit (Substudy Participants only)
Additional Treatment Related Costs																	
	TB test - Quantiferon	if applicable per site standards	2,097.00	1.0	2097		0.00		0.00		0.00		0.00		0.00		0.00
	TB test - Mantoux	if applicable per site standards	542.00	1.0	542		0.00		0.00		0.00		0.00		0.00		0.00
TO BE INVOICED	Serum Pregnancy test	WOCBP	2,210.00	1.0	2210		0.00		0.00		0.00		0.00		0.00		0.00
	Urine Pregnancy test	WOCBP	1,255.00	10.0	12550	1.00	1,255.00	1.00	1,255.00	1.00	1,255.00	1.00	1,255.00	1.00	1,255.00	1.00	1,255.00
	Chest X-ray - includes interpretation and report	if performed at Screening	2,674.00	1.0	2674		0.00		0.00		0.00		0.00		0.00		0.00
	CT Chest - includes interpretation and report	if performed at Screening	10,000.00	1.0	10000		0.00		0.00		0.00		0.00		0.00		0.00
	MRI Chest - includes interpretation and report	if performed at Screening	10,000.00	1.0	10000		0.00		0.00		0.00		0.00		0.00		0.00
	Participant Assent	Substudy Participants only	1,033.00	1.0	1033		0.00		0.00		0.00		0.00		0.00		0.00
	Knee MRI - includes interpretation and report	Substudy Participants only per protocol	20,000.00	2.0	40000		0.00		0.00		0.00		0.00	1.00	20,000.00		0.00
	Additional Study Coordinator Fee - Substudy	Assess knees of participant for relevant history. Monitor if any discontinuation criteria for substudy have been met or not. Applicable from Screening through Week 12	2,854.00	2.0	5708	0.25	713.50		0.00		0.00		0.00		0.00		0.00
	DE/Admin Fee - Substudy	Substudy PRO data entry HSS Pedi-FABS (1 month recall); HSS Pedi-FABS (1 year recall)	1,756.00	1.0	1756		0.00		0.00		0.00		0.00		0.00		0.00
	Dispense Investigational Product - Week 12	Substudy participants only	800.00	1.0	800	1.00	800.00		0.00		0.00		0.00		0.00		0.00
Summary Costs	**Per Subject Cost Subtotal**				244,025.40		32,352.80		11,983.40		17,302.70		17,302.20		24,682.80		11,537.40
	Additional Cost Subtotal				89,370.00		2,768.50		1,255.00		1,255.00		1,255.00		21,255.00		1,255.00
	Subtotal				333,395.40		35,121.30		13,238.40		18,557.20		18,557.20		45,937.80		12,792.40
	Overhead				100,018.62		10,536.39		3,971.52		5,567.16		5,567.16		13,781.34		3,837.72
	INVESTIGATOR COST PER SUBJECT with Overhead				**433,414.02**		**45,657.69**		**17,209.92**		**24,124.36**		**24,124.36**		**59,719.14**		**16,630.12**

Other Study Level Costs	Additional Procedures Not included in the Per Subject Cost (Procedures not tied to a specific visit) - All Fees Inclusive of Overhead		
	Procedure	**Comments**	**Cost**
	Local IRB/EC Fees - Initial Review (10% TDS included)	To be invoiced one time fee	83,333.00
	Local IRB/EC Fees - Amendment (10% TDS included)	To be invoiced as incurred	33,333.00
	Record Archiving	one time fee at closeout Budget 1 for 100% of sites	200,000.00
	Screen Fails	Applicable to subjects who SF at Visit 1. Cost reflects V1 with 25% reduction, no overhead paid. **Max 3 SFs per site**	30,631.43
	Brief Physical Examination - unscheduled visit	As clinically indicated; Invoice as incurred	2,592.20
	Vital Signs - repeat or for unscheduled visit	As clinically indicated; Invoice as incurred	1,349.40
	ECG - repeat or for unscheduled visit	As clinically indicated; Invoice as incurred	1,300.00
	Hematology - repeat or for unscheduled visit	As clinically indicated; Invoice as incurred	848.90
	Clinical Chemistry - repeat or for unscheduled visit	As clinically indicated; Invoice as incurred	2,506.40
	Coagulation Panel - repeat or for unscheduled visit	As clinically indicated; Invoice as incurred	2,427.10
	Lipid Profile - repeat or for unscheduled visit	As clinically indicated; Invoice as incurred	3,504.80
	Urinalysis	As clinically indicated; Invoice as incurred	635.70
	Study Coordinator Fee (hourly rate) - unscheduled visit	As clinically indicated; Invoice as incurred	3,710.20
	DE/Admin Fee (hourly rate) - unscheduled visit	As clinically indicated; Invoice as incurred	2,282.80
	TB test - Quantiferon - repeat or for unscheduled visit	As clinically indicated; Invoice as incurred	2,726.10
	TB test - Mantoux - repeat or for unscheduled visit	As clinically indicated; Invoice as incurred	704.60
	Knee MRI - includes interpretation and report - unscheduled visit	As clinically indicated; Invoice as incurred	26,000.00
	Serum Pregnancy test - repeat or for unscheduled visit	As clinically indicated; Invoice as incurred	2,873.00
	Urine Pregnancy test - repeat or for unscheduled visit	As clinically indicated; Invoice as incurred	1,631.50
	Subject Travel Reimbursement- Site	To be invoiced as incurred; Receipts required	1,000.00
	Continuous ECG Monitoring	As clinically indicated; Invoice as incurred	4,106.70
	Cardiac Consultation	If clinically indicated; includes Cardiologist one hour; Invoice as incurred	5,100.00

Exhibit 2 to Attachment A

ICON
A Symbol of Excellence

Beneficiary Details Form
India OU India

Protocol Number	B7451094	**ICON Study No.**	9002/0888	**Site No.**	1012
Therapeutic Area	Dermatology				

Payee Information

Payee Full Name	Aurangabad Health Care & Research LLP
Payee Description (tick)	Institution / Principal Inv / Sub-Inv / X Other: SMO
GST applicable	X Yes / No / Reason
VAT/ GST Registration No.	2 7 A B R F A 2 1 8 6 R 1 Z J (10 digits)

Payee Address and Contact Details

Street	Shop no.126, CTS no.12482/1, Chetan Trade Centre,		
City	AURANGABAD	**Post Code**	431001
Country	INDIA	**State/Province**	MAHARASHTRA
***Remittance email address**	ahrllp20@gmail.com	**Phone # (code)**	8830049295
****PPF/ SOW Email Address 1**	druskulkarni@gmail com		
****PPF/ SOW Email Address 2**	drrenuka.ahr@gmail.com		
****PPF/ SOW Email Address 3**			
****PPF/ SOW Email Address 4**			
***** Finance Representative** *(full name and email address)*	Dr.Ujwala Kulkarni, druskulkarni@gmail.com	**Phone # (code)**	8830049295
Principal Investigator First Name	Dr. Ashish	**Middle name** Ramchandrarao	**Last name** Deshmukh
Degree	MBBS,MD(Skin & VD),DNB	**Primary Specialty**	Dermatologist

**Payment notification relating to payments will be electronically sent to the remittance email address above.*
***PPF/SOWs will be electronically sent to the PPF/SOW email addresses (1-4) above. PPF/SOW can be to sent up to 4 email addresses.*
It is mandatory to provide remittance email address and at least one PPF/SOW email address.
**** Person or Department to review/discuss Finance issues.*

Beneficiary Account Details

Bank Account Holder (Name)	Aurangabad Health Care & Research LLP		
Bank Account Number	5 0 5 1 6 3 7 0 5 2 1 (mandatory) min 9 to 16 digits		
PAN Number	A B R F A 2 1 8 6 R (mandatory) 10 digits		
IFSC Code	I D I B 0 0 0 A 6 7 8 (mandatory) 11 digits		
Bank Name	INDIAN BANK	**Currency of Payment: INR**	
Branch Name	AURANGABAD,JALNA ROAD BRANCH		
Bank Address	Chetan Trade centre,Opp.SF School,	mandatory	
Street	Jalna road		
City	Aurangabad	**Post Code**	431001
Country	India	**State/Province**	Maharashtra

ICON's standard payment method is 'electronic/ wire' unless bank account is not compatible.
Payee must be the owner of the bank account listed below. Above information is required for payments. Incomplete information may delay payments.

I, the undersigned beneficiary/I, the signatory on the behalf of the beneficiary, hereby declare that the information provided in this Beneficiary Details Form is both true and correct. I, the undersigned beneficiary/I, the signatory on the behalf of the beneficiary acknowledge that the information I have provided herein: (i) may constitute personal data, and (ii) serves to enable ICON to make payment/s to me/to the beneficiary on behalf of the Study Sponsor in accordance with the Clinical Study Agreement(s) for the Study or Studies which I/the beneficiary participate(s) in as a Clinical Investigator/Institution or member of the study team - each subsequent Study being subject to the execution of a Clinical Study Agreement. I, the undersigned beneficiary/I, the signatory on the behalf of the beneficiary acknowledge that the processing of this data is necessary for the performance of such Clinical Study Agreement(s) and undertake to promptly inform ICON of any changes to the information stated in the Beneficiary Details Form.
Furthermore, I, the undersigned beneficiary/I, the signatory on the behalf of the beneficiary agree that ICON and SPONSOR may disclose for any lawful purpose, within their sole discretion, the terms of this Agreement, including without limitation, the total compensation (including fees and expenses) payable or paid pursuant to this Agreement. I, the undersigned beneficiary/I, the signatory on the behalf of the beneficiary consent to the processing of my/beneficiary personal data by the Sponsor, ICON and/or its affiliates for the above mentioned purposes and grant my consent for the transfer of my/beneficiary personal data to ICON and/or its affiliates, Sponsor(s), regulatory authorities, auditors and study related personnel. I, the undersigned beneficiary/I, the signatory on the behalf of the beneficiary understand and agree that for the purposes described above my/beneficiary personal information may be transfer to third countries (such as the United States) which may not provide the same level of personal data protection. ICON will take all reasonable security precautions to protect your/beneficiary personal data against all unlawful forms of processing.

I, the undersigned beneficiary/I, the signatory on the behalf of the beneficiary will notify ICON immediately of any changes to the above beneficiary details.

Payee Signature ______________________ **Date** ______________

Payee Name *(Print)* Aurangabad Health Care & Research LLP

Attachment B
INDEMNIFICATION AND RESEARCH INJURY POLICY

Pfizer has authorized CRO to bind Pfizer to the commitments in the policy described below.

Pfizer agrees to indemnify, defend or cover costs of defense for, and hold harmless ("**Indemnify**") the Study investigators; any institution at which Study activities are conducted, its officers, agents, and employees; and the IRB/IEC that approved the Study (collectively, "**Indemnified Parties**") against any demand or claim for damages ("**Claim**") arising out of a Research Injury, the design of the Study, the specifications of the Study Protocol, or Pfizer's use of Study Data.

Excluded from this Agreement to Indemnify are any Claims to the extent resulting from

(a) failure by any Indemnified Party to comply with the Protocol *

(b) failure of any Indemnified Party to comply with any applicable law, the Rules or any governmental regulations, or

(c) negligence or willful misconduct by any Indemnified Party.

Pfizer, through CRO, further agrees to reimburse Institution for the actual cost of diagnostic procedures and medical treatment necessary to treat a Research Injury. Institution agrees to directly pay the providers of all such services, whether or not the provider is affiliated with the Institution. Institution acknowledges that neither Pfizer nor CRO will directly interface with or make payments to providers or Study Subjects in connection with treatment or procedures necessary to treat a Research Injury.

Research Injury. For purposes of this Indemnification and Research Injury Policy, the term "**Research Injury**" means adverse event, physical injury, or illness caused by treatment or procedures required by the Protocol that the Study Subject would not have received if the Study Subject had not participated in the Study. Principal Investigator and Institution agree to provide or arrange for prompt diagnosis and medical treatment of any Research Injury experienced by a Study Subject. Principal Investigator further agrees to promptly notify CRO of any Research Injury.

Notice and Cooperation. Principal Investigator and Institution agree to provide CRO with prompt notice of, and Pfizer with full cooperation in handling and resolving, any Claim that is subject to Indemnification. However, failure to provide timely notice will not relieve Pfizer of its obligation to Indemnify except to the extent that Pfizer is prejudiced by the delay. Such cooperation will include assisting Pfizer in the management of a Claim until it is fully resolved, which may entail Pfizer requesting and reviewing medical bills and records related to a Research Injury. If so requested by Pfizer, Principal Investigator and Institution agree to authorize Pfizer to carry out the sole management of defense of an Indemnified Claim.

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* Slight deviations that do not contribute to the injury or jeopardize the validity of the Study will not be considered a failure to adhere to the Protocol.

Settlement or Compromise. No settlement or compromise of a Claim subject to Indemnification will be binding on Pfizer without Pfizer's prior written consent. Pfizer will not unreasonably withhold such consent of a settlement or compromise. No party will admit fault on behalf of any other party or enter into a non-monetary settlement that places future obligations on another party without the written approval of the affected party.

Attachment C
EQUIPMENT AND MATERIALS

CRO/Pfizer-Provided Equipment and Materials

CRO/Pfizer-Provided Equipment

CRO or Pfizer will provide the equipment identified below ("**CRO Equipment**") for use by Principal Investigator or Institution in the conduct or reporting of the Study: NONE

CRO/Pfizer-Provided Materials

CRO or Pfizer will provide the proprietary materials owned or licensed by CRO or Pfizer and identified below ("**CRO Materials**") for use by Principal Investigator or Institution in the conduct or reporting of the Study.

Materials Supplied: NONE

Vendor-Provided Equipment or Materials

CRO or Pfizer will arrange for a vendor to provide the following equipment or proprietary materials ("**Vendor Property**") for use in this Study: NONE

Ownership, Responsibilities, and Liability

Ownership. CRO Equipment, CRO Materials, and Vendor Property are and remain the property of CRO, Pfizer, the vendor, or the licensor, as the case may be.

Responsibilities. The party receiving and using them will bear the risk of loss or damage to CRO Equipment, CRO Materials, and Vendor Property. If any CRO Equipment, CRO Materials, or Vendor Property must be replaced by CRO, Pfizer or vendor during Study conduct as the result of loss or damage by a party to this Agreement, CRO reserves the right to deduct, from future Study funding payments, the cost to CRO or Pfizer of the replacements.

Liability. Neither CRO nor Pfizer has any liability for damages of any sort, including personal injury or property damage, resulting from the use of CRO Equipment, CRO Materials, or Vendor Property except to the extent that (1) such damages were caused by the negligence or willful misconduct of CRO, Pfizer, or the vendor or (2) a personal injury constitutes a Research Injury to a Study Subject, as described in Attachment B to this Agreement.

Attachment D
PFIZER INTERNATIONAL ANTI-BRIBERY AND
ANTI-CORRUPTION BUSINESS PRINCIPLES

Pfizer has a long-standing policy forbidding bribery and corruption in the conduct of our business in the United States or abroad. Pfizer is committed to performing business with integrity, and acting ethically and legally in accordance with all applicable laws and regulations. We expect the same commitment from the consultants, agents, representatives or other companies and individuals acting on our behalf ("Business Associates"), as well as those acting on behalf of Business Associates (e.g., subcontractors), in connection with work for Pfizer.

Bribery of Government Officials

Most countries have laws that forbid making, offering or promising any payment or anything of value (directly or indirectly) to a Government Official when the payment is intended to influence an official act or decision to award or retain business.

"Government Official" shall be broadly interpreted and means:

(i) any elected or appointed Government official (e.g., a legislator or a member of a Government ministry);

(ii) any employee or individual acting for or on behalf of a Government Official, agency, or enterprise performing a governmental function, or owned or controlled by, a Government (e.g., a healthcare professional employed by a Government hospital or researcher employed by a Government university);

(iii) any political party officer, candidate for public office, officer, or employee or individual acting for or on behalf of a political party or candidate for public office;

(iv) any employee or individual acting for or on behalf of a public international organization;

(v) any member of a royal family or member of the military; and

(vi) any individual otherwise categorized as a Government Official under law.

"Government" means all levels and subdivisions of governments (i.e., local, regional, or national and administrative, legislative, or executive).

Because this definition of "Government Official" is so broad, it is likely that Business Associates will interact with a Government Official in the ordinary course of their business on behalf of Pfizer. For example, doctors employed by Government-owned hospitals would be considered "Government Officials."

The U.S. Foreign Corrupt Practices Act (the "FCPA") prohibits making, promising, or authorizing a payment or providing anything of value to a non-U.S. Government Official to improperly or corruptly influence that official to perform any governmental act or make a decision to assist a company in obtaining or retaining business, or to otherwise gain an improper advantage. The FCPA also prohibits a company or person from using another company or individual to engage in any such activities. As a U.S. company, Pfizer must comply with the FCPA and could be held liable as a result of acts committed anywhere in the world by a Business Associate.

Anti-Bribery and Anti-Corruption Principles Governing Interactions with Governments and Government Officials

Business Associates must communicate and abide by the following principles with regard to their interactions with Governments and Government Officials:

- Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly make, promise, or authorize the making of a corrupt payment or provide anything of value to any Government Official to induce that Government Official to perform any governmental act or make a decision to help Pfizer obtain or retain business. Business Associates, and those acting on their behalf in connection with work for Pfizer, may never make a payment or offer any item or benefit to a Government Official, regardless of value, as an improper incentive for such Government Official to approve, reimburse, prescribe, or purchase a Pfizer product, to influence the outcome of a clinical trial, or to otherwise benefit Pfizer's business activities improperly.

- In conducting their Pfizer-related activities, Business Associates, and those acting on their behalf in connection with work for Pfizer, must understand and comply with any local laws, regulations, or operating procedures (including requirements of Government entities such as Government-owned hospitals or research institutions) that impose limits, restrictions, or disclosure obligations on compensation, financial support, donations, or gifts that may be provided to Government Officials. If a Business Associate is uncertain as to the meaning or applicability of any identified limits, restrictions, or disclosure requirements with respect to interactions with Government Officials, that Business Associate should consult with his or her primary Pfizer contact before engaging in such interactions.

- Business Associates, and those acting on their behalf in connection with work for Pfizer, are not permitted to offer facilitation payments. A "facilitation payment" is a nominal payment to a Government Official for the purpose of securing or expediting the performance of a routine, non-discretionary governmental action. Examples of facilitation payments include payments to expedite the processing of licenses, permits or visas for which all paperwork is in order. In the event that a Business Associate, or someone acting on their behalf in connection with work for Pfizer, receives or becomes aware of a request or demand for a facilitation payment or bribe in connection with work for Pfizer, the Business Associate shall report such request or demand promptly to his or her primary Pfizer contact before taking any further action.

Commercial Bribery

Bribery and corruption can also occur in non-Government, business to business relationships. Most countries have laws which prohibit offering, promising, giving, requesting, receiving, accepting, or agreeing to accept money or anything of value in exchange for an improper business advantage. Examples of prohibited conduct could include, but are not limited to, providing expensive gifts, lavish hospitality, kickbacks, or investment opportunities in order to improperly induce the purchase of goods or services. Pfizer colleagues are not permitted to offer, give, solicit or accept bribes, and we expect our Business Associates, and those acting on their behalf in connection with work for Pfizer, to abide by the same principles.

Anti-Bribery and Anti-Corruption Principles Governing Interactions with Private Parties and Pfizer Colleagues

Business Associates must communicate and abide by the following principles with regard to their interactions with private parties and Pfizer colleagues:

- Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly make, promise, or authorize a corrupt payment or provide anything of value to any person to influence that person to provide an unlawful business advantage for Pfizer.

- Business Associates, and those acting on their behalf in connection with work for Pfizer, may not directly or indirectly, solicit, agree to accept, or receive a payment or anything of value as an improper incentive in connection with their business activities performed for Pfizer.

- Pfizer colleagues are not permitted to receive gifts, services, perks, entertainment, or other items of more than token or nominal monetary value from Business Associates, and those acting on their behalf in connection with work for Pfizer. Moreover, gifts of nominal value are only permitted if they are received on an infrequent basis and only at appropriate gift-giving occasions.

Reporting Suspected or Actual Violations

Business Associates, and those acting on their behalf in connection with work for Pfizer, are expected to raise concerns related to potential violations of these International Anti-Bribery and Anti-Corruption Principles or the law. Such reports can be made to a Business Associate's primary point of contact at Pfizer, or if a Business Associate prefers, to Pfizer's Compliance Group by e-mail at corporate.compliance@pfizer.com or by phone at 1-212-733-3026.

(+91) 76202 86181
(+91) 93596 54447
MED EXPRESS
CLINICAL RESEARCH SOLUTIONS PRIVATE LIMITED
EMAIL: MEDEXPRESS.CRS@GMAIL.COM
JUNA BAZAR NOOR COLONY OPP POST OFFICE AURANGABAD MAHARASHTRA 431001

Memorandum of Understanding

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This Agreement is made on 01 Jun 2023, by and between "**MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD.**" having its Office at Juna Bazar Opp Post office Aurangabad Maharashtra 431003 referred as a party- A **(here in after referred to as the "SMO")**

And

Mahatma Gandhi Mission (MGM) Medical College & Hospital, N-6, Cidco, Aurangabad, Maharashtra 431 003 referred as a party-B **(here in after referred to as the "Institution")**

The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfil conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promise and mutual covenants herein contained and for Other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties here to as follows

MGM Medical College& Hospital appoints **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD.** Services As a site management organization on **Exclusive basis for period of 10 years w.e.f 01st June2023 to 1st June 2033. (Will be reviewed and updated accordingly)**

Obligations of MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD Services:

MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD. is a site management Organization based in Aurangabad providing end to end clinical research services to the Hospitals and Offers a complete range of Clinical Research in all therapeutic areas. We expertise in site Management Activities, Project Management, Medical Writing, Monitoring, Safety Reporting, Regulatory services, Potential Site selection, Faster patient Recruitment, Quality compliance & Maintenance, and Clinical Research Expertise in India.

MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD. Services is desirous of working with Hospital for the purpose of conducting ICH-GCP complaint phase I-IV clinical trials for new drug & treatment.

MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD Services Shall play vital role in getting clinical trials to the hospital /Hospital from the sponsors and CROs and execute them in Hospital.

MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD. Services will manage study Operations and study services as directed by study protocol for the duration of the clinical trial.

MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD Services will appoint a Clinical Research Coordinators (CRC)/existing site coordinator who will be a point of contact with Sponsor & CRO and ensure smooth conduct of trial at the site.

MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD will appoint project manager (PM) who will be responsible to coordinate and over-see the progress and management of CRC activities & trial, ensure data quality, resolve screening, enrolment or general issue if any, follow up on post -monitoring action elements and study training as per needs and frequent discussion with investigator & sponsor / CRO on trial progress.

MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD will appoint Quality check (QC Experts) who will be responsible to ensure adherence to the protocol, regulatory requirements record keeping and retention.

Study co-ordination, project management and quality management will be done by **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** services. **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** personnel, CRC, PM, QC Experts will assist PI and the Instuitions in all trial related activities.

MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD will bear all the administrative cost related to the various activities undertaken by PM, CRC or any other staff placed by **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** Services which includes telecommunication, travel cost, training cost at various centres across India or abroad.

MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD will be exclusively conducting/managing all trial at the Hospital during the tenure of this agreement. This agreement will last for 10 (ten) years and can be renewed further on mutual agreement.

Following activities will be carried out by appointed CRCs

1. Performing all the activities in strict adherence to the ICH-GCP guidelines, Schedule Y India GCP and :

Regulatory requirement

2. Preparation for site selection visit and Site Initiation Visit (SIV)
3. Communication & Follow up with IRB/IEC Submission and Approval
4. Accurate and complete documentation of relevant EC documentation

5. Regulatory documents Collection

6. Patient Identification for assigned study form OPD or Hospital Database.

7. Maintenance and update of Trial Master File (TMF), site binders and relevant files

8. Preparation for site Monitoring Initiation Visit (SMV) and resolving all action items generated during previous monitoring visits

9. Conduct Study according to International Conference of Harmonization (ICH) E6 and India Good Clinical Practice (GCP) regulation

10. Assisting Principal Investigator in administrating ICF and its procedures

11. Ensure protocol & applicable regulatory guidelines compliance and adherence

12. Patients pre- screening enrolment and recruitment

13. Preparing source notes and CRF filling

14. Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates

15. Coordinate and schedule subject's regular follow up visits and procedures, maintain regular

Telephonic contact with patients to preventing lost to follow- up and missed visits.

16. Managing Clinical Trial Materials (CTM) maintenance, Accountability, distribution and logistics at site

17. Coordinate all site-specific queries- medical, administrative, subject reimbursements and other study
related activities.

18. Reporting and coordinating all AE/SAEs according to their timelines as per regulatory norms

19. Filling up and maintaining trial related logs likes source documentation, drug dispensing logs, subject
log, visit logs, Investigational product log, temperature log, SAE and EC communication log

20. Documentation of protocol deviation as appropriate and communicate any impacting subject safety to the ethics committee

21. Coordinate with central and local lab for logistics and sample flow

22. Attend study related meeting as appropriate

23. Preparing sites for Monitoring / Auditing visits coordinate close out visit and Archival at site

24. Any other required activities during the trials.

25. Identification of potential database from different therapeutic area of PIs

26. Communication with Investigators/ Hospitals and conduct protocol specific feasibility

27. Other duties as requested by **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** Services Management

B. Hospital permits

1. Hospital will give the space and required facilities to appointed CRC &**MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** in order to perform clinical trials activities under respected PI.
2. Hospital will allow **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** and Sponsors of Clinical trials to access the facility to verify source documents.
3. Hospital will allow **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** to bring Sponsors of clinical trials to meet with PI/SITE representatives at a mutually convenient time.
4. Hospital shall permit **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** to exclusively manage all clinical trial commenced by **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** Services

C. Term of Agreement

The term of this Agreement shall be for a period of 10 years commencing on the effective date 1st June 2023. However, this Agreement shall be reviewed annually by both parties if needed.

D. Relationship of the parties

1. Hospital and **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** are independent parties. Both parties agree that their relationship is that of an independent contractor and not employer and employee.
2. Neither party shall have express or implied rights nor authority to assume or create any obligation or responsibility on behalf of or in the name of the other party by reason of this Agreement, except as provided in this Agreement.

E. GCP, ICH and CFR compliance

Hospital agrees to comply with International Conference of Harmonization & Good Clinical Practices (ICH-GCP) and all India regulations, CDSCO requirement and circulars there under.

F. Confidentiality

1. The parties here recognize and agree that due to the complex and competitive nature of the business, the confidential of information concerning both parties Is of critical importance. Either party shall not, either during or after the term of this Agreement, disclose to any third party any confidential information and all Information or information relative to the work or the business of either party without the written consent of either party **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** agrees that it shall not during, or at any time after

the termination of this Agreement, directly or indirectly disclose or use any information for any reason whatever, without the prior written consent of SITE.

3. Hospital shall not disclose to any third party any and information about new studies received from **MED EXPREES CLINICAL RESEARCH SOLUTION PVT. LTD.**

G. Indemnification

Hospital shall indemnify and hold harmless **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** against any losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by SITE, its agents, directors or employees, **MEDEXPREES CLINICAL RESEARCH SOLUTION PVT. LTD.** shall indemnify and hold harmless hospital against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of act or commission by **MED EXPREES CLINICAL RESEARCH SOLUTION PVT. LTD,** its agents, directors, or employees. In no event will either party be required to indemnify or hold harmless the other's negligence or gross negligence.

H. Compensation and Agreement

1. The Hospital, principal Investigator, **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** Services and Sponsor and/or CRO will enter into a quadripartite clinical trial agreement before/at the time of placement of each trial at the Hospital.
2. All feasibilities and payments shall be routed through **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** and pricing while bidding for the trial shall be discussed mutually and final correspondence with the Sponsor/CRO also would be handled by **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** Services for smooth and hassle-free finalization of Clinical Trial Agreements.

3. Getting payment from sponsor and giving to Hospital and /or Investigator is the responsibility of **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** Services.
4. **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** will be payee name for all trial related payment.
5. All payment shall be due and payable to the hospital on actual work i.e. number of subject randomized or visits completed.
6. The payment of remuneration shall be after deduction of all taxes under applicable laws.
7. All invoices will be requested from the hospital for study payment and all study related payment will be done to MGM Medical College & Hospital, in a period of 15 working days after receiving the payment from the sponsor/CRO.

8. The details of study budget sharing in INR is as follow:
   - **100%** study payment will be paid to **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** from Sponsor/ CRO for each study. In case study payment will not receive from the sponsor end then SMO will be the official party who will bear the pending payment.
   - **65%** study payment will be paid to Hospital /Principal Investigator from **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD**
   - **35%** study payment fees will be paid to **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT.LTD**
   - **100%** CRC fees will be paid to **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** from sponsor /CRO.
   - Subject Travel reimbursement amount will be paid to trial patients at actual basis & copy of acknowledgement receipts of travels reimbursement will provide to hospital from **MED EXPREES CLINICAL RESEARCH SOLUTION**.
   - Additional **30%** Institutional overhead will be paid from **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** received from sponsor /CRO.
   - **MED EXPREES CLINICAL RESEARCH SOLUTIONS PVT. LTD** will pay Lab Cost, subject Hospitalization, SAE Medical Management charges at actual basis to Hospital /Principal Investigator received from sponsor /CRO.

(**Note**: Hospital/Principal Investigator should provide dedicated working printer, stationary, Electricity, Working place, Internet connection facility to our study team.)

I. Termination of Agreement

1. This Agreement shall be terminated by mutual agreement by giving sixty (60) days prior written notice by either party after the completion of any ongoing trials.

J. Permission to use personal Information or Statement

For good consideration, the undersigned authorizes SMO and its assigns to use, publish or reprint in whole or part any basic information about my identity, practice, and participation in clinical research including any specific details of my clinical research that do not conflict with a previously contacted privacy agreement.

The two parties shall consult with each other and medicate any disputes which may arise about the contact. If all attempts fail the two parties can appeal to the organization of arbitration in judicial court of the state of Maharashtra India.

1) Authorized Signature: ..... Name: Dr. Rajendra Bohra Title : Dean Date: 01/06/2023 Hospital Name: **Mahatma Gandhi Mission (MGM) Medical College& Hospital** **Stamp:** DEAN MGM'S MEDICAL COLLEGE AURANGABAD	**2) Authorized Signature:** ..... Name: Dr. Deepak Bhosle Title: Professor & Head Dept. of Pharmacology and Clinical Trial Center Date: 01/06/2023 Hospital Name: **Mahatma Gandhi Mission (MGM) Medical College & Hospital** **Professor & H.O.D.** **Stamp: Department of Pharmacology MGM's Medical College Aurangabad.**
MED EXPREES CLINICAL RESEARCH SOLUTION **1) Authorized Signature:** ..... Name: Mr. Aniruddha Jadhav Title: Director Date: 01/06/2023 Address: **Juna Bazar Opp. PostOffice, Aurangabad 431001, Maharashtra, India.** **Stamp:** DIRECTOR MED EXPRESS CLINICAL RESEARCH SOLUTIONS Pvt. Ltd.	**MED EXPREES CLINICAL RESEARCH SOLUTION** **1) Authorized Signature:** ..... Name: Mr. Mujahed Khan Title: Director Date: 01/06/2023 Address: **Juna Bazar Opp. Post Office, Aurangabad, 431001, Maharashtra, India.** **Stamp:** DIRECTOR MED EXPRESS CLINICAL RESEARCH SOLUTIONS Pvt. Ltd.

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

Rs. 100

e-Stamp

Certificate No.	:	IN-KA70818471196253V
Certificate Issued Date	:	03-Feb-2023 02:01 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ BANGALORE12/ KA-JY
Unique Doc. Reference	:	SUBIN-KAKACRSFL08337119996633348V
Purchased by	:	NOVOTECH CLINICAL RESEARCH INDIA PRIVATE LIMITED
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	NOVOTECH CLINICAL RESEARCH INDIA PRIVATE LIMITED
Second Party	:	DR MOHAMMAD HAFIZ DESHMUKH MGMMCAH AHCAR LLP
Stamp Duty Paid By	:	NOVOTECH CLINICAL RESEARCH INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

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NOVOTECH CLINICAL RESEARCH INDIA PRIVATE LIMITED IN-KA70818471196253V RS 100 03-FEB-2023 02 01 PM

Please write or type below this line

CLINICAL TRIAL AGREEMENT

Dated February 07, 2023

This Clinical Trial Agreement ("Agreement") is made and entered into by and among **Novotech Clinical Research India Private Limited** (**"CRO"**), having an address Level 3, Unit 302,148 Embassy Square, Infantry Road, Bangalore 560001,India, **Dr. Hafiz Deshmukh, MBBS, MD ("Investigator") and Mahatma Gandhi Mission (MGM) Medical College & Hospital**, an institution located at N-6,CIDCO, Aurangabad, 431003, Maharashtra, India (**"Institution"**) & **Aurangabad Health Care & Research LLP (SMO)** for the conduct of a clinical trial ("Trial") in accordance with the terms and conditions noted below

Protocol Number: LYT-100-2022-204
Site : Mahatma Gandhi Mission (MGM) Medical College & Hospital
CTA India Template Version 01 Final
Date 07-Feb-2023

Novotech Clinical Research India Private Limited Bangalore

1. Terms

"Protocol" shall mean the **Protocol LYT-100-2022-204: "A Randomized, Double-blind, Four-Arm Active and Placebo-controlled Dose-Finding Trial to Evaluate the Efficacy, Tolerability, Safety and Dose Response of LYT-100 in Patients with Idiopathic Pulmonary Fibrosis (IPF)"** and all current and future amendments thereto as signed and approved by the Investigator each of which is incorporated into this Agreement by this reference. "Trial" shall mean the conduct of the clinical trial as set forth in the Protocol. This Trial will be a Multicenter Trial with each Investigator completing up to **5** subjects. "Enrolled Subject" shall mean any subject admitted to participate in the Trial in accordance with the terms and conditions of the Protocol. "Clinical Trial Drug" shall mean Sponsor's (as defined below) investigational drug **LYT-100**.

2. Term of the Agreement

The term of this Agreement shall commence on the date that it is fully executed and shall terminate six (6) months after the earlier of the following: (i) the date the Trial is completed in accordance with the terms of the Protocol and this Agreement and final clinical research data is received and approved by CRO; or (ii) the date the Trial is terminated as provided for in Section 7 herein.

3. Investigator Obligations

The Investigator shall direct the Trial and in connection therewith shall (and shall cause each member of the Trial Team [as defined below] to) adhere to this Agreement and the Protocol, all applicable federal, state and local regulations and guidelines, including the clinical practice requirements as are specified in the New Drugs and Clinical Trials Rules, 2019 and Good Clinical Practices guidelines are met and according to the Drugs & Cosmetics Rules, 1945, all relevant laws and ethics prevalent in India and "Good Clinical Practices". Strict compliance by the Institution, Investigator, and the Trial Team (as defined below) with the Protocol and this Agreement is required.

CRO will provide Investigator with a template informed consent form. The Investigator shall complete the template with the Investigator's and Institution's information. The Investigator may also add any other particular information required under any applicable law. If the Investigator makes any changes to the text of the informed consent form, it shall be returned to CRO or designee for review and approval prior to submission to the Institutional Ethics Committee (IEC).

The IEC shall receive a copy of the Protocol and the informed consent form as part of the original submission to the IEC for written approval. Any modifications to the Protocol or the informed consent form recommended by the Investigator or the IEC, after IEC review, must be brought to the attention of CRO. The Protocol and the informed consent form may not be altered without the prior written consent of CRO. If Protocol modifications are made after IEC approval has been obtained, these modifications must also be approved in writing by the IEC. If appropriate, the informed consent form approved by the IEC shall be modified to reflect changes in the Protocol. The modified informed consent form shall also be submitted to the IEC for written approval. Prior to each Enrolled Subject beginning the Trial, Investigator shall cause such Enrolled Subject to execute the final informed consent form approved by the IEC and CRO (the "ICF"). As required, and from time to time, the Investigator shall be responsible for obtaining additional IEC approvals and for submitting IND Safety Reports to the IEC.

The Investigator shall submit the following documents to CRO for review and approval before conducting the Trial and shall retain copies for FDA review: (i) a signed Statement of Investigator form (Form FDA 1572) with the Investigator's curriculum vitae or other statement of qualification and that of any sub investigators named on Form FDA 1572 attached thereto; (ii) documentation of IEC approval of the Protocol and the ICF; (iii) a signed copy of the Protocol, including any subsequent amendments thereto, (iv) a properly completed and signed Financial Disclosure Form for each person listed on the Form FDA 1572, (v) a signed Investigator undertaking to the Drugs Controller General of India (DCGI).

The Investigator thoroughly understands the Protocol and, as of the date of signing this Agreement, has no further questions or concerns about the Trial's design or conduct. Notwithstanding the foregoing, in the event of a conflict between the terms and conditions of the Protocol and the terms and conditions of this Agreement, the terms and conditions of the Protocol shall prevail for the interpretation of medical and scientific matters and the terms of this Agreement shall prevail for all other matters.

The Investigator shall exercise independent medical judgment as to the eligibility of each subject in the Trial (subject to the guidelines set forth in the Protocol) and, before including any subject in the Trial or initiating any Trial related procedures, shall cause each subject to execute a copy of the ICF. Investigator shall maintain independent records that corroborate subject eligibility and show that each subject executed the ICF before inclusion in the Trial. Investigator shall make available to CRO a copy of each Enrolled Subject's executed ICF.

The Investigator shall have a trial coordinator (or sub investigator if there is no trial coordinator) to assist the Investigator with the administration of the Trial. The Investigator may have one or more sub investigators work on the Trial. Each such sub investigator shall be under the direct control and supervision of the Investigator and shall be subject to all of the terms and conditions of this Agreement, including all obligations of the Investigator, and Investigator and Institution shall remain fully responsible and liable for such trial coordinators or sub investigators. No sub investigator may work on the Trial unless he or she is qualified through the appropriate level of experience and training necessary to conduct the Trial. Each sub investigator's name shall appear in the appropriate section on the FDA Form 1572.

In accordance with federal regulations, the Investigator shall provide careful custody and accurate dispensing records for the Clinical Trial Drug. In addition, the Investigator shall retain shipping invoices for supplies received from CRO.

The Investigator represents that: (i) Investigator is permitted to enter into this Agreement and perform the Trial; (ii) the terms and conditions of this Agreement are not inconsistent with and do not conflict with Investigator's present employment and other contractual agreements; and (iii) Investigator has the experience necessary to perform the Trial.

Institution represents that it has the staff, facilities and subject population necessary to perform the Trial.

The Investigator and each sub investigator, trial coordinator, lab personnel, and any other Institution employee or agent associated with the performance of the Trial at the Institution

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(hereinafter collectively referred to as the "Trial Team") shall be available during normal business hours for consultation with CRO or its designee by telephone and during periodic site visits to assess Trial progress.

If the Investigator leaves the Institution or otherwise becomes unavailable during the term of this Agreement, the Institution may nominate a replacement subject to CRO's approval, in CRO's sole and absolute discretion.

4. SMO Obligations:

1. SMO will manage Study Operations and Study services as directed by Study protocol for the duration of the clinical trial.

2. SMO will appoint Clinical Research Coordinator (CRC) who will be the point of contact for Sponsor & CRO and ensure smooth conduct of trial at the site.

3. The Investigator and Institution and SMO and Study Staff acting as independent contractors of Novotech and Sponsor and shall not be considered the employee or agents of Novotech and Sponsor.

4. Neither Novotech nor Sponsor shall be responsible for any employee benefits, pensions, workers compensation, withholding or employment-related taxes as to the Investigator or Institution or SMO or their staff

5. It is hereby agreed and acknowledged by the Parties and Sponsor that Novotech has no relationship whatsoever with the SMO and that the SMO is acting as independent contractor of the Institution.

4. SMO agrees to abide by all obligations placed on institution in the provisions of this Agreement concerning Confidentiality (section 9), Publication (section 10), Property of Sponsor (section 11), Debarment (section 12), and Indemnification (section 14).

5. Clinical Trial Drug

CRO shall provide Investigator with a clinical supply of Clinical Trial Drug for administration during the Trial in accordance with the Protocol and this Agreement. The Investigator, Institution, or any member of the Trial Team shall not distribute the Clinical Trial Drug to any other person except in connection with subject treatment pursuant to the Protocol. None of Institution, Investigator or any member of the Trial Team shall use or promote the Clinical Trial Drug, except as specifically described in this Agreement and the Protocol. Institution, Investigator and the Trial Team shall administer the Clinical Trial Drug only to Enrolled Subjects under Investigator's direct supervision. If requested by CRO in writing, Investigator and Institution shall be responsible for the destruction of all unused supplies of the Clinical Trial Drug if the Trial is terminated, suspended, discontinued or completed.

It is understood that the Clinical Trial Drug provided hereunder is experimental in nature. CRO makes no representations or warranties, express or implied, including, without limitation, any

implied warranty of merchantability, fitness for a particular purpose or non-infringement, regarding the Clinical Trial Drug, any information supplied by CRO hereunder or any other subject matter of this Agreement. Additionally, CRO makes no representations of any kind, express or implied, regarding the safety or efficacy with respect to the Clinical Trial Drug in any form.

6. Safety

The Investigator shall notify CRO immediately of any deaths or Serious Adverse Experiences (as defined in the Protocol) in Enrolled Subjects whether or not such events are believed to be associated with the Clinical Trial Drug. These events, regardless of cause or relationship to the Trial, shall be reported directly to the Medical Monitor identified for the Trial and followed by a written report to the following address:

Medical Monitor: Ganashree P. (ganashree.p@novotech-cro.com)
CRO: Novotech Clinical Research India Private Limited
Address: Level 3, Unit 302, 148 Embassy Square, Infantry Road, Bengaluru, Karnataka, 560001, India
Phone: +91 80 4551 4400

The Investigator shall also bring all safety issues that are identified after the Trial is underway to the attention of his/her IEC.

7. Trial Records

a. Record Maintenance. The Investigator shall maintain independent case histories for each subject, including complete records of subject identification, clinical observations, and Clinical Trial Drug disposition ("Records"). Blank Case Report Forms (either paper or electronic format) will be provided to the Investigator by CRO or designee. The Investigator shall record all entries on Case Report Forms in a timely manner following each subject visit. The Investigator shall ensure all completed Case Report Forms are accurate and shall submit all such complete forms to CRO or its designee in a timely manner. Upon completion or earlier termination of the Trial, all Case Report Forms, completed or otherwise, shall be promptly returned to CRO.

b. Record Retention. Institution and Investigator shall maintain the Records for two (2) years following the date a marketing application is approved for the Clinical Trial Drug for the indication which is being investigated or, if no application is to be filed or if the application is not approved for the Clinical Trial Drug, until the later of (i) two (2) years after CRO has provided written notice to the Investigator that the investigation of the Clinical Trial Drug has been discontinued, or (ii) as required by Regulatory Agency guidelines.

c. Record Access. During the term of this Agreement, Institution and Investigator agree to permit representatives of CRO or its designee to examine (and, as applicable, to make copies of), at any reasonable time during normal business hours: (i) the facilities where the Trial is being conducted; (ii) raw Trial data; and (iii) any other relevant information necessary for CRO or its designee to confirm that the Trial is being conducted in conformance with the Protocol, this Agreement and in compliance with applicable FDA laws and regulations and as per New Drug and Clinical Trial Rules 2019 to the Drugs & Cosmetics Rules, 1945. The parties acknowledge that the FDA or DCGI may conduct independent inspections of the Trial under its jurisdiction. Each of

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Investigator and Institution shall be obligated to inform CRO of the FDA's / DCGI's intent to conduct an inspection immediately upon such party's receipt of notice from the FDA / DCGI. In addition, the Investigator and Institution shall cooperate fully in such audits and inspections.

The subjects' original medical records and other original source documents that are pertinent to the Trial shall be made available to CRO or its designee and/or the FDA / DCGI upon request. Subject permission for such access shall be obtained by having each prospective subject sign the written ICF before entering such subject in the Trial. No subject shall be enrolled in the Trial until the subject has executed the ICF.

8. Termination

CRO reserves the right to terminate the Trial for any reason upon prior written notice to the Investigator and Institution. CRO reserves the right to terminate the Trial without advance written notice if subject safety becomes a concern to CRO, in its sole and absolute discretion.

Upon termination, the Investigator shall deliver to CRO, at the expense of CRO, materials and information generated during the Trial including, without limitation, the Case Report Forms (whether or not completed) and safety information. Any unused Clinical Trial Drug will be destroyed on site or returned to CRO as directed by CRO. In case of termination, the payments due under this Agreement shall be prorated based on actual work properly performed in accordance with the Protocol and this Agreement as of the date of the termination.

9. Confidentiality

The parties acknowledge and agree that as among CRO, Investigator, Institution, SMO, and the Trial Team, Confidential Information shall be the sole and exclusive property of CRO or Sponsor. "Confidential Information" shall mean all information disclosed by Sponsor, CRO or its designee or developed by the Institution, the Investigator. SMO or the Trial Team and related to or arising out of the Trial, including, without limitation, the Protocol, Case Report Forms and all materials and information concerning CRO or Sponsor, the Clinical Trial Drug, and the Trial disclosed to the Institution, Investigator, SMO or the Trial Team or generated by Institution, Investigator, SMO, the Trial Team, Sponsor or CRO during the Trial. No Confidential Information shall be disclosed to any third party without Sponsor or CRO's prior written permission except to members of the IEC or those members of the Trial Team that have a "need to know" (provided such members shall agree to be subject to the confidentiality provisions set forth herein). Institution, Investigator, SMO and the Trial Team shall not use Confidential Information for any purpose other than the conduct of the Trial and the evaluation of its results, and shall promptly return to CRO all written Confidential Information, and any copies thereof, at the request of CRO. Notwithstanding the foregoing, the Institution may publish the results of the Trial in strict accordance with Section 9 below.

The Investigator, SMO and Institution each shall protect the Confidential Information from disclosure to third parties with the same degree of care each such party would protect its own confidential information, but in all cases, no less than a reasonable degree of care. In further recognition of the value of Confidential Information, each of the Institution, SMO and the Investigator acknowledges that it shall not engage in the reproduction of Confidential Information other than necessary for conduct of the Trial. When requested by CRO or at the termination of this Agreement, whichever first occurs, each of the Institution, SMO and the Investigator immediately

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shall deliver to CRO all Confidential Information and all copies thereof in its possession or in the possession of its employees, except for original Trial records, which shall remain the property of the Institution.

The Institution, SMO and the Investigator each acknowledges that (i) the covenants set forth in this Section 8 are essential elements of the transactions contemplated in this Agreement that, but for the agreement of the Institution and the Investigator and SMO to comply with such covenants, CRO would not have entered into such transactions, and that each of the Institution and the Investigator and SMO has consulted with, or has had the opportunity to consult with, counsel and has been advised in all respects concerning the reasonableness of such covenants as to scope and limit of time; (ii) CRO will not have any adequate remedy at law if the Institution, SMO or the Investigator violates the terms of this Section 8 or fails to perform any of its other obligations hereunder; and (iii) CRO shall have the right, in addition to any other rights it may have, to obtain in any court of competent jurisdiction temporary, preliminary and permanent injunctive relief to restrain any breach, threatened breach, or otherwise to specifically enforce any of such covenants or any other obligations of the Institution or the Investigator or SMO if he or she fails to perform any of his or her obligations under this Agreement.

The provisions of this Section 9 do not apply to any Confidential Information which:

(1) Institution or Investigator or SMO can demonstrate by written records was lawfully known to Institution or Investigator prior to receiving such Confidential Information either directly or indirectly from CRO;
(2) is generally made known to the public or becomes generally known to the public through no action or omission on the part of Institution, Investigator, SMO or the Trial Team;
(3) is lawfully obtained by Institution or Investigator or SMO from sources independent of CRO who have a lawful right to disclose such Confidential Information; or
(4) is required to be disclosed by law or court order, provided CRO shall be given written notice prior to such disclosure and the reasonable opportunity to protect such Confidential Information from disclosure.

In any dispute over whether information is "confidential," for purposes of enforcement of this Section, it shall be the burden of Institution or Investigator to show that such contested information is not proprietary or confidential, or does not constitute a "trade secret," as that term is defined under governing law.

10. Publication

At the conclusion of the Trial, a single or multicenter (as appropriate) abstract reporting the primary results of the Trial will be prepared and presented at a meeting determined by CRO. A single or multicenter (as appropriate) publication may be prepared for submitting to a reputable scientific journal. Other publication of the results of the Trial is not permitted until after the presentation or publication of the single or multicenter Trial results are approved and presented.
Institution shall submit all proposed abstracts, publications, papers or other written materials related to the Trial to CRO at least sixty (60) days prior to submission of such written materials for presentation or publication. If requested in writing by CRO, Institution shall withhold publication for an additional ninety (90) days from the date of such request to allow CRO to file a patent application or take such other measures as CRO deems appropriate to establish or preserve its

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proprietary rights. Notwithstanding the foregoing, Institution shall not include any Confidential Information in any disclosure without the prior written consent of CRO, provided that the results of the Study may be published by Institution after Institution's compliance with the procedures set forth in this Section 10.

11. Property of Sponsor

Investigator, SMO and Institution acknowledge and agree that inventions (whether or not patentable), discoveries, processes, improvements, techniques, methods, formulations, compositions, specifications, designs, reagents, antibodies, skills, concepts, trade secrets, and any technical information, copyrights, patents, trademarks, know-how, documentation and data (recorded in any form and including, without limitation, the results of the Trial) relating thereto, and other intellectual property conceived, generated or reduced to practice as a result of the Trial or owned by CRO or **PureTech LYT100, Inc.** ("Sponsor"), prior to the Trial (collectively, "Technology") shall be the sole and exclusive property of Sponsor, and nothing in this Agreement shall be construed to confer upon or grant Institution, Investigator, SMO, or any member of the Trial Team any right, title or interest therein. Institution, SMO and Investigator hereby assign any and all right, title and interest, if any, in and to such Technology to Sponsor and Sponsor will have exclusive ownership rights to such Technology, and Institution and Investigator and SMO shall take all acts reasonably required to convey such right, title and interest in such Technology to Sponsor.

Institution shall promptly notify Sponsor of any new Technology and shall provide reasonable assistance to Sponsor in gaining patent protection for such Technology. Sponsor shall reimburse Institution for all reasonable expenses incurred in connection therewith. Any patent application shall be filed, maintained, and prosecuted by Sponsor or its designee.

12. Debarment

Investigator warrants and represents that Investigator is not now, nor has Investigator ever been, an individual, corporation, partnership, association or entity that has been debarred by the FDA pursuant to 21 U.S.C. §335 (a) or (b) (a "Debarred Person").

Institution warrants and represents that neither it, nor any member of the Trial Team, is now or has ever been a Debarred Person.

Institution further warrants and represents that no Debarred Person has performed or rendered, or will be permitted to perform or render, any services or assistance relating to activities taken pursuant to this Agreement.

SMO warrants and represents that it has not been debarred by the FDA pursuant to 21 U.S.C. §335a, et seq. or under an equivalent provision of any country where the Services are provided, and it will not use in the performance of the Services any person or entity that has been debarred by the FDA pursuant to 21 U.S.C. §335a, et seq. or under an equivalent provision of any country where the Services are provided.

Institution, SMO and Investigator further warrant and represent that they have no knowledge of any circumstances which may affect the accuracy of the foregoing warranties and representations, including, but not limited to, FDA / DCGI investigations of, or debarment proceedings against,

Institution, Investigator, SMO or any other person or entity performing services or rendering assistance relating to activities taken pursuant to this Agreement.

Institution, SMO and Investigator each shall immediately notify CRO if such party becomes aware of any change in circumstances that would render any of the foregoing representations or warranties untrue or misleading in any material respect.

13. Payment

Grant payments hereunder will be made by CRO, to the payee identified in Exhibit A attached hereto and incorporated herein. Any delay in such payments shall in no way relieve Institution or Investigator of any of their respective obligations under this Agreement unless and only to the extent this Agreement is terminated pursuant to Section 8.

14. Indemnification

CRO agrees to indemnify, hold harmless, and defend Institution, its trustees, regents, directors, officers and employees (including the Investigator), physicians and all other qualified personnel working under their supervision (collectively, the "Institution Indemnitees") from and against all claims, demands, actions and proceedings (collectively, "Claims") which may be brought or asserted against Institution Indemnitees to recover damages and losses for or attributable to bodily injury, sickness, disease, or death directly resulting from the administration of the Clinical Trial Drug.

CRO's obligation to indemnify hereunder shall be conditioned upon: (i) the use of the Clinical Trial Drug and the conduct of the Trial in accordance with the Protocol, this Agreement and any other written information, instructions, or warnings furnished by Sponsor, CRO or its designee; (ii) IEC approval of the Trial, Protocol and ICF as required hereunder; (iii) ICF compliance with applicable law; and (iv) timely receipt by CRO, in accordance with Section 3 above, of an ICF signed by the injured subject prior to enrollment.

The Institution and Investigator understand that the sole indemnification liability of CRO to the Institution Indemnitees will be the indemnification described above.

CRO shall not be obligated to indemnify, defend or hold harmless any Institution Indemnitee and SMO's trustees, regents, directors, officers and employees (including the Designated Partner), physicians and all other qualified personnel working under their supervision (collectively, the "SMO Indemnitees") with respect to any claims, demands, costs or judgments arising out of: (i) a failure of any Institution Indemnitee and/or SMO Indemnitee to adhere strictly to the terms of the Protocol or this Agreement; (ii) a subject's pre-existing condition other than the condition that is the subject of the Protocol; (iii) negligence, malpractice, or willful misconduct by any Institution Indemnitee and/or SMO Indemnitee; (iv) a breach of any representation or warranty given by an Institution Indemnitee and/or SMO Indemnitee hereunder; or (v) a violation of any applicable federal, state or local law or regulation by any Institution Indemnitee and/or SMO Indemnitee.

The Institution shall indemnify, defend and hold CRO, Sponsor, and their respective, shareholders, members, officers, director, employees and agents ("CRO Indemnitees") harmless from any and all liability, loss (including reasonable attorneys' fees) or damage they may suffer as the result of claims, demands, costs or judgments against them which arise or are alleged to arise from or are

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connected with or are alleged to be connected with: (i) an Institution Indemnitee's or any other Trial Team member's failure to adhere strictly to the terms of the Protocol and/or this Agreement except as provided above, including, without limitation, the enrolling of a subject in the Trial with a pre-existing condition unrelated to the condition being studied; or (ii) an Institution Indemnitee's or any other Trial Team member's negligence, malpractice, or willful misconduct; or (iii) an Institution Indemnitee's or any other Trial Team member's breach of any representation or warranty or any applicable federal, state or local law or regulation.

CRO's and Institution's agreement to indemnify, defend and hold the other harmless is conditioned on the indemnified party: (i) providing written notice to the indemnifying party of any claim, demand or action arising out of the indemnified activities within thirty (30) days after the indemnified party has knowledge of such claim, demand or action; (ii) permitting the indemnifying party to assume full responsibility to investigate, prepare for and defend against any such claim, demand or action; (iii) assisting the indemnifying party, at the indemnifying party's reasonable expense, in the investigation of, preparation for and defense of any such claim, demand or action; and (iv) not compromising or settling any claim, demand or action without the indemnifying party's prior written consent, not to be unreasonably withheld.

Except as provided in this Section 14, no party shall be responsible or liable with respect to any subject matter of this agreement or any attachment or terms and conditions related thereto under any contract, negligence, strict liability, or other theory for (i) any loss or inaccuracy of data or cost of procurement of substitute goods, services or technology, (ii) any indirect, incidental, special or consequential damages or (iii) any matter beyond its reasonable control.

15. Assignment/CRO's Rights

This Agreement is for professional services. Neither Institution nor SMO nor Investigator may assign, delegate or otherwise transfer any of its rights or obligations under this Agreement without the prior written consent of CRO. Institution, Investigator and SMO understand and agree that CRO may assign this Agreement in whole or in part to any affiliate or in connection with the merger, consolidation or transfer of all or substantially all the assets to which this Agreement relates. Furthermore, CRO may assign any of its obligations hereunder to an unrelated third-party service provider, provided CRO remains primarily liable for such obligations and shall have the right to enforce the terms of this Agreement.

16. Survival

The terms of Paragraphs 8, 9, 10, 13, 14 and 15 shall survive the expiration or termination of this Agreement, and any other provision of this Agreement that by its nature and intent remains valid after termination will survive termination.

17. Entire Agreement

This Agreement, including the Protocol, and Exhibit A, incorporated herein by reference, represent the entire Agreement between CRO, the Investigator, SMO and Institution with respect to the subject matter hereof and thereof. This Agreement may not be modified except in writing, signed and approved by the duly authorized representatives for each party.

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18. Governing Law

This Agreement is governed by the laws of India that are applicable to contracts negotiated, executed and performed within India. The parties agree that any claim or controversy arising out of or relating to this Agreement or breach thereof shall be settled by the competent Courts in Delhi as per the laws prevalent in India.

19. Notice

Except as set forth in Section 6 above, any notice required to be given under this Agreement shall be personally delivered by overnight commercial courier service with tracking capabilities, or by facsimile (followed by such commercial courier service delivery or certified mail) which shall be deemed given when transmission is confirmed, at the addresses specified below:

If to CRO:

Novotech Clinical Research India Pvt Ltd.
Address:
Level 3, Unit 302, 148 Embassy Square, Infantry Road,
Bengaluru, Karnataka, 560001, India
Attention: General Counsel
Email: legal@novotech-cro.com

If to Institution:

Mahatma Gandhi Mission (MGM) Medical College & Hospital
N-6. CIDCO, Aurangabad - 431003. Maharashtra. lndia
Attention: Dr. Rajendra Bohra Dean
Telephone: 0240-6601100
Email: mgmmca@themgmgroup.com
Institute Witness: Dr. Deepak Bhosle Professor & Head. Department of Pharmacology
Telephone +917770087870
Email: drdeepakmgm@gmail.com

SMO Address:

Aurangabad Health Care & Research LLP
Shop No.126, CTS No.12482/1 Chetan Trade Centre,
Opp.S. F School, Jalna Road, Aurangabad, Pin 431001,
Maharashtra, India

Attention: Dr. Renuka Madnurkar

Mobile Number: +919420285937

Email id: drrenuka.ahr@gmail.com

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20. Relationship of the Parties

The Institution, Investigator, SMO or any members of the Trial Team shall not be deemed an agent or employee of CRO, and none of these shall have any authority to bind CRO. As an independent contractor, neither Investigator nor any member of the Trial Team performing the Trial shall participate in any CRO employee benefit plans nor receive any other compensation beyond that stated above. Payments for services rendered under this Agreement shall be made in full at the agreed rate without any deductions for taxes of any kind whatsoever, this being in conformity with non-employee status. It is understood that any taxes that may be due and payable as a result of the payments herein specified by CRO shall be entirely the recipient's responsibility. It is understood that, as part of this Agreement, the recipient undertakes to pay all taxes on such payments for which it may be liable when due.

21. Use of Name

Except as required by law, no party may use another party's name in any promotional material, advertising material, or other materials without the prior written consent of such other party.

22. Trademark Usage

No party shall use another party's trademarks, service marks, trade names, logos or other commercial or product designations, for any purpose, without such other party's prior written consent.

23. Severability

If for any reason a court of competent jurisdiction finds any provision of this Agreement, or portion thereof, to be unenforceable, that provision of the Agreement shall be enforced to the maximum extent permissible so as to affect the intent of the parties, and the remainder of this Agreement shall continue in full force and effect.

24. No Waiver

Failure by CRO, SMO, Investigator or Institution to enforce any provision of this Agreement shall not be deemed a waiver of future enforcement of that or any other provision.

25. Force Majeure

Neither party shall be liable for any failure or delay in its performance under this Agreement due to causes including, without limitation, acts of God, acts of civil or military authority, fires, epidemics, floods, earthquakes, riots, wars, sabotage, labor shortages or disputes, and governmental actions, which are beyond its reasonable control; provided that the delayed party: (i) gives the other party written notice of such cause promptly, and in any event within fifteen (15) days of discovery thereof; and (ii) uses its reasonable efforts to correct such failure or delay in its performance. The delayed party's time for performance or cure under this Section 25 shall be extended for a period equal to the duration of the cause or sixty (60) days, whichever is less.

26. Financial Disclosure

For purposes of this paragraph, Investigator or any subinvestigator performing services pursuant to this Agreement, or any spouse or dependent child of Investigator or such subinvestigator, shall be jointly referred to as "Investigator Personnel." Before conducting the Trial, Investigator and Institution agree to submit a written disclosure of: (i) any financial arrangement in which financial compensation to any Investigator Personnel who performs services pursuant to this Agreement

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could be affected by the outcome of the Trial as defined in 21 CFR 54.2(a); (ii) any proprietary interest by any Investigator Personnel in the Clinical Trial Drug or test product, as defined in 21 CFR 54.2(c); (iii) any significant equity interest owned by any Investigator Personnel in CRO, as defined in 21 CFR 54.2(b); and (iv) receipt by any Investigator Personnel of any significant payments of other sorts as defined in 21 CFR 54.2(f). Investigator and Institution further agree to assist CRO, upon request, in obtaining any information and executing any documents necessary to comply fully with 21 CFR Part 54, or any rules or regulations therein. The Investigator and Institution also agree to update CRO with regard to any relevant changes in financial status that occur during the Trial and for one (1) year after Trial completion.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the day and year first above written.

INVESTIGATOR: Dr. Hafiz Deshmukh

Dr. HAFIZ DESHMUKH
Assistant Professor
Dept. of Pulmonary Medicine
MGM Medical College & Hospital
Aurangabad. Reg. No. 2008/12/3906

By: _____ Date 13/Feb/2023

INSTITUTION: Mahatma Gandhi Mission (MGM) Medical College & Hospital
NAME & TITLE: Dr. Rajendra Bora (Dean)

DEAN
MGM'S MEDICAL COLLEGE
AURANGABAD

By: _____ Date _____

NAME & TITLE: Dr. Deepak Bhosale
Title: Professor & HOD, Pharmacology Department

Professor & H.O.D.
Department of Pharmacology
MGM's Medical College
Aurangabad

By: _____ Date 13/Feb/2023

SMO:
NAME & TITLE: Dr. Renuka Madnurkar
Designated Partner

Aurangabad Health Care & Research LLP
Shop No. 126, CTS No. 1248211, Chetan
Trade Centre Opp. S.F. School, Jalna Road,
Aurangabad MH India,

By: _____ Date 13/Feb/2023

CRO: Novotech Clinical Research India Private Limited
NAME & TITLE: Mr. Sanjay Kabra (Director Clinical Learning and Development Clinical Operations)

Novotech Clinical Research India Private Limited
Bangalore

By: _____ Date 07/Feb/2023

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Per Subject Fee

All costs are exclusive of any applicable TAXES/GST (18%) and TAXES/GST of 18% shall be added and paid whenever any invoice is raised.

The CRO will pay INR 562,510 (includes 30% overhead charges) (local tax excluded) per subject who has completed the Clinical Trial in accordance with the Protocol. The complete budget sheet is attached as EXHIBIT A at the end of this trial agreement.

Such amount is divided as follows:

Visit Payment (INR) (Includes 30% IOH)	
Screening	85,800
Baseline	73,385
Visit 3	58,175
Visit 4	59,475
Visit 5	55,575
Visit 6	58,175
Visit 7	54,275
Visit 8	81,575
Visit 9 (Follow UP)	36,075
Total Per Patient Fee	562,510

The per patient fee above includes funds to reimburse the patient travel and food expenses for up to INR 5,000 per visit upon receipt of the actual receipts.

A subject is considered as having completed the Clinical Trial when he/she has completed the specified Clinical Trial period and is evaluated per the Protocol.

In case of subjects included but not having completed the Clinical Trial, the amount to be paid will be calculated according to the fees for the visits actually performed by this subject. Where visits are conducted but not all per Protocol tests performed, the CRO reserves the right to withhold partial payment at its discretion. No payment will be made for an ineligible subject incorrectly enrolled into the Clinical Trial or in case the subject did not complete the Clinical Trial due to negligence, malpractice, breach of Protocol, or any willfully wrong act or omission on the part of the Investigator or Institution.

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3 Screen Failures without a participant enrolled will be reimbursed, subsequent SFs will be based on the recruitment rate and at the approval of the Sponsor. Re-imbursement will be based on procedures that actual performed and against eCRF. For any Subjects that are randomized but are not administered Clinical Trial Drug or that do not complete the study, site will be compensated for those procedures that have been performed, pursuant to the per-patient study budget.

The CRO will pay both the costs charged by the Independent Ethics Committee for review of the Protocol.

Central Laboratories will perform all pathology tests. All costs associated with the Central Laboratory, including courier charges, are borne separately by the CRO.

Unless otherwise agreed by the CRO in writing, the CRO will not be liable for any other payment other than those specified in this Agreement.

The parties estimate that the whole Clinical Trial will cost approximately INR **562,510** (Includes 30% IOH) per patient (local tax excluded) assuming full enrolment by the Investigator of 5 completed Clinical Trial subjects.

Frequency of Payments

Routine payments will be made quarterly based on the CRF sections that have been completed, monitored and collected up until that time. It is expected that CRFs will be completed by the site within 7 days of a patient's visit.

A minimum of 30 days payment terms apply on receipt of invoice.

Two final quarterly invoices will be withheld for the payment until:

- ❑ the delivery of all CRFs, duly filled and revised and after the positive opinion on the part of the CRO regarding their filling;
- ❑ receipt of all responses to the data clarification forms (DCFs) from the Investigator;
- ❑ database lock has occurred;
- ❑ the Investigator has returned all remaining Investigational Product;
- ❑ return and receipt of all essential documents from the Investigator;
- ❑ the IEC has been informed of Clinical Trial closure by the Investigator;
- ❑ return and receipt of CRO equipment from the Investigator.

Method of Payment
(please tick one box)

☐ Please make payment by cheque.

Payee Name : Aurangabad Health Care & Research LLP OR

× Please make payments via Electronic Funds Transfer (EFT).

Bank:	Indian Bank
Bank Account Name:	Aurangabad Health Care & Research LLP
Account No.:	50516370521
IFSC Code:	IDIB000A678
Name & Fax No.:	+919420285937
(for remittance)	

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EXHIBIT A Grant payments

Trial Information	
Trial Name:	012-2021_Progressive Fibrosing Interstitial Lung Disease (PF-ILD)
Arm:	Standard Arm_Post Award Update_75th percentile_16-Jun-2022
Project:	012-2021_Progressive Fibrosing Interstitial Lung Disease (PF-ILD)
Phase:	Phase III
Indication:	Idiopathic Fibrosing Alveolitis, Idiopathic Pulmonary Fibrosis, Interstitial Pulmonary Fibrosis, IPF

Table 1, Per Subject Fee

Name	OH?	Total Quantity	Screening Visit (V1)	Visit 2 (W0)	Visit 3 (W4)	Visit 4 (W8)	Visit 5 (W12)	Visit 6 (W16)	Visit 7 (W20)	Visit 8 (W24, ET)	PU	Revised Selected cost (INR) "editable values"	Total Cost/patient
Informed Consent Process	Y	1.00	1.00									5,000.00	5,000.00
HRCT	Y	1.00	1.00									INV	INV
Handling CT scans, preparation	Y	1.00	1.00									2,500.00	2,500.00
Demographic Information	Y	1.00	1.00									1,500.00	1,500.00
Initial History Only	Y	2.00	1.00	1.00								1,500.00	3,000.00
Inclusion/Exclusion Criteria	Y	2.00	1.00	1.00								2,500.00	5,000.00
Adverse Events Assessment	Y	9.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	2,250.00	20,250.00
Review Concomitant	Y	9.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1,500.00	13,500.00
Phys Exam & Vitals Only	Y	2.00	1.00							1.00		4,500.00	9,000.00
Brief Visit w/ Vitals	Y	7.00		1.00	1.00	1.00	1.00	1.00	1.00	1.00		2,250.00	15,750.00
Blood Collect, Ship & Prep (for	Y	8.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00		4,500.00	36,000.00
Urine Collection, Prep & Ship	Y	8.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00		1,000.00	8,000.00
Dip Stick UA w/ Microscopy	Y	8.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00		1,000.00	8,000.00
Cotinine test (urine)	Y	4.00	1.00	1.00		1.00				1.00		1,000.00	4,000.00
Healthcare Res Util Quest	Y	8.00		1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1,000.00	8,000.00
Spirometry	Y	6.00	1.00	1.00	1.00	1.00		1.00		1.00		3,000.00	18,000.00
Diffusing Capacity	Y	2.00	1.00							1.00		3,000.00	6,000.00
Patient-initiated spirometry per	Y	7.00	1.00		1.00	1.00	1.00	1.00	1.00	1.00		1,500.00	10,500.00
ECG w/ Interpret. & Report	Y	3.00	1.00	1.00						1.00		3,000.00	9,000.00
K-BILD (55), EQ-5D (45) and	Y	1.00		1.00								1,200.00	1,200.00
K-BILD, EQ-5D and SGRQ	Y	1.00					1.00					1,000.00	1,000.00
K-BILD, EQ-5D and SGRQ and	Y	1.00								1.00		2,250.00	2,250.00
Review questionnaires for	Y	8.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00		2,250.00	18,000.00
Randomization	Y	1.00		1.00								1,000.00	1,000.00
Vital status assessment	Y	1.00								1.00		1,000.00	1,000.00
Compliance / drug	Y	7.00		1.00	1.00	1.00	1.00	1.00	1.00	1.00		1,500.00	10,500.00
Trial medication termination	Y	1.00								1.00		1,000.00	1,000.00
Disease Specific Interview 30	Y	1.00								1.00		2,250.00	2,250.00
Training On Home Monitoring	Y	1.00	1.00									1,500.00	1,500.00
Per Patient Activity Totals:			43,000.00	30,450.00	21,750.00	22,750.00	19,750.00	21,750.00	18,750.00	39,750.00	4,750.00	222,700	222,700

Selected Other Direct Costs

Name	OH?	Total Quantity	Screen V1	Visit 2 (W0)	Visit 3 (W4)	Visit 4 (W8)	Visit 5 (W12)	Visit 6 (W16)	Visit 7 (W20)	Visit 8 (W24, E	PU	Revised Selected cost (INR) "editable value"	Total cost/patient
Administer 1st trial medication	Y	1.00		1.00								1,000.00	1,000.00
Physician's Fees without Exam	Y	9.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	2,000.00	18,000.00
Study Coordinator Fee Per Visit	Y	9.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	2,000.00	18,000.00
Patient Daily Reimbursement	Y	9.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	1.00	3,000.00	27,000.00
Total Costs			23,000.00	26,000.00	23,000.00	23,000.00	23,000.00	23,000.00	23,000.00	23,000.00	23,000.00	73,000.00	241,000.00

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Overall Patient Cost	Screening	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Discontinuation	Follow Up	
	Screen V1	Visit 2 (W0)	Visit 3 (W4)	Visit 4 (W8)	Visit 5 (W12)	Visit 6 (W16)	Visit 7 (W20)	Visit 8 (W20, ET)	FU	Total cost/Patient
Costs Not Charged with Overhead										
Costs Charged with Overhead	66,000.00	56,450.00	44,750.00	45,750.00	42,750.00	44,750.00	41,750.00	62,750.00	27,750.00	432,700.00
Overhead at 30%	19,800.00	16,935.00	13,425.00	13,725.00	12,825.00	13,425.00	12,525.00	18,825.00	8,325.00	129,810.00
Selected Cost Per Visit	85,800.00	73,385.00	58,175.00	59,475.00	55,575.00	58,175.00	54,275.00	81,575.00	36,075.00	562,510.00

Table 2, Invoiceable Costs

Name	Site Cost (INR)	30% OH	Site Cost (INR)
HRCT	8,000	2,400	10,400
Televisit fee	1,000	300	1,300
COVID-19 test	1,000	300	1,300
Screen failure	Per Invoice	Per Invoice	To be paid on actual procedures performed up to full cost of Screening Visit, plus applicable overhead (+ PI and SC time) 3 SFs without a participant enrolled will be reimbursed, subsequent SFs will be based on their recruitment rate and upon sponsor approval.
unscheduled visit	Per Invoice	Per Invoice	To be paid based on actual procedures performed, including PI time, SC time and patient transport reimbursement, plus applicable overhead fee.

Table 3, Site Level Other Direct Costs

Name	OH	Site Cost (INR)	30% OH	Total payment (INR)	Payment Frequency
Study Start-up Fee (one off)	Y	100,000	30,000	130,000	To be paid upon SIV
Study Close-out Fee	Y	50,000	15,000	65,000	To be paid upon IRB approval date of study termination report
Site Administrative fee (Telephone, Internet, Printing, Stationery, etc) (per month)	Y	3,000	900	3,900	To be paid upon SIV until COV
Calibration Syringe	N	45,000	N/A	45,000	Pass through cost, pay upon receipt of a valid invoice by the

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					vendor
Archiving/per site (estimated for 25 years)	Y	333,333	99,999.90	433,332.90	• The Institution will archive all relevant records for 25 years after the completion of the study at Sponsor's expense. • Document Archiving fee is based on actual inventory and invoice at the time of document storage to the Institution. • Payment will be made after submission of study completion or termination letter and upon receipt of a valid invoice by the Institute.

Novotech Clinical Research India Private Limited Bangalore

CLINICAL TRIAL AGREEMENT

This Memorandum of understanding, (hereinafter called MoU) between Mahatma Gandhi Mission's Medical College & Hospital, N-6 CIDCO, Aurangabad -431003, Maharashtra, India (herein after called MGM Medical College & Hospital, Aurangabad) and (the second party) Hetero Healthcare Limited Sy. No.80-84, Melange Towers, 4th Floor, "C wing", Patrika Nagar, Madhapur, Hyderabad – 500 081, Telangana (herein after called HHCL, Hyderabad) and (the third party), Grapecity Research Solutions LLP, Shree Prasad, Block No D-2, Prakash Housing Society, Kalewadi Phata, Thergaon, Pune 411033, Maharashtra (herein after called Grapecity Research Solutions LLP,Pune) entered into on this 16th February 2023.

Preamble:

'MGM Medical College & Hospital, Aurangabad', 'HHCL, Hyderabad' and 'Grapecity Research Solutions LLP,Pune' are willing to jointly participate in the study "Comparative Clinical evaluation of Efficacy and Safety Of Clotrimazole Vaginal Film vs Canesten V6 Vaginal Tablet In The Management Of Symptomatic Vulvovaginal Candidiasis in non pregnant women – Open Label, Randomized, Comparative, Parallel, Prospective, Multicentric Study ".

The Institute of the project will be Mahatma Gandhi Mission's Medical College & Hospital, N-6 CIDCO, Aurangabad -431003, Maharashtra, India.

And

The Investigator of the project will be Dr. Laxmi Rachakonda Nagbhushanam, Consultant Gynaecologist & Obstetrics, Department of Clinical Pharmacology and Therapeutics, Clinical Trial Centre, MGM Medical College & Hospital, Aurangabad, Maharashtra, India-431003.

And

The responsible person from the sponsor will be Dr. U. Shobha Jagdish Chandra, Head, Clinical Pharmacology and Therapeutics, Hetero Healthcare Limited, Hyderabad.

And

The SMO of the project will be Grapecity Research Solutions LLP, Shree Prasad, Block No D-2, Prakash Housing Society, Kalewadi Phata, Thergaon, Pune 411033, Maharashtra

Scope of MOU

This MOU will cover the joint efforts of 'MGM Medical College & Hospital, Aurangabad', Maharashtra, 'HHCL, Hyderabad', Telangana and 'Grapecity Research Solutions LLP, Pune', Maharashtra in the area of study titled "Comparative Clinical evaluation of Efficacy and Safety Of Clotrimazole Vaginal Film vs Canesten V6 Vaginal Tablet In The Management Of Symptomatic Vulvovaginal Candidiasis in non pregnant women – Open Label, Randomized, Comparative, Parallel, Prospective, Multicentric Study".

Objective of the study to be done:

1. To evaluate the clinical efficacy of Clotrimazole Vaginal film as compared to Canesten V6 vaginal tablet in the management of symptomatic vulvovaginal candidiasis in non pregnant women.

2. To assess the safety of Clotrimazole vaginal film as compared to Canesten V6 vaginal tablet in the management of symptomatic vulvovaginal candidiasis in non pregnant women.

Responsibilities of MGM Medical College & Hospital, Aurangabad

1. Enrolment of non-pregnant patients with Symptomatic Vulvovaginal Candidiasis.

2. Adherence to the study protocol.

3. Evaluating Vaginal discharge, whiff test, pH measurement, Microscopic examination for budding filaments, mycelia, Vaginal signs and symptoms along with their severity scores Treatment Emergent Adverse Events, Acceptance of study medication by patient during the study.

4. Conducting clinical evaluation at screening &baseline(day 0), day 3 (on telephone), and day 7(at study site).

5. Conducting Safety evaluation for any TEAEs at day14 (End of study).

6. Reporting of adverse events to the sponsor.

Responsibilities of HHCL, Hyderabad

1. Shipping of study medication to the principal investigator as per schedule.

2. Ensuring proper monitoring during the progress on the trials.

3. Maintaining and retaining adequate records and reports.

4. Ensuring that the investigation is conducted in accordance with the study protocol.

5. Providing the investigators with the information they need to conduct the investigation properly.

Responsibilities of Grapecity Research Solutions LLP, Pune:

1. Managing the Study Operations and Study services as directed by Study protocol for the duration of the clinical trial.

2. "Grapecity Research Solutions LLP, Pune" will appoint a Clinical Research Coordinator (CRC) who will be a point of contact with Sponsor & SMO and ensure smooth conduct of trial at the site.

Following activities will be carried out by appointed CRC:

1. Performing all the activities in strict adherence to the ICH-GCP guidelines, Schedule Y Indian GCP and regulatory requirement.
2. Communication & Follow up with IRB/IEC Submission and Approval
3. Patient Identification for assigned study from OPD or Hospital Database.
4. Maintenance and update of Trial Master File (TMF), site binders and relevant files.
5. Preparation for Site Monitoring Initiation Visit (SMV) and resolving all action items generated during previous visit.
6. Conduct study according to International Conference of Harmonization (ICH) E6 and Indian Good Clinical Practice (GCP) regulation
7. Assisting Principal Investigator (PI) in administrating ICF and its procedure.
8. Ensure protocol &applicable regulatory guidelines compliance and adherence.
9. Assisting PI in patients pre-screening, screening enrolment and recruitment.
10. Preparing source notes and CRF filling
11. Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates
12. Coordinate and schedule subject's regular follow up visits and procedures, maintain regular telephonic contact with patients to preventing lost to follow-up and missed visits.
13. Managing clinical trial materials (CTM) maintenance, Accountability, distribution and logistics at site
14. Coordinate all site specific queries-medical, administrative, subject reimbursements

and other.

15. Reporting and coordinating all AE/SAEs according to their timelines as per regulatory norms.
16. Filling up and maintaining trial related logs likes source documentation, drug dispensing logs, subject log, visit logs, Investigational product log, temperature log, logistics log, SAE and EC communication log
17. Documentation of protocol deviation as appropriate and communicate any impacting subject safety to the ethics committee.
18. Attend study related meeting as appropriate
19. Preparing sites for Auditing visits coordinate close out visit and Archival at site
20. Preparation for Site selection visit and Site Initiation Visit (SIV)
21. Regulatory Documents Collection
22. Coordinate with central and local lab for logistics and sample flow
23. Any other required activities during the trials.

Administration:

Overall responsibilities of the project will rest with MGM Medical College & Hospital, Aurangabad, Maharashtra, HHCL, Hyderabad, Telangana & Grapecity Research Solutions LLP, Pune, Maharashtra.

Financial Arrangements:

Funds for the projects will be from HHCL, Hyderabad, Telangana and the proportion of funds to be related to 'Grapecity Research Solutions LLP, Pune', Maharashtra are as follows:

CLINICAL TRIAL BUDGET			
	Per patient	**For 30 patients/per study**	**Total**
Complete charges	15,000	15,000 x 30	₹ 4,50,000
Institutional (IOH) overhead charges	NA	30%	₹ 1,35,000
Lab charges	500	(500x2x30) + (500x1x5)	₹ 32,500
		Total cost excluding EC fee	**₹ 6,17,500**
		GST 18%	**₹ 1,11,150**
		Total cost (+ GST 18%)	**₹ 7,28,650**
Note: Ethics committee fee will be provided separately according to the EC requirement.			

Payment terms:

1. Ethics committee fee will be paid along with the submitted EC documents.
2. Total cost excluding EC fee i.e ₹ 6,17,500 will be paid in two instalments.
3. 50% of ₹ 6,17,500 i.e., ₹ 3,08,750 will be paid after getting Ethics Committee approval for conducting the study.
4. The remaining 50% i.e., ₹ 3,08,750 will be paid after completion of study.
5. Payment will be done within 45 days from the date of receiving the invoice.
6. The payment invoice will be raised to Hetero Healthcare Limited, Hyderabad with GSTIN 36AABCH6890D1ZJ.

Payee Details:

Payee Name:	Grapecity Research Solutions LLP
Pan card Number	AAPFG8186L
GSTIN of Payee	27AAPFG8186L1ZH
Account Number	007305009846
IFSC Code	ICIC00003363
Bank Name	ICICI Bank Ltd.

The following supplies will be provided to MGM Medical College & Hospital, Aurangabad, Maharashtra.

- Study medication
- Protocols, CRFs, ICFs and Patient information sheets.

Intellectual Property Rights:

1. Any publication shall be by mutual consent of Investigator and sponsor (HHCL).

Duration of MOU:

This MOU will be in force for a period of 1 year (years from the date of it's signing).

Amendments to the MOU:

Amendments if any, before the expiry of this MOU shall be made by all the three parties in writing after mutual agreement.

Resolution of Dispute:

The place of jurisdiction for any dispute or claim before a court or an arbitrator shall be Hyderabad.

Seal of parties:

In witness there of parties MGM Medical College & Hospital, Aurangabad, Maharashtra, HHCL, Hyderabad, Telangana & Grapecity Research Solutions LLP, Pune Maharashtra, have signed this MOU as mentioned below.

	MGM Medical College & Hospital, Aurangabad, Maharashtra *(FIRST PARTY)*	**MGM Medical College & Hospital, Aurangabad, Maharashtra** *(FIRST PARTY)*	**MGM Medical College & Hospital, Aurangabad, Maharashtra** *(FIRST PARTY)*	**HHCL, Hyderabad, Telangana** *(SECOND PARTY)*	**Grapecity Research Solutions LLP, Pune, Maharashtra** *(THIRD PARTY)*
Name	Dr. Rajendra Bohra	Dr. Deepak Bhosle	Dr. Laxmi Rachakonda Nagbhushnam	Dr. U. Shobha Jagdish Chandra	Dr. Sunil Chaudhary
Designation	Head of Institute	Head of Department Pharmacology & Clinical Trial Centre	Consultant Gynaecologist	Head of Department Clinical Pharmacology &Therapeutics	Director
Date	28-2-23.	24.2.23	28-02-2023	20.02.23	03 Mar 2023
Signature					
Seal	DEAN MGM'S MEDICAL COLLEGE AURANGABAD	Professor & H.O.D. Department of Pharmacology MGM's Medical College Aurangabad.	Dr. Lakshmi Rachakonda MBBS, MD (OBGY) Professor and HOD MGM Medical College & Hospital, Aurangabad Reg. No. 57147	HETERO HEALTHCARE LTD. Hyderabad	Grapecity Research & Solutions LLP Pune

भारतीय गैर न्यायिक

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Rs. 100

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ONE HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA

HT 227256

अनंत एस. चांगड
मुद्रांक विक्रेता
प.क्रं. -ABD-158
सिडको, औरंगाबाद.

- 3 JAN 2014

अ.क्र. 860 रु. 06/1/14 किंमत 100/-

हस्ते : Dr Akhish Deshmukh

कोणाकरिता : MADVL

NOTARY GOVT OF INDIA S.R. DOUND AREA AURANGABAD & BEED DISTRICT'S Reg. No. 3435 NOTARIAL

NOTARY GOVT OF INDIA S.R. DOUND AREA AURANGABAD & BEED DISTRICT'S Reg. No. 3435 NOTARIAL

MEMORANDUM OF UNDERSTANDING

This MOU is in between Marathwada association of dermatologists, venereologists & Leprologists and MGM Medical College & hospital henceforth referred as MADVL & MGM respectively.

It is mutually agreed that the two machines i. e. Intense light (IPL) and Narrow band UVB (NBUVB which are owned by MADVL should be kept in Skin OPD of MGM hospital.

The revenue generated through the utilization of the machine will be divided as 70 % and 30 % (70% to MADVL & 30 % to MGM)

All the expenses towards maintenance, repair, servicing, parts replacement etc will be done by MADVL.

MADVL sincerely thanks MGM for this collaboration and expects the same in the future also.

DR. A. G. SHROFF
Dean MGM Medical College & Hospital

DR. P. R. SURYAWANSHI
Deputy Dean MGM Medical College & Hospital

DR. M. Y. KHEDKAR
Professor & Head
Department of Skin VD.

DR. PRASHANT PALWADE
Secretary, MADVL

DR. GOVIND KALE
Vice President, MADVL

NOTARY
S.P.DOUND
AREA AURANGABAD & BEED DISTRICT'S
Reg. No. 3435
GOVT. OF INDIA

NOTED & REGISTERED
AT Sr. No. 8113 20 14
THIS DOCUMENT CONTAINS
02 PAGES

BEFORE ME
SUNIL PANDITRAO DOUND
B.A.,LL.B.
Advocate Notary Govt. of India
AREA-AURANGABAD & BEED DIST's
☎: (0240)-2481952 (M)9371003334
Reg. No. 3435

06/1/14

Date: 25/03/2019

To,
The Dean,
MGM Medical college and Hospital,
Aurangabad

Sub: Regarding purchase of IPL machine

Respected sir,

With respect to conversation happened with Dr. PravinSuryawanshi sir kindly allow the old IPL machine [which was belonging to MADVL(Marathwada Association of Dermatology, Venereology and Leprology)]to take from OPD. The new IPL machine from dermaindia company is already installed in OPD. The charges of new machine with exchange to old are fixed by Dr.Pravinsuryawanshi sir and are attaching herewith.
Thanking you

Dr. A R Deshmukh
HOD Skin and VD

Plz Hod
to take old machine
out
25/3

(740)

THROUGH PROPER CHANNEL

Date:-09/08/19

To,

The Dean

MGMMedical College &Hospital

Aurangabad.

Subject- Regarding purchase of IPL machine

Respected Sir,

As per discussion done with Dr. Pravin Suryvanshi Sir, we purchased new IPL machine for 3 lakh Rs. This was done in exchange for old IPL machine which was belonging to Marathwada Association of Dermatologist (MADVL). Already 2 lakh Rs is paid to dermaindia but1 lakh is remaining which is to be paid to Marathwada Association of Dermatologist (MADVL).

I request you to pay the remaining amount.

Thanking you.

Ashis

Dr Ashish Deshmukh

Professor & Head

Skin & VD

Recommended

A/C

9/8/19.

→ To Vice Chairman for approval,

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MAHATMA GANDHI MISSION

MEDICAL COLLEGE & HOSPITAL

N-6 CIDCO, Aurangabad

Date: 09/09/2016

To,
I/C – Organizing camps activity
Samta Memorial Foundation
Mumbai.

Sub: To Start Eye Camp Activity

R/Sir,
With reference to your letter dated 03/09/2016, as per your request Dept of Ophthalmology, MGM Medical College Aurangabad is ready to start Eye camp activity in rural/tribal areas in collaboration with Samta Memorial Foundation, Mumbai.
We are ready to do Free Cataract Surgeries of poor and needy camp patients.
As stated in your letter and verbal discussion with HOD – Ophthalmology you will be provided following facilities through Samta memorial Foundation.

1) **Lens, drugs/medicines and surgical blades for the operative patients as per requirements by Ophthalmology dept.**
2) Advertisement /Publicity of Camp in rural areas
3) Transportation to camp pts.
4) Tea, Breakfast, meals and black goggles to camp pts.

We are always ready to help poor and needy pts in future also.

Dr. A.G. Shroff
Dean
MGM Medical College
Aurangabad

Dr. J.P. Mishrikotkar
Prof & Head – Dept of Ophthalmology
MGM Medical College
Aurangabad

Tel.: 91-0240-6601100, 2483401, Fax- 91-0240- 2487727
Email – mgmdeptofophthalmology@gmail.com, mgmdean@rediffmail.com