INDIAN COUNCIL OF MEDICAL RESEARCH
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भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health and Family Welfare, Government of India

No.5/10/FR/18/2014-RCH

Dated: 27.03.2019

Subject: Payment of final installment of the 3rd year grant -in-aid for the "Ad-hoc" New Scheme entitled: "**Impact of radiations from cell phone towers and cell use on health of pregnant women, neonates and infants: A multidisciplinary collaborative effort**" under Dr. Maninder Singh Setia.

MEMORANDUM:

Reference this office letter of even number dated 27.03.2019

The Director General ICMR sanctions the payment of **Rs. 22,56,512/- (Rupees Twenty Two Lakh Fifty Six Thousand Five Hundred and Twelve Only)** as the final installment of the grant for incurring expenditure in connection with the above mentioned research scheme. The amount of **Rs.** 22,56,512/- may be debited in the provision of **Rs.** 22,56,512/- made for the above-mentioned research scheme for the current financial year.

A formal bill for **Rs.** 22,56,512/- is sent herewith for payment of RTGS/demand draft to The Director, MGM Institute of Health Sciences, Sec-01, Kamothe, Navi Mumbai-410209, after adjusting unspent balance amount of Rs. Nil/- as on 19/03/2019, a net amounts of Rs. 22,56,512/- may be released.

RFC No. RCH/Ad-hoc/25/2016-2017 Dated: 9.3.2017

Administrative Officer,
for Director-General

Accounts V Section, ICMR

Copy to:

1. The Director, MGM Institute of Health Sciences, Sec-01, Kamothe, Navi Mumbai-410209.
   A Bank Draft/ RTGS for the amount of **Rs.** 22,56,512/- final installment will be sent to you in due course. The grant has been sanctioned on the condition laid down in our letter referred to above.
2. IRIS Cell (P & I) Section,
3. Dr. Maninder Singh Setia, Epidemiologist, Dept. of Epidemiology, MGM Institute of Health Sciences, Sec-01, Kamothe, Navi Mumbai-410209.
4. Mr B.S. Yadav Sr.T.O. ICMR,

for Director-General

वी. रामलिंगस्वामी भवन, पोस्ट बॉक्स नं. 4911,
अंसारी नगर, नई दिल्ली - 110 029, भारत
Tel: +91-11-26588895 / 26588980 / 26589794
+91-11-26589336 / 26588707

MGM Institute of Health Sciences (HO)

Head Office-3rd Floor, MGM Education Complex,
Plot No-1 & 2, Sect-1, Kamothe, Navi Mumbai

ICMR Mobile Tower Research Project

Ledger Account

1/4/2019 — 31/3/20

1-Apr-2017 to 31-Mar-2020

Date		Particulars	Vch Type	Vch No.	Debit	Credit
1-4-2017	Dr	**Opening Balance**				**65,433.00**
4-5-2019	Cr	**IDBI Bank S A/c-0183104000278850 ICMR** *Ch.No.: 805712 Being amount paid to Dr. Revathi Natesan towards Salary for the month of April,19*	IDBI Payment	68	36,400.00	
	Cr	**IDBI Bank S A/c-0183104000278850 ICMR** *Ch.No.: 805712 Being amount paid to Dr. Kishor Raut towards Salary for the month of April,19*	IDBI Payment	69	17,760.00	
7-5-2019	Cr	**IDBI Bank S A/c-0183104000278850 ICMR** *Ch.No. : 805712 Being amount paid to Mr. Samadhan A. Patil towards ICMR Project Salary for the period April, 19*	IDBI Payment	75	16,860.00	
	Cr	**IDBI Bank S A/c-0183104000278850 ICMR** *Ch.No. : 805713 Being amount paid to MGM Medical College & Hospital (Against Salary deduction of Mr. Samadhan A.Patil) towards ICMR Project Salary for the period April, 19*	IDBI Payment	76	1,940.00	
16-5-2019	Dr	**IDBI Bank A/c - 0183104000132763** *Being ICMR Project Fund for the year 2019 -20 Received*	IDBI Receipt	58		22,56,512.00
28-5-2019	Cr	**IDBI Bank S A/c-0183104000278850 ICMR** *Ch.No.: 805714 Being amount paid to Dr. Priyanka Kailash Tiwari towards Salary for the month of April,19*	IDBI Payment	149	36,400.00	
	Cr	**IDBI Bank S A/c-0183104000278850 ICMR** *Ch.No.: 805715 Being amount paid to Mr. Jeevan Shankar Urankar towards Salary for the month of April,19*	IDBI Payment	150	18,800.00	
	Cr	**IDBI Bank S A/c-0183104000278850 ICMR** *Ch.No.: 805716 Being amount paid to Mr. Faiyyaj Harun Shaikh towards Salary for the month of April,19*	IDBI Payment	151	18,800.00	
	Dr	**Advance to Project** *Ch.No.: 871765 Being amount transfer to ICMR project account due to shortage of funds in ICMR project for making salary payment for the month of April, 19*	Journal	186		90,000.00
11-6-2019	Cr	**IDBI Bank S A/c-0183104000278850 ICMR** *Ch.No.: 805717 Being amount paid to Dr. Priyanka Kailash Tiwari towards Salary for the month of May, 19*	IDBI Payment	186	36,400.00	
		Carried Over			1,83,360.00	24,11,945.00

continued ...

INDIAN COUNCIL OF MEDICAL RESEARCH
ANSARI NAGAR, NEW DELHI –110029.

No. 5/4/1-7/19-NCD-II

Date: 30-8-19

To

The Dean
MGM Medical College,
Sector-18 Kamothe,
Navi Mumbai410 209

Subject: - " Randomized controlled study to assess effectiveness and acceptability of mobile app based interventional tool for cardiovascular disease self-management and risk factor control among diabetic patients " under Dr. Ipseeta Ray Mohanty, Mumbai.

Sir,

The Director-General of the Council sanctions the above mentioned research scheme initially for a period of one year from **01-09-2019** subject to extension upto the total duration specified in para 3(3) below.

The Director-General of the Council also sanctions the budget allotment of Rs. **11,26,750/-** (**Rupees eleven lakh twenty six thousand seven hundred fifty only**) as detailed in the attached statement for the period ending the **31-08-2020.**

The grant-in-aid will be given subject to the following conditions:-

1. The payment of the grant will be made in lump-sum to the head of the Institution. The first instalment of the grant will be paid generally as soon as a report regarding the commencement of the project and appointment of the staff is received by the Council. The demand for payment of the subsequent instalment of the grant should be placed with the Council in the prescribed proforma attached.

2. The staff appointed on the project should be paid as indicated in the budget statement attached.

3. The approved duration of the scheme is **3 years.** The annual extension will be given after review of the work done on the scheme during the previous year.

4. A report on the progress made will be submitted to the Council as and when called for.

5. The Institute will maintain a separate account of the receipts and the expenditure incurred on the scheme and will furnish a utilization certificate and an audited statement of account pertaining to the grant.

PTO

6. The other terms and conditions are indicated in Annexure-1

7. The Host Institute shall utilize the grant after following the provisions laid down in the GFRs 2017 and T. A. Rules.

8. The PI may be advised to keep the fund in a separate Saving Bank Account opened for research funds received from ICMR so as to ensure that interest earned thereon is also credited in to the Fund Account.

The receipt of this letter may please be acknowledged.

Yours faithfully,

(Ishwar Likhar)
Admn. Officer
for Director-General

This issue with the concurrence
of Finance Section vide RFC No. NCD/Adhoc/70/2019-20 dated 30/8/19

No.5/4/1-7/19-NCD-II

1. Copy together with a copy of the budget statement forwarded for information to Dr. Ipseeta Ray Mohanry, Professor, Pharmacology, M. G. M. Medical College, Sector-18 Kamothe, Navi Mumbai-410 209.
2. Copy together with a copy of the budget statement forwarded to the **Accounts Section** for information and necessary action.
3. Copy together with a copy of the budget statement forwarded to the **Budget Section** for compilation of the Council's budget.
4. IRIS Code Number (2019-0502)
5. A.O., NCD.
6. Mr. Hemnat Kumar , Sr. T. O. , ICMR, New Delhi

For Director-General

Budget Statement for the period
(01-09-2019 to 31-08-2019)

No. 5/4/1-7/19-NCD-II

Date: 30-8-19

Subject: - " Randomized controlled study to assess effectiveness and acceptability of mobile app based interventional tool for cardiovascular disease self-management and risk factor control among diabetic patients " under Dr. Ipseeta Ray Mohanty, Mumbai.

Staff	**1st year (Rs.)**
Contingency (Recurring)	
Contingency	25,000
Investigation Rs 3000/-per patients (3 time points 0&3 and 6 months) Total patients =300 total cost=300X3000=900000/- Dyslipidemia Lipid profile (TG, LDL, HDL, TC) Atherogenic index (Rs 400/- test) Glycemic control Fasting blood sugar, Glycosylated –Rs 100/- test hemoglobin Rs 500/- test Hemostasis High-sensitivity C- reactive protein Rs 500/- test Apolipoprotein A Rs 500/- test Apolipoprotein B1 Rs 500/- test	400000
Patient follow up and stationary	50000
Data entry and analysis	60000
Total (A)	**535000/-**
Overhead Charge (5%) (B)	**26750/-**
Non-Recurring (Equipment)	
Digital BP Measurement apparatus	10000
Body Composition monitor	40000
Healthy heart mobile app development online version	500000
Total (C)	**550000/-**
(B) Travel	**15000**
Total (A+B+C+D)	**11,26750/-**

(Rupees eleven lakh twenty six thousand seven hundred fifty only)

ANNEXURE-I

TERMS AND CONDITION OF THE GRANT

i) Approval of the research proposal and the grant being released is for the specific project sanctioned and should be exclusively spent on this project within the stipulated time.

ii) Expenditure should be on no account exceed the budget sanctioned for the enquiry. Expenditure incurred over the above the sanctioned amounts against one or more sub-heads of expenditure such as pay, allowances, contingencies etc, shall be met without reference to the ICMR, by re-appropriation of savings under remaining sub-heads provided by re-appropriation of incurred during the financial year is within the over all sanctioned ceiling of that year.

iii) No expenditure shall be incurred on items not sanctioned by the Council. Savings should also not be re-appropriated for meeting or incurring expenditure on staff that has not been sanctioned by the council.

iv) The grant paid by the Council shall be refunded in full by the Institution if and when the grantee concerned discontinues a scheme midway or does not follow the detailed technical programme laid down and approved.

v) Receipts realised by the project officer and the sale proceeds, if any, will be remitted to the Council as miscellaneous receipts and should not be utilized for meeting expenditure on the scheme.

vi) All facilities for the conduct of the research scheme basic equipment and other ordinary laboratory chemicals, glass ware, furniture and other help as may be required for the smooth working of the scheme shall be provided by the institute.

Staff :.

vii) The staff employed on the research scheme will not be treated as employees of the Council and the deployment of such staff at the time of completion or termination of the project will not be the concern/responsibility of the Council. They will be subjected to administrative control of the Institution and will be appointed generally in accordance with the normal recruitment rules and procedure of the Institute.

viii) The Council will not be liable to bear any expenditure on pension/provident fund contribution and/or leave salary contribution incurred and committed by the grantee Institution for persons appointed on deputation from another organizations.

viii (A) An undertaking on part-I (specimen attached) (Appendix 'A') to be obtained from the Head of the Institute where extra-mural project funded by ICMR are being sanctioned, may be sent to Council. The second part of the U.K. to be obtained from each employees, by the Principle Investigator.

No grant will be released unless the undertaking is receive by us sufficiently in advance to consider any release.

* undertaking

Release of funds

ix) The first installment of the grant will be paid as soon as a report regarding the commencement of the project and appointment of staff is received by the Council. The Demand for payment of subsequent installments of the grant should be placed with the Council in the prescribed form (Appendix 'B').

x) The institute will maintain separate audited account for this project. If it is found expendient. Keep a part of whole of the grant in a back account earning interest, the interest thus earned should be reported to the Council. The interest thus earned will be treated as a credit to be adjusted towards further installment of the grant.

xi) The accounts will be subject to audit by the authorized auditor of the Institutions. In case, facilities are not available for such auditing, the account will be audited by the Council's own internal auditors. Latest by the end of December, following the financial year for which the grand is paid, an audit certification from, the auditors to the effect that "the accounts have been audited and that the money was actually spent on the objects for which it was sanctioned" shall be submitted to the Council.

xii) Further grants will be stopped unless audited statements of accounts, utilization certificates are received within a period of one year after the end of the financial year for which grant was sanctioned.

Stores:

xiii) All expendable and non-expendable articles required for work of the enquiry should be purchased in accordance with the procedure in vogue in the institution. For permanent and semi-permanent assets acquired solely or mainly out of the grant, a separate audited record in the form of register in the prescribed Performa enclosed shall be maintained by the Institute. The term "assets means (1) immovable property and (ii) movable property of capital nature where the value exceeds Rs. 1,000/-. Separate assets registers for items costing Rs. 20,000/- or more and less than Rs. 20,000/- each item may be maintained. (Appendix "C").

For other stores purchased from the Council's grant, the Performa will be the same as is being used by the Institute.

All the assets acquired from the grant will be property of the Council and should, not without the prior sanction of the Council, be disposed of or encumbered or utilized for purpose other than those for which the grant has been sanctioned.

Publications

The financial assistance rendered by the council should be acknowledged in any published account of work for which the grant is given.

The council publishes own journal " Indian Journal of ('B') Medial research", In case, it is proposed to publish the papers based on the work done under the auspices of the Council in Journals other than the IJMR, the name of the journal in which it is proposed to publish the paper may please be intimated. A reprint of paper when published may please be sent to the Council for information and record.

Prior permission of the Council should be obtained before publication of any such papers in a foreign journal.

Patents

The Council shall have the right to make out patents in respect of inventions/discoveries make under a scheme/project financed by the council. The officer-in-charge or the staff employed on ICMR Schemes shall not apply or obtain patents for any invention/discovery made by them without prior approval of the council.

All patents will be registered with NDRC in the name of the Indian Council of Medical Research.

Termination of Enquiry:

Prior permission of the Council should be obtained if the investigator desires to discontinue the enquiry. The reasons for discontinuing the scheme should invariably be scated. The investigator should submit a complete and detailed report of the work done by him on the project till the date of relief.

Any unspent balance out of the funds given to the institute shall be refunded to the ICMR on termination of the scheme.

A final report is required to be submitted within one month from the date of termination of the enquiry.

A list (in duplicate) of non-expendable and expendable articles together with property registers and suggestions for disposal of the articles should be sent to the Council within a month from the date of termination of the enquiry.

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MEMORANDUM OF UNDERSTANDING

For

'Rotasiil® Vaccine Intussusception Surveillance in Kerala, Karnataka, Maharashtra and Gujarat, India'

This Memorandum of Understanding is entered on the # of 20 April 2020 between

Christian Medical College, Vellore

Here after referred to as the 'First Party'

And

MGM College, Aurangabad

Here after referred to as the 'Second Party'

First party

Christian Medical College Vellore an institution administered by Christian Medical College Vellore Association, a Society functioning as per the provisions of the Societies Registration Act, 1860 having its Registered Office at Ida Scudder Road, Vellore 632 004, represented by its Principal, Dr Anna B. Pulimood hereinafter referred to as **"CMCVellore".**

Second party

MGM Medical College & Hospital (N-6 CIDCO, Aurangabad) is a constituent unit of MGM Institute of Health Sciences (MGMIHS) Deemed to be University, Kamothe, Navi-Mumbai, represented by Dean Dr. R.B. Bohra.

PREAMBLE

The project, **'Rotasiil® Vaccine Intussusception Surveillance in Kerala, Karnataka, Maharashtra and Gujarat, India'** funded by Bill and Melinda Gates Foundation, USA with the Christian Medical College (CMC), Vellore as the primary grantee, with the Translational Health Science and Technology Institute (THSTI), John Snow Inc. (JSI) and Centers for Disease Control and Prevention (CDC), Atlanta, USA as partners, will generate data on safety of Rotasiil® vaccine with respect to intussusception through Universal Immunization Program (UIP) in the states of Kerala, Karnataka, Maharashtra and Gujarat, India. The aforesaid project protocol is attached herewith as Appendix-I.

As rotavirus vaccines are introduced into the UIP in India, monitoring their safety is a high priority. A key issue for rotavirus vaccines is demonstration of safety, especially with regard to intussusception, an uncommon but serious intestinal blockage associated with previously licensed rotavirus vaccines. A low-level risk for intussusception has been identified with both internationally licensed rotavirus vaccines that are only available in the private sector in India. Given the low background incidence of IS and dearth of reliable data, the potential for vaccine-associated risk is best evaluated after public introduction. Implementing monitoring at healthcare facilities that recognize and manage cases of pediatric intussusception will facilitate the analysis of association between intussusception and Rotasiil®.

The purpose of this MoU is to ensure that each of the parties participating in the surveillance study have a common understanding of their obligations to collect and manage data pursuant to the study protocol.

ARTICLE 1

SCOPE OF THE WORK

Expected outcome:

This study will establish a sentinel site-based platform for systematic collection of data on epidemiology of intussusception in terms incidence rates, age group, seasonality, in children less than 2 years of age. Data from this sentinel system will be used to assess if vaccination with Rotasiil® is associated with an increased risk of intussusception.

Primary Objectives:

To describe the epidemiology (e.g. age distribution and seasonal patterns) of intussusception (IS) hospitalizations among children <2 years of age using sentinel hospital surveillance sites

To assess the potential risk of intussusception associated with Rotasiil® among vaccinated children.

To provide data biannually to the National Adverse events following immunization (AEFI) committee and to World Health Organization (WHO) country office of India, and seek to build enabling mechanisms for future linkage of research to national programs.

ARTICLE 2

RESPONSIBILITIES OF THE FIRST PARTY

The first party will serve as a **central coordinating unit** and has been tasked, *inter alia,* with the following responsibilities in order to ensure smooth execution of the deliverables as follows:

- Identify potential hospital sites for sentinel surveillance, engage in discussions and develop sub-contracts for financial support for the conduct of surveillance.
- Conduct training workshops for site surveillance teams
- Develop and provide electronic Case Report Forms (CRFs) for the surveillance sites.
- Coordinate monitoring and evaluation of implementation of study protocol in the sentinel sites.
- Coordinate with CDC for periodic summary reporting and data analysis.
- Coordinate meetings for data analysis and sharing.

The progress during the period of the study will be reviewed periodically by CMC and necessary mid-course corrections will be made to resolve the problems, if any, in any aspect pertaining to the study faced by partner institutions, or related agencies.

ARTICLE 3

RESPONSIBILITIES OF THE SECOND PARTY

By signing this MoU, the second party undertakes the following responsibilities

- Implement the study protocol to enroll all eligible cases of Intussusception during the specified period of the study.
- Maintain an intussusception log book as per the protocol.
- Obtain informed consent for enrollment of patients by trained project personnel.
- Complete eCRFs for each all enrolled patients in a timely fashion.
- Obtain a detailed immunization history from the patient's relatives and a vaccination card photocopy.
- Obtain a photocopy of, pre and post treatment, ultrasound reports and images from the hospital records.
- Obtain a photocopy of the procedure notes by the Surgeon/Radiologist from the hospital records.
- Provide a copy of intussusception log book and monthly report form to CMC Vellore.

ARTICLE 4

PUBLICATIONS

All data from the study will be published in peer-reviewed journals with the consent and approval from all site investigators and included in reports to the government and the World Health Organization.

No data will be published without inclusion of site investigators as co-authors on publications. Where ever appropriate, summary presentations of site data may be presented to national authorities, duly acknowledging sites.

Investigators will retain a soft copy of all eCRFs and can analyze their own data after the study period.

ARTICLE 5

DURATION OF MOU

The MoU will be valid for a period of three years. This MoU will take effect from the ## of ###, and will continue to be valid unless either or both of the parties disengage from the MoU.

ARTICLE 6

RESOLUTION OF DISPUTES

In case of any disputes, controversies or disagreements arising out of implementation of this MoU, either party may issue a notice in writing to the other party to reconcile. Both parties will use their best efforts to resolve such disputes through direct discussions which shall be held no later than 30 days of receipt of notice.

ARTICLE 7

FINANCIAL COMMITMENTS

Appendix-B

Application form / checklist: Key Components of an MoU or MoA

Go through this checklist ticking or giving details on all items that are relevant. (NB this can be filled as a soft copy word processor document)

	Component	Comment
1.	MOU/MOA Contact person in MGM Name: Emp. No.: Department:	Dr. Mohammad Haseeb Associate Professor, Pediatrics, MGM Medical College & Hospital, Aurangabad
2.	Title:	Rotasiil® Vaccine Intussusception Surveillance in Kerala, Karnataka, Gujarat and Maharashtra, India
3.	Name of partnering organisation	
4.	Describe the <u>partner</u>, is it: • Governmental / Non-Governmental? • Based in India or abroad? • If foreign based, is it also registered in India? • Public / Private / Corporate / NGO? • Non-profit or for-profit entity? • If an NGO, is it a trust, society, S12 Company? • A Christian organization? • What are its mission and goals? • Are these in alignment with CMC's mission and objectives? • Have they any hospital / healthcare activities? • Educational institutions: what are their fees for Undergraduate students - Medical / Nursing / Para – Medical? • Who will represent/sign on their behalf?	Non-Governmental India NA Private Non-Profit Trust NA NA NA Yes
5.	<u>Benefits and outputs</u>: Please specify anticipated outputs of this interaction both physical and intellectual and the plans on how this will be owned, shared and utilized in future What are the benefits for CMC students, faculty, other CMC staff? What if any is the likely benefit to the institution in the short and long term? How does this benefit CMC's Mission?	Preamble and Article 1
6.	Date of commencement (may be date of signing or some future date)	20 April 2020
7.	Main purpose	Article 1
8.	Subsidiary purposes / objectives / expected benefits	Article 1

Annexure II

BUDGET PROPOSAL FOR ROTASIIL® VACCINE INTUSSUSCEPTION SURVEILLANCE IN KERALA, KARNATAKA, MAHARASHTRA AND GUJARAT, INDIA (for 6 months)

A. Staff Salary	**Amount**
1. Medical Officer / Nurse	2,40,000
2. Field worker	90,000
B. Stationery and Internet charges	12,000
Non recurring • Ethical Committee charges • Institutional charges	Paid
C. Travel and Transport	
Transport charges for field workers (To arrange vaccine card copy) Courier charges for transport of documents to CMC	12,000 12,000
D. Overheads (5 %)	18,300
TOTAL	**3,84,300/-**

Total in words: Three lakh eighty-four thousand and three hundred only.

PRINCIPAL
Christian Medical College,
Vellore - 632 002, Tamil Nadu, India.

DEAN
MGM'S MEDICAL COLLEGE
AURANGABAD

CHALLAN
MTR Form Number-6

GRN	MH002568897202021P	BARCODE		Date	24/07/2020-11:42:50	Form ID	

Department	Inspector General Of Registration	**Payer Details**	
Type of Payment	Non-Judicial Stamps Duty on Imnpressing Documents SoS Mumbai only	**TAX ID / TAN (If Any)**	MUMP15856B
		PAN No.(If Applicable)	AADCP2043E
Office Name	BOM1_MUMBAI CITY 1 SUB REGISTRAR	**Full Name**	PPD Pharmaceutical Development India PvtLtd
Location	MUMBAI		
Year	2020-2021 One Time	**Flat/Block No.**	101 A wing Fulcrum
		Premises/Building	
Account Head Details	**Amount In Rs.**	**Road/Street**	Hiranandani Business Park Sahar Road
0030048201 Amount of Tax	820.00	**Area/Locality**	Andheri East
		Town/City/District	
		PIN	4 0 0 0 9 9
		Remarks (If Any)	GSK214094_India_ MGM Medical College and Hospital_ Dr Syed Qadri_ CTA
		Amount In Words	Eight Hundred Twenty Rupees Only
Total	820.00		

Payment Details	SBIEPAY PAYMENT GATEWAY	**FOR USE IN RECEIVING BANK**			
Cheque-DD Details		Bank CIN	Ref. No.	10000502020072400294	3219067887715
Cheque/DD No.		Bank Date	RBI Date	24/07/2020-11:43:17	Not Verified with RBI
Name of Bank		Bank-Branch		SBIEPAY PAYMENT GATEWAY	
Name of Branch		Scroll No. , Date		Not Verified with Scroll	

Department ID : Mobile No. : 8291277497

NOTE:- This challan is valid for document to be registered in Sub Registrar office only. Not valid for unregistered document.

सदर चलन केवळ दुय्यम निबंधक कार्यालयात नोदंणी करावयाच्या दस्तासाठी लागु आहे. नोदंणी न करावयाच्या दस्तांसाठी सदर चलन लागु नाही.

Print Date 24-07-2020 11:44:28

CLINICAL TRIAL AGREEMENT

THIS CLINICAL TRIAL AGREEMENT ("**Agreement**"), is entered into as of DATE of last signature, ("**Effective Date**") by and between

PPD Pharmaceutical Development India Private Limited, Office 101, A-Wing, Fulcrum, Hiranandani Business Park, Sahar Road, Andheri (East), Mumbai-400099, Maharashtra, India **(''PPD**").

and

Mahatma Gandhi Mission,s Medical College & Hospital, with its principal place of business at N-6,Cidco Aurangabad,431003,Maharashtra, India, represented by **Dr. Rajendra Bohra, The Dean**, a duly authorized representative with authority to contract on behalf of the Institution ("**Institution**")

and

Dr. Syed Umar Quadri, with his/her offices located at Mahatma Gandhi Mission's Medical College & Hospital N-6, Cidco Aurangabad,431003 Maharashtra,India("**Principal Investigator**").

And

Site Management Organization-Doclin Clinical Research Services (SMO), with its principal place of business at 445, Maruti Galli, Main Road, Hangarge, Mandoli – Belagavi-590010 Karnataka India represented by Mr. Maruti Patil, a duly authorized representative with authority to contract on behalf of the **SMO** (hereinafter referred to as the "SMO")

PPD, SMO, Institution and Principal Investigator are herein referred to each as a "**Party**" and, collectively, as the "**Parties**".

WHEREAS

I. PPD is a global contract research organization that is currently assisting **GlaxoSmithKline Research & Development Limited,** with its registered address at 980 Great West Road Brentford Middlesex, TW8 9GS UK ("**GSK**") or one of its Affiliates in the conduct of the clinical trial in accordance with the protocol entitled "**A randomized, double-blind, placebo-controlled, study evaluating the efficacy and safety of otilimab IV patients with severe pulmonary COVID-19 related disease"** ("**Clinical Trial**"), Protocol Number: **214094** and any amendments thereto ("**Protocol**"). GSK is the sponsor of the Clinical Trial. PPD is an Affiliate of PPD International Holdings Inc. and has been engaged by PPD International Holdings Inc. to support the performance of the Clinical Trial;

II. The Institution and Principal Investigator desire to participate in the conduct of the Clinical Trial, in accordance with the Protocol;

III Institution has authorized SMO to act as a payee in this Agreement and PPD has no obligation whatsoever to pay Institution or other service providers in the event SMO fails to reimburse Institution or other service provider for payments submitted by PPD to SMO hereunder.

IV. The Parties agree to conduct the Clinical Trial in accordance with the terms and conditions hereinafter set forth.

THEREFORE, IT IS AGREED AS FOLLOWS:

1. Clinical Trial Performance

1.1 Institution and Principal Investigator shall provide certain services ("**Services**") related to the conduct of the Clinical Trial, in accordance with the Protocol and any subsequent amendments made thereto in accordance with this Agreement, and with all applicable laws, rules and

regulations relating to the Clinical Trial. The Protocol is subject to approval by the appropriate Institutional Review Board or Ethics Committee or equivalent body (collectively "**IRB**"). The informed consent ("**Informed Consent**") is subject to approval by the IRB. If there is any discrepancy or conflict between the terms contained in the Protocol and this Agreement, the terms of the Protocol shall govern and control with respect to clinical matters and the terms of the Agreement shall govern and control with respect to all other matters.

1.2 Prior to the commencement of the Services, Institution and Principal Investigator shall review the Protocol and notify PPD if they cannot comply with any of the terms contained therein. If in the course of performing the Services, in accordance with generally accepted standards of clinical research and medical practice relating to the benefit, well-being and safety of the subjects ("**Subject(s)**") a deviation from the Protocol is required, such standards will be followed. In such case, the Party aware of the need for a deviation shall immediately notify PPD and GSK of the facts supporting such deviation as soon as the facts are known to such Party. The notification shall also be confirmed in writing within three (3) working days of the original notification being made to PPD and GSK.

1.3 The Institution and Principal Investigator agree to carry out the Services in strict compliance with:

(a) all specifications and timelines established in this Agreement;

(b) the Protocol and any amendments to the Protocol;

(c) the provisions of the current version of the World Medical Association's Declaration of Helsinki, in particular, neither the Institution nor the Principal Investigator must at any time jeopardise the health or well-being of any patient by unwarranted continuation of the Clinical Trial;

(d) applicable national laws, regulations and guidelines including without limitation the "Ethical Guidelines for Biomedical Research on Human Subjects" based on the ICH-GCP laid down by Indian Council of Medical Research (**ICMR**), and the Guideline for Good Clinical Practice (**GCP**) of the International Conference on Harmonisation (**ICH**) of Technical Requirements for the Registration of Pharmaceuticals for Human Use and with other generally accepted applicable Guidelines of the ICH a copy of which has been provided to Institution and Principal Investigator. (ICH Topic E6, Consolidated Guideline 1.5.96);

(e) the Clinical Trial is conducted under an Investigational New Drug (**IND**) the conditions specified in the Agreement and in accordance with New Drugs and Clinical Trials Rules, 2019 and

(f) Indian GCP and New Drugs and Clinical Trials Rules, 2019 Rule and its amendments.

(legislation identified in clauses c, d, e and f above hereinafter referred to as **Applicable Laws**)

1.4 The Clinical Trial shall be conducted only at the following location: Mahatma Gandhi Mission's Medical College & Hospital N-6, Cidco Aurangabad,431003 Maharashtra,India

1.5 The Institution agrees that the Clinical Trial will be conducted under the direction of the Principal Investigator in accordance with the Protocol and this Agreement.

1.6 The Principal Investigator will perform Services as agreed under this Agreement personally. In the event the Principal Investigator can no longer function in such capacity, then PPD and the Institution shall attempt to agree on a replacement. PPD shall have the right to approve any new Principal Investigator designated by the Institution. The new principal investigator shall be required to agree to the terms and conditions of this Agreement. If a mutually acceptable replacement cannot be agreed upon, PPD may terminate this Agreement in accordance with Clause 16.

1.7 The Institution and the Principal Investigator shall not subcontract any Services to another person or entity without PPD's prior written approval.

1.8 Notwithstanding anything herein to the contrary, if during the term of this Agreement, information that becomes available to PPD or GSK which affects the safety or efficacy of the Clinical Trial Product (as that term is defined at Clause 3.1 below), or if the Clinical Trial Product is approved by any regulatory agency, the Parties shall negotiate, in good faith, a modification of this Agreement to either (i) reduce the number of Subjects to be studied; and/or (ii) terminate the Clinical Trial, and/or (iii) modify any other relevant provision of this Agreement.

1.9 The Clinical Trial includes the collection by Institution of human biological materials from Clinical Trial Subjects for research use, Institution will comply with all Applicable Laws, rules, regulations and codes of practice and guidance relating to the collection, storage, use, shipping, and disposal of human biological materials in the conduct of the Clinical Trial and with respect to any such human biological materials from the Clinical Trial retained in Institution's possession. Institution and GSK will mutually agree to appropriate informed consent (including, as appropriate, for any genetic analyses) for the Clinical Trial and for research use of any human biological materials, with ethics approval. Institution agrees that any human biological materials collected as part of the Clinical Trial that are transferred to GSK or a GSK contractor, or held by Institution for GSK, will be under the custodianship and control of GSK.

1.10 Clinical Trial Staff Personal Information: All Processing of the Clinical Trial Staff Personal Information shall at all times comply with, and the parties will cooperate with each other to take the necessary measures to ensure adherence to Applicable Laws. Institution is responsible for supplying the Clinical Trial Staff with sufficient information regarding the collection of, handling, and use of their Personal Information by GSK. "**Clinical Trial Staff**" as used herein means the individuals providing services on behalf of Institution with respect to the Clinical Trial at Institution, including without limitation sub investigators, Clinical Trial coordinators, and other Institution employees, agents, or subcontractor. "**Personal Information**" as used herein means any information or set of information relating to a person that identifies such person or could reasonably be used to identify such person. Clinical Trial Staff Personal Information in this section includes the work contact information, and professional experience/educational background and qualifications that is routinely provided to and held by GSK in relation to a clinical study. "**Processing**" and its conjugates, including without limitation "**Process**" as used in this section means any operation or set of operations that is performed upon Personal Information, including without limitation collection, recording, retention, alteration, use, disclosure, access, transfer, storage or destruction.

2. Term of Clinical Trial

2.1 This Agreement shall take effect on the Effective Date and shall continue until each Party hereto has fully fulfilled its obligations towards the other Party ("**Expiration Period**"), unless terminated in accordance with Clause 16.

2.2 In the event that the Clinical Trial is extended beyond the Expiration Period, the Parties agree that such an extension will be covered by this Agreement and shall not necessitate any

amendment to this Agreement. Any continuation of the Services under this Agreement shall be confirmed in writing by PPD, prior to the Expiration Period.

2.3 Notwithstanding the above, the Services will not commence until PPD is granted appropriate IRB and regulatory approval and the Institution has received copies of said approvals.

2.4 Patient recruitment at the Institution is scheduled to start in **AUGUST 2020** and to be completed by the **30th of OCTOBER, 2020**. The Institution shall use its best efforts to complete Subject enrolment by **the 19th of OCTOBER, 2020.** The Institution is aware that enrollment is competitive in the Clinical Trial and Institution will be informed on the maximum number of Subjects through the duration of the Clinical Trial / ("**Enrolment Maximum**"). PPD may at any time modify this Enrollment Maximum or end enrollment at Institution at any time at PPD's discretion, including, but not limited to, upon the completion of the overall Study enrollment goal across all Study centers. The Institution will not enroll more Subjects than the Enrolment Maximum and neither PPD nor GSK will be obligated to make any payment with respect to any Subject enrolled in excess of the Enrolment Maximum unless otherwise approved in writing by PPD or GSK to exceed the Enrolment Maximum. If, during the Clinical Trial, it becomes apparent that Institution and/or Principal Investigator are not able to complete the Clinical Trial on schedule, they will notify PPD immediately.

2.5 In the event the Institution is unable to complete the enrolment by such date, PPD may reassign the Institution's enrolment slots, thereby reducing the number of Subjects enrolling at the Institution in the Clinical Trial. The Institution acknowledges that the Clinical Trial is part of a multi-center clinical trial. When the enrolment goal of **800** Subjects for the Clinical Trial as a whole is reached, enrolment will be closed at all institutions, including the Institution, regardless of whether the Institution or any other institution has reached its individual enrolment goal.

2.6 All Subject visits will be completed no later than **21ST OF DECEMBER. 2020** ("**Visits Completed Date**"). All electronic case report form ("**eCRF**") information associated with a Subject's visit must be satisfactorily completed within seven (2) calendar days after the Subject's visit or, if applicable, receipt of the Subject's test results. All final eCRF data will be entered into the eCRF and submitted to PPD no later than two (2) calendar days after the Study subject's final visit or, if applicable, receipt of the subject's final test results. All data queries from GSK must be completed and returned to GSK within seven (7) calendar days or, if during final clean up, one (1) calendar day, or such other time set by GSK. In all instances described in this clause, time is of the essence.

3. Supply of the Clinical Trial Product and Equipment

3.1 During the course of the Clinical Trial, PPD shall procure that GSK will provide the Institution with **GSK3196165 (otilimab)** ("**Clinical Trial Product**"), or other materials as GSK determines necessary for the conduct of the Clinical Trial (collectively, the "**Materials**").

3.2 The Parties acknowledge that GSK shall be responsible for packaging, labelling and shipping the Clinical Trial Product supplies to the Institution at GSK's own expense and in full compliance with all Applicable Laws.

3.3 The Clinical Trial Product will be distributed by GSK via a distribution depot to the Institution's pharmacy, which should already be aware of storage and conservation conditions required for the Clinical Trial Product.

3.4 The Principal Investigator and the Institution: (i) shall use the Materials only to conduct the Clinical Trial in accordance with the Protocol; (ii) shall not chemically, physically, or otherwise modify the Materials, except if specifically required by the Protocol; and (iii) shall

handle, store, and ship or dispose of the Materials with appropriate care in compliance with all applicable local, state, and federal laws, rules, and regulations including, but not limited to, those governing hazardous substances.

3.5 Upon termination of the Clinical Trial or this Agreement, all unused Materials provided by GSK shall be promptly returned at GSK's expense, to an address provided by GSK or, at GSK's option and expense, destroyed with the destruction certified in writing.

3.6 Any Materials provided by GSK or by PPD in the course of the Clinical Trial may not be transferred to any other location or to any third party without the prior written consent of PPD.

3.7 Equipment

(a) Loaned Equipment ("**Loaned Equipment**") means any equipment temporarily provided to Institution by PPD or GSK pursuant to this Agreement only for use in the Clinical Trial, including, but not limited to computer hardware and software if provided for the Principal Investigator and other Clinical Trial Staff to use, collect, enter, and report Clinical Trial data to GSK.

(b) Transferred Equipment ("**Transferred Equipment**") means any equipment permanently transferred to Institution by GSK or a GSK Affiliate pursuant to this Agreement, including, but not limited to computer hardware and software if provided for the Principal Investigator and Clinical Trial Staff to use, collect, enter, and report Clinical Trial data to GSK.

(c) If applicable, with respect to Loaned Equipment provided by GSK for use in the Clinical Trial, 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 Clinical Trial and only as described in the Protocol and any other written directions provided by PPD or GSK, that the Loaned Equipment will not be transferred by Institution to the possession of any third party without the written consent of GSK, and that, at the completion of the Clinical Trial or at GSK's request, Institution will return the Loaned Equipment and all related training materials and documentation to GSK or to a vendor designated by PPD or GSK.

(d) Principal Investigator and Clinical Trial 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 internet connection, telephone line, and/or facsimile line as necessary to use the Loaned Equipment. If Institution fails to return the Loaned Equipment within the timeframe specified by PPD or GSK, Institution will be responsible for reimbursing PPD for any penalties, late fees, and/or replacement costs.

(e) 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.

4. Obligations of the Parties

4.1 *Institution obligations*

Institution shall:

(a) be responsible for providing, at its sole cost and expense, the premises, adequate personnel, equipment (subject to Clause 3.7) and other resources necessary to conduct the Clinical Trial, in accordance with this Agreement, the Protocol and the conditions imposed by the IRB;

(b) ensure that the Principal Investigator observes current legislation, strictly complies with this Agreement, the Protocol, ethical regulations on clinical trials with medicines and collaborates in the performance of monitoring visits by PPD, audits by auditors appointed by PPD/GSK or its Affiliates and inspections by competent health authorities;

(c) promptly advise PPD as soon as possible if Institution observes or becomes aware of: (i) material non-compliance with the Protocol, ICH Good Clinical Practice guidelines, or any Applicable Laws, rules or regulations, (ii) incomplete or inaccurate recording of data or any significant misconduct, (iii) any changes of personnel, facilities or clinical research methods at the Institution that may affect the Clinical Trial, or (iv) any other matters, events, conditions or difficulties that may jeopardize the proper conduct of the Clinical Trial;

(d) notify PPD and the IRB, in writing, of any unanticipated or serious adverse reactions to the Clinical Trial Product, in accordance with Clause 11 below and the procedures set forth in the Protocol;

(e) maintain adequate records with respect to Clinical Trial Subject identification, clinical observations, laboratory tests, and Clinical Trial Product receipt and disposition;

(f) cooperate with PPD and GSK or its Affiliates in their efforts to monitor the Clinical Trial at the Institution premises;

(g) use the data obtained from the Clinical Trial Subjects only for the purposes and in connection with the Clinical Trial and as outlined in the Protocol; and

4.2 *Principal Investigator Obligations*

Principal Investigator shall:

(a) be responsible for overseeing all medical aspects of the Clinical Trial;

(b) ensure that the Clinical Trial activities are performed in accordance with the Protocol, the guidelines provided by the correspondent IRB, the terms of this Agreement and any other local applicable legislation to the performance of clinical trials in human subjects;

(c) oversee the submission of IRB and Ethical Approval;

(d) oversee the enrolment of patients at the Institution, in accordance with the inclusion/exclusion criteria defined in the Protocol;

(e) inform all individuals to be enrolled in the Clinical Trial before they agree to participate in the Clinical Trial about the purpose(s), methods and conditions of conducting the Clinical Trial, its expected therapeutic benefit and Clinical Trial-related risk;

(f) oversee and review all eCRFs for accuracy and completeness and to provide these forms and any other Clinical Trial data or samples to PPD in accordance with Clause 2.6 and in the format and manner agreed upon by the Parties and in an anonymised form;

(g) obtain an Informed Consent from each Subject recruited for the Clinical Trial (or if permitted, their legal representative), in accordance with this Agreement, applicable local laws and regulations. The form of such Informed Consent must be the most current form approved by the IRB, GSK and PPD, and must contain language necessary to permit regulatory agencies, the IRB, GSK and its Affiliates and PPD to have full access to and use of personally identifiable information, including patient health information, as defined in applicable privacy laws, rules and regulations and according to internationally recognized standards and data protection principles;

(h) not allow a Clinical Trial Subject to be enrolled simultaneously in this Clinical Trial and another clinical trial without PPD and GSK prior written approval;

(i) ensure that all Clinical Trial data, Clinical Trial records and eCRFs, including any documents which identify and link each Clinical Trial Subject to their eCRF, are stored securely, such that they are accessible only with the knowledge of the Institution and the Principal Investigator;

(j) promptly report (in writing) any serious or unexpected adverse events to the GSK, PPD and the IRB; in accordance with Clause 11 below and following the procedures set forth in the Protocol;

(k) notify GSK, PPD, and the IRB (if applicable), in writing, of any deviations from the Protocol;

(l) engage with GSK in the collaboration of the final report of the Clinical Trial, granting approval thereto upon signing it;

(m) report on the progress of the Clinical Trial to the IRB (as appropriate);

(n) perform the Services in accordance with the highest professional standards of skill, care and diligence and in compliance with all Applicable Laws and regulations;

(o) notify PPD of any provisions in its local law, or of any changes in that law, which do or could affect the Principal Investigator's ability to conduct the Clinical Trial or to perform his/her duties as defined in this Agreement;

(p) provide PPD with the complete results of the tests and all of the data obtained during the Clinical Trial;

(q) submit all data and other information related to the Clinical Trial in a timely manner;

(r) cooperate with PPD, GSK and its Affiliates and regulatory authorities in all their efforts to monitor the Clinical Trial and conduct audits and inspections;

(s) within twenty-four (24) hours of first knowledge of any SAE (as that term is defined at Clause 11.1 below), notify PPD, and the IRB, in writing, of any unanticipated or serious adverse reactions to the Clinical Trial Product and follow the procedures set forth in the Protocol and Clause 11;

(t) if he/she is not able to continue as Principal Investigator by reason of retirement, transfer or similar reasons, he/she shall provide written notice to PPD as soon as possible and at least within three (3) weeks of such departure; and

(u) inform the patients involved in the Clinical Trial that all their personal data collected through the Informed Consent form and other means will be kept in a file whose ownership correspond solely to GSK. Principal Investigator shall collect and process all personal data in accordance with applicable local regulation on personal data on behalf of GSK and only throughout the duration of the agreement signed with GSK and only for the purposes established in the said agreement.

4.3 PPD Obligations

PPD shall:

(a) be responsible for obtaining regulatory approval for the Clinical Trial and register a trial on Clinical Trials Registry – India (CTRI) National Institute of Medical Statistics.

(b) be responsible for the submission to the IRB and any competent regulatory authority;

(c) be responsible for the monitoring of the Clinical Trial;

(d) provide to the Institution the Protocol, Informed Consent forms and access to eCRFs; and

(e) inform the Institution and the Principal Investigator of chemical/pharmaceutical, toxicological, pharmacological and clinical data and results to justify the design and duration of the Clinical Trial.

4.4 SMO Obligations

SMO shall

(a) act as a payee in this Agreement for payments payable to Institution/Principal Investigator

5. Funding of the Clinical Trial and Payments

5.1 As consideration for the performance under the terms and conditions of this Agreement, PPD will pay the Institution via SMO in accordance with **Exhibit A**. Institution will not be compensated for any Subjects who were enrolled without a properly executed informed consent form or who do not meet the inclusion/exclusion criteria for the Clinical Trial. The Institution shall be responsible for compensating all other entities and individuals who were involved in the conduct of the Clinical Trial, including (without limitation) the Principal Investigator and the Clinical Trial Staff.

5.2 Payments under this Agreement are pass-through payments from GSK. PPD shall make payment to the Institution via SMO, in accordance with **Exhibit A**.

5.3 Payments are dependent upon the reports and other information pursuant to Clauses 4.1 and 4.2 being submitted in a timely and satisfactory manner. Payment for partially completed Services, e.g, early withdrawal of Subject, shall be made on a pro-rata basis for Services performed according to **Exhibit A**. No payment will be due or paid for Services performed that are deemed violations of or deviations from the Protocol or this Agreement.

5.4 Invoices are payable within sixty (60) days following receipt of a valid invoice, as described in the payment terms of **Exhibit A**.

5.5 Payments for Services rendered under this Agreement shall be made in full in accordance with the Agreement, without deductions for taxes of any kind. Any taxes due and payable as a result of the payments by PPD to the Institution shall be Institution's sole responsibility and Institution shall pay all such taxes for which it is liable in a timely manner.

5.6 PPD will reimburse the Institution for travel costs incurred by Subjects in accordance with **Exhibit A**.

5.7 The Institution acknowledges and agrees that it shall be solely responsible for paying the appropriate amount of all local taxes/GST with respect to all fees and compensation paid pursuant to this Agreement.

5.8 SMO, Institution and Principal Investigator agree that GSK or its Affiliates may make public the amount of funding provided to the Institution by PPD for the conduct of the Clinical Trial and may identify the SMO,Institution and the Principal Investigator as part of this disclosure. Institution has obtained the Principal Investigator's consent to this disclosure.

5.9 Statement of Investigator Financial Interest form

The Principal Investigator hereby acknowledges the requirements of the FDA Financial Disclosure Rule and agrees to fill in and return to PPD, upon PPD or PPD representative's request, the Statement of Investigator Financial Interest form before the start of the Clinical Trial. The Principal Investigator also consents to the disclosure of the so filled Form to the FDA if necessary.

5.10 Institution and Principal Investigator shall not charge any Subject or third-party payor for Clinical Trial procedures required by the Protocol that are paid for by PPD or GSK under this Agreement or for any Clinical Trial Product that is provided or paid for by PPD or GSK under this Agreement.

5.11 All of PPD's payment obligations are conditioned upon Institution reporting to PPD and/or GSK all data required by the Protocol and other governing documents for the Clinical Trial, including all adverse events, and upon Institution's compliance with standards identified in this Agreement.

5.12 The amounts paid under this agreement are bona fide fair market value compensation for the work conducted under this Agreement. The Parties agree that no payments by PPD pursuant to this agreement shall be passed in whole or in part, directly or indirectly, to any third party as a rebate or discount for the purchase of GSK products. Notwithstanding the foregoing, commercially reasonable payments to a subcontractor who is performing Services under the terms of this Agreement that meet the criteria for bona fide Services are not considered to be a pass-through rebate or discount payments (even if the subcontractor is a GSK customer).

6. Clinical Trial Subject

6.1 Informed Consent of each of the Subjects participating in the Clinical Trial shall be obtained in accordance with applicable local laws and regulations in India, including completion of the approved Informed Consent form, which has been approved by the IRB. The Institution/Principal Investigator shall administer the Clinical Trial Product only to Subjects from whom Informed Consent has been properly obtained by the Principal Investigator under Clause 4.2(g) and this Clause 6. The Institution/Principal Investigator shall maintain adequate documentation of its obtainment of the Informed Consent of each Subject.

6.2 PPD, the Institution and the Principal Investigator shall hold in confidence the identity of the Subjects and shall comply with all Applicable Laws regarding the confidentiality of their identities and their individual medical records.

6.3 The method of explanation to the patient and the obtaining of consent should be conducted in accordance with the directions of the IRB and is a Principal Investigator responsibility. Each Subject shall be provided with their own copy of the patient information sheet (hard copy or electronic copy) which they can retain for their own records.

6.4 Data Rights of Subjects

(a) The parties agree that, as between them, Institution is best able to manage requests from Subjects for access, amendment, transfer, blocking, or deletion of Personal Information. In the event GSK receives a request from a Subject for such access, amendment, transfer, blocking, or deletion, GSK shall forward the request to Institution.

(b) Institution shall respond to Subjects' requests for access, amendment, transfer, blocking, or deletion of Personal Information in accordance with Applicable Laws and the Agreement. Institution acknowledges that in order to maintain the integrity of Clinical Trial results, the ability to amend, block, or delete Personal Information may be limited, under Applicable Laws.

(c) GSK acknowledges that Subjects may withdraw their informed consent to Clinical Trial participation and consent to Processing of Personal Information at any time as described in the Informed Consent Form signed by the Subject. Institution shall promptly notify GSK of any such withdrawal that may affect the use of the Personal Information under the Agreement. Institution will use its best efforts to clarify what the Subject's expectations are if the Subject withdraws from the Clinical Trial, including what forms of communication the Institution may use to follow-up with the Subject, if any, about their Subject's status after withdrawing from the Clinical Trial.

(d) The obligations of this Section 6.4 shall survive termination of this Agreement.

7. Clinical Trial Results and Intellectual Property

7.1 The Parties are in agreement that all of the Materials and data gained through the conduct of the Services shall be the property of GSK.

7.2 GSK shall exclusively own all rights, title ("**Rights**") in and to any invention, and interest in and to inventions (in any clinical specimens or samples obtained from the Subject), discoveries, know-how, patents (whether patentable or not), copyright, trade secrets and other intellectual rights, including but not limited to inventions, discoveries and technology relating to the Clinical Trial Product or otherwise generated by the Clinical Trial (collectively, "**Inventions**"). The Institution and Principal Investigator hereby irrevocably transfer and assign any and all their Rights in any Invention to GSK. The Inventions will be the sole property of GSK.

7.3 The Institution and Principal Investigator agree to: (i) immediately notify in writing to PPD of any Invention, and (ii) to cooperate and assist GSK to apply for and to execute applications, assignments, affidavits, or other documents, reasonably necessary to obtain any patent, copyright, trademark or other statutory protection for the Inventions, as GSK deems appropriate, and (iii) to treat all Inventions as confidential information in accordance with Clause 8.

7.4 Neither the Institution nor the Principal Investigator shall acquire any rights of any kind with respect to the Inventions or to the Clinical Trial Product.

7.5 The obligations of this Clause shall survive after the term or termination of this Agreement.

8. Confidential Information

8.1 Institution/Principal Investigator and their employees and agents and third parties involved in the Clinical Trial by the Principal Investigator and/or Institution shall not disclose to any third party or use for any purposes other than for the performance of the Clinical Trial any data, records or other information (hereinafter, collectively "**Information**") disclosed to Institution/Principal Investigator by GSK or PPD or generated as a result of this Clinical Trial without the prior written consent of GSK and shall sign a written non-disclosure agreement. Such Information shall remain the confidential and proprietary property of GSK and shall be disclosed only to Institution/Principal Investigator and their employees or agents who have a "need to know". The obligation of nondisclosure shall not apply to the following Information:

(a) that is generally known to the public or that becomes publicly available through no act or omission on the part of Institution/Principal Investigator;

(b) that is disclosed to Institution/Principal Investigator by a third party legally entitled to disclose such information;

(c) which the Institution/Principal Investigator, as applicable, can demonstrate that it possessed prior to, or developed independently from, disclosure or development of this Agreement;

(d) that is required by law to a government authority or by order of a court of competent jurisdiction, provided that (i) such disclosure is subject to all applicable governmental or judicial protection available for like material; (ii) reasonable advance notice is given to GSK; and (iii) all reasonable steps to limit the scope of such disclosure have been taken.

8.2 The obligations of this Clause shall survive after the term or termination of this Agreement.

9. Publications

9.1 GSK will post a Clinical Trial Protocol summary on a publicly available protocol register prior to the enrollment of Subjects.

9.2 GSK will post a Clinical Trial results summary on a publicly available results register no later than twelve (12) months following completion of the Clinical Trial at all Clinical Trial sites as defined in the Clinical Trial Protocol. Posting of summary Clinical Trial results may occur prior to publication of Clinical Trial results in the peer-reviewed literature. GSK will also post full Clinical Trial Protocol and statistical analysis plan at the time of results summary posting.

9.3 GSK will seek to publish the Clinical Trial results in the searchable, peer reviewed scientific literature. First publication and all subsequent publications of the Clinical Trial results from all Clinical Trial sites ("**GSK Publication(s)**") or disclosure(s) of the Clinical Trial results shall be coordinated by GSK.

9.4 Any participation of Principal Investigator or other representatives of Institution as a named author of this GSK Publication will be determined in accordance with the International Committee of Medical Journal Editors ("**ICMJE**") Uniform Requirements for Manuscripts

(or if more stringent, the authorship criteria of the specific journal). Institution and Principal Investigator acknowledge that the enrolment of Subjects alone is not a qualification for authorship. If the Principal Investigator or other representative of Institution is a named author of the GSK Publication, as an author (s)he: (1) will enter into a written author agreement prior to the beginning of the work on the GSK Publication; (2) will have access to the Clinical Trial data from all Clinical Trial sites as necessary to fully participate in the development of the GSK Publication; and (3) will disclose as part of the GSK Publication that GSK financially supported the Clinical Trial and the GSK Publication, and will disclose any personal financial relationship with GSK. GSK will not compensate authors for authorship activities.

9.5 If considered appropriate by GSK, the Principal Investigator or other Institution personnel involved with the Clinical Trial may participate in the Publication Steering Committee ("**PSC**") or core writing team(s) for the Clinical Trial or in public presentations of the Clinical Trial results. Persons participating as a member of a PSC, in core writing team(s)' activities or in public presentation of the Clinical Trial results will not receive any payment, honorarium or other fee for participation in such activities nor ownership to nor other title or interest in work product arising out of such activities. However, GSK will reimburse such persons or the Institution (as the case may be and as advised by such persons) for their reasonable travelling and lodging expenses while travelling at GSK's request, provided that travel and lodging expenses have been authorized by GSK in writing in advance and that GSK receives proper original receipts.

9.6 Institution and Principal Investigator agree that GSK may make public the names of the Principal Investigator and the Institution as part of a list of investigators and institutions conducting the Clinical Trial when making either Protocol or results summary register postings. Institution and Principal Investigator agree that GSK may make public the amount of funding provided to Institution by GSK for the conduct of the Clinical Trial and may identify Institution and Principal Investigator as part of this disclosure. Principal Investigator agrees that when (s)he speaks publicly or publishes any article or letter about a matter related to the Clinical Trial or Clinical Trial Product or that otherwise relates to GSK, Principal Investigator will disclose that he/she was an investigator for the Clinical Trial.

9.7 Once the Clinical Trial is published in a scientific journal, GSK may list the Clinical Trial on an external website for patient-level data sharing for further research and may also make available the full Clinical Trial report on the GSK register.

9.8 Institution, consistent with scientific standards and in a scientific forum, may publish or present the Clinical Trial results from site's Clinical Trial data (an "**Institution Publication**"), provided that the Institution Publication does not also disclose any GSK Confidential Information other than the Clinical Trial results from Institution's Clinical Trial data. Institution shall submit to GSK for review and comment any proposed Institution Publication at least thirty (30) days prior to submitting the Institution Publication to any third party. If GSK requests a delay in order to file patent applications relating to new investigational product, Institution agrees to delay submitting the Institution Publication to any third party for up to one hundred twenty (120) days after GSK's request. Institution also agrees that any Institutional Publication shall only be made after the GSK Publication, and consistent with any limitations and restrictions that may apply, provided that the GSK Publication is submitted within eighteen (18) months after last subject last visit at all sites as defined in the Clinical Trial Protocol. The Institution Publication will reference the GSK Publication(s). Institution agrees that GSK's financial support of the Clinical Trial will be disclosed in any Institution Publication. Institution shall ensure that Principal Investigator complies with the obligations identified in this subsection.

9.9 Subjects' personal Information, such as name or initials, shall not be publicly disclosed at any time.

9.10 The obligations of this Section shall survive termination of this Agreement.

10. Data Protection and Security

10.1 Institution and Principal Investigator shall comply and shall require any of the persons or entities performing the Services on their behalf to comply, with all Applicable Laws, rules, regulations, and guidelines governing the privacy of personally identifiable information and patient health information in India.

10.2 PPD guarantees that the Protocol establishes the mechanisms that allow the disassociation of data with a personal nature of the Subjects participating in the Clinical Trial.

10.3 Institution assures PPD and GSK that the Principal Investigator shall inform the Subjects involved in the Clinical Trial that all their personal data collected through the Informed Consent form and other means will be kept in a file which is owned by GSK. All personal data collected shall be treated with the privacy, confidentiality and safety measures established by the relevant applicable regulation.

10.4 All parties shall comply with all Applicable Laws, including without limitation all Applicable Laws relating to the privacy and security of Personal Information and shall implement appropriate technical and organizational measures in such a manner that Processing will meet the requirements of the General Data Protection Regulation ("**GDPR**") and ensure the protection of the rights of the data subject.

10.5 With respect to the coded Clinical Trial data provided to GSK, the Institution and GSK are both considered data controllers for the Processing of the Personal Information and will both act in accordance with the Applicable Data Protection Law.

10.6 Before Processing any Personal Information each party shall ensure, taking into account industry good practice, the costs of implementation and the nature, scope, context and purpose of Processing, as well as the risk of varying likelihood and severity for the rights and freedoms of natural persons, that appropriate technical and organizational controls are in place to prevent unauthorized or unlawful Processing of any Personal Information it may hold and to protect any such Personal Information from accidental loss, damage or destruction.

10.7 Security Breaches

(a) Notification of Security Breaches. The parties agree to notify each other without undue delay after of discovery of a Security Breach.

i. Notice of a Security Breach to GSK, will be sent via e-mail to **csir@gsk.com**
ii. Notice of a Security Breach to Institution will be sent to **mgmmca@themgmgroup.com**

(b) In the course of notification to each other, the parties will provide, as feasible, sufficient information for the parties to jointly assess the Security Breach and make any required notification to any government authority within the timeline required by Applicable Data Protection Laws. Such information may include, but is not necessarily limited to:

i. The nature of the Security Breach the categories and approximate number of data subjects and records;
ii. The likely consequences of the Security Breach, in so far as consequences are able to be determined; and

iii. Any measures taken to address or mitigate the incident.

(c) The parties will jointly decide on the basis of all available information and Applicable Laws if the Security Breach will be considered a reportable Security Breach and arrange for notification to data subjects and/or government authorities if required by Applicable Laws. Where the parties decide that notification is required by Applicable Data Protection Laws, the party that incurred the Security Breach shall be responsible for providing such notification.

(d) Assistance in Event of Security Breach. In the event of a Security Breach relating to the Personal Information and/or GSK Confidential Information collected or received by a party under this Agreement, the receiving party agrees to assist and fully cooperate with the sending party with any internal investigation or external investigation by third parties, such as law enforcement, through the provision of information, employees, interviews, materials, databases, or any and all other items required to fully investigate and resolve any such incidents and provide information necessary to provide required notifications. The breached party agrees to take such remedial actions as the parties mutually agree is warranted.

(e) Neither party shall disclose, without the other party's prior written approval, any information related to the suspected Security Breach to any third party other than a vendor hired to investigate/mitigate such Security Breach and bound by confidentiality obligations, except as required by Applicable Laws.

(f) Institution agrees to indemnify GSK, for all losses resulting from any Security Breach due to negligence or wilful misconduct by Institution, its agents, its Affiliates, or any vendor retained by Institution, including but not limited to legal damages, government penalties, and/or mitigation expenses.

11. Adverse Events Reporting

11.1 For the purposes of this Agreement an Adverse Event ("**AE**") shall mean any untoward medical occurrence whether thought to have been caused by the Materials or the Clinical Trial or not and Serious Adverse Event ("**SAE**") shall mean any adverse event which is fatal, life threatening, disabling or incapacitating, requires in-patient treatment or prolongs existing hospitalization, is a congenital anomaly in the off-spring of the patient or which may require intervention to prevent the previously stated outcomes.

11.2 Any SAE must be reported as defined in the Protocol within twenty-four (24) hours of first knowledge of any SAE and using the eCRF. This applies also for any event that could affect the safety of the Clinical Trial participants or the conduct of the Clinical Trial.

11.3 The Institution is responsible for ensuring that the Principal Investigator notifies GSK, the Institution and the Responsible Ethics Committee of any Adverse Events (including Serious Adverse Events) that occur during the course of the Clinical Trial in accordance with the Protocol, and relevant ethical and regulatory guidelines, and in the case of the Institution and the Responsible Ethics Committee with their policies and procedures.

11.4 Nothing in this Agreement shall remove or restrict any obligation on Institution and/or Principal Investigator to report clinical safety information arising during the Clinical Trial to the regulatory authorities in India, in accordance with the local requirements or comply with any other legal or administrative obligation in connection with the Clinical Trial.

11.5 The Institution shall monitor the Subjects in accordance with the Protocol. The Institution shall require the Principal Investigator to promptly (within twenty-four (24) hours of the occurrence of any SAE) report via the electronic eCRF all SAEs that may be associated with the administration of the Clinical Trial Product that occurs during the course of the Clinical

Trial. Failure to comply with this Clause shall constitute reasonable grounds for PPD to terminate this Agreement as provided in Clause 16.

11.6 GSK maintains its own Investigator Brochure(s) ("**IB(s)**") for the Clinical Trial Product(s) being investigated under the Clinical Trial, so GSK will provide these IB(s), and any updates and/or supplements to these IB(s), to the Institution during the course of the Clinical Trial for information purposes.

11.7 GSK agrees to reimburse the Institution/Principal Investigator for reasonable and necessary medical expenses incurred as a direct result of diagnosing and treating of an SAE related to the Clinical Trial Product and Clinical Trial related procedure and incurred during the course of the Clinical Trial, provided that the Clinical Trial Product was administered in accordance with the Protocol and the SAE did not occur as a direct result of the Institution or Principal Investigator's negligence or misconduct. The Institution/Principal Investigator agrees to treat any such illness or injury. Payments will be made following an invoice per treatment and confirmation by GSK or PPD that the treatment has been performed as a result of such SAE. Institution or Principal Investigator will provide all information reasonably requested by GSK or PPD to confirm such treatment.

11.8 Without prejudice to the foregoing if injury is suffered by a Subject while participating in the Clinical Trial, the GSK agrees to operate in good faith in accordance with the guidelines entitled "GlaxoSmithKline's – Clinical Trial Compensation Guidelines" (refer **Exhibit C**) and New Drugs and clinical trials rules, 2019, and the Principal Investigator shall make clear to the Subjects that the Clinical Trial is being conducted subject to these Guidelines.

12. Recordkeeping and Audits

12.1 The Institution and Principal Investigator shall keep complete and systematic data related to the Clinical Trial and the Services performed and any other records generated as a part of this Agreement for a minimum period of twenty-five (25) years from the issue date of the Clinical Trial report/summary or equivalent. GSK will inform the Principal Investigator of the date on which the GSK required retention period will expire.

12.2 Upon the expiration of the above time period, Institution is responsible for complying with any remaining relevant local, organizational, state, national and/or regulatory guidelines for records retention. If, at any time during the retention period, Investigator and/or Institution are unable to comply with the record retention responsibilities in this Section (e.g., Principal Investigator retirement; Principal Investigator is no longer employed by or associated with Institution; or, Institution site closure), Principal Investigator or Institution shall transfer responsibility for record retention to another party at the Institution or to a third party off-site archive facility. Principal Investigator or Institution must provide written notice to PPD and/or GSK prior to such transfer which specifies the name and address of the new responsible party and, if applicable, the new file location address.

12.3 During the Institution's regular business hours and with reasonable advance notice, PPD, GSK or its Affiliates or their designee may audit the Institution's records, facilities, equipment, or procedures related to Institution's obligations under this Agreement. Such audits may include, without limitation, Institution's records related to the Clinical Trial and the performance of the Services, in order to verify Institution's compliance.

12.4 If any governmental or regulatory authority notifies the Institution/Principal Investigator that it will inspect Institution's records, facilities, equipment, or procedures, or otherwise take action related to the Clinical Trial and/or the Services under this Agreement, Institution/Principal Investigator shall co-operate with the authority and notify PPD and GSK as soon as is practicable (to the extent possible, within two (2) business days and prior to the inspection or action), allow

the authority to conduct an inspection or take other legal action, allow PPD and GSK to be present at the inspection or participate in any response to the action, and provide PPD with copies of any reports issued by the authority and Institution's proposed response for GSK's prior review and approval (such approval not to be unreasonably withheld).

13. Insurance

13.1 PPD declares that an insurance policy to cover the conduct of the Clinical Trial, in pursuance of current national laws, is in place. Said policy shall be maintained and updated throughout the duration of the Clinical Trial.

13.2 The insurance of the GSK does not relieve the Investigator, Institution and/or their agents participating in the Clinical Trial from their obligation to be liable and responsible to GSK and PPD for their own negligence and wilful misconduct, or their failure to adhere to the terms of the Protocol or any laws or regulation applicable to the Clinical Trial. The Principal Investigator and Institution each represent and warrant that they possess, through insurance or otherwise sufficient financial resources to meet their obligations under this Agreement. The Institution shall provide evidence of its insurance upon request by PPD.

14. Representations and Warranties

14.1 Institution and Principal Investigator represent and warrant to the best of their knowledge, that the Institution and the Principal Investigator are not bound by any other agreement which could prevent, or be violated by, or under which there would be a default as a result of, the execution and performance of this Agreement, and that each will not enter into any such conflicting agreements during the term of this Agreement.

14.2 Institution represents and warrants that all persons involved in the Clinical Trial and the Principal Investigator (i) have not been debarred or convicted of a crime which could lead to debarment under any applicable law, rule or regulation; (ii) have not been disqualified as a testing facility under applicable local regulation; or (iii) are not disqualified as a clinical investigator under applicable local regulation. If such persons later become debarred or receive notice of any action or threat of action with respect to debarment and Institution/Principal Investigator gain knowledge thereof, PPD will immediately be notified.

14.3 Institution shall indemnify GSK and PPD against all direct losses, damages, liabilities and expenses (including legal expenses) incurred by PPD and/or GSK as a result of any breach of the warranties contained in this Clause.

14.4 Principal Investigator hereby warrants that he is authorized to perform the Services at the Institution premises under his/her own name and that the performance of the correspondent agreement and the acceptance of any payments is not in violation of legal or internal regulations of the Institution or other entity to which Principal Investigator is associated or any agreement to which Principal Investigator is bound. Likewise, Principal Investigator further warrants that he/she has obtained all required consents from and/ or filed all required notifications to/from the Institution board or other regulatory or self-regulatory authority, board or committee.

15. Limitation of Liability and Indemnification

15.1 Institution and Principal Investigator shall indemnify, defend and hold harmless PPD and GSK and its Affiliates from any and all losses, injuries, harm, costs or expenses, including without limitation, reasonable attorney's fees, incurred by PPD or GSK or its Affiliates as a result of the negligence or wilful misconduct of Institution and/or Principal Investigator**.**

15.2 A Party shall give written notice to the other Parties as soon as is practicable of the details of any claim or proceedings brought or threatened against it by a third party in respect of which a claim will or may be made under Clause 15.1 above.

15.3 Upon request by Institution and/or Principal Investigator, indemnification of Institution and Principal Investigator by GSK shall be governed by a separate letter agreement between GSK, Institution and Principal Investigator.

15.4 Nothing in this Clause 15 or otherwise in this Agreement shall exclude or in any way limit Institution' liability for (i) fraud, (ii) death or personal injury caused by its negligence; and (iii) any liability to the extent the same may not be excluded or limited as a matter of law.

15.5 No Party shall be liable to the other Parties for any punitive, exemplary damages or for an indirect or consequential loss or damage resulting from any breach of this Agreement even if the other Parties have been advised of the possibility of such damages.

15.6 Each Party's agreement to indemnify and hold the other Party or Parties harmless is conditional 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 ten (10) 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 or demand, (iii) assisting the indemnifying Party, at the indemnifying Party's reasonable expense, in the investigation of, preparation for and defence of any such claim or demand, and (iv) not compromising or settling such claim or demand without the indemnifying Party's written consent.

15.7 The obligations of this Clause shall survive termination of this Agreement.

16. Termination

16.1 PPD may terminate this Agreement at any time, without cause, by giving thirty (30) days written notice to the Institution and Principal Investigator if any of the following conditions occur:

(a) the authorization and approval to perform the Clinical Trial in India is withdrawn by the IRB or any other competent authority;

(b) if PPD's agreement with GSK is terminated;

(c) if available data indicate that it is not safe to continue to administer the Clinical Trial Product to Subjects;

(d) if overall Clinical Trial enrolment has not been met, even if the enrolment at the Institution has not been completed;

(e) the Principal Investigator is unable to continue, and an acceptable successor is not agreed upon;

(f) adherence to the Protocol is poor, or Clinical Trial data recording is chronically inaccurate or incomplete;

(g) the Clinical Trial is terminated;

(h) material breach of this Agreement; or

(i) by mutual agreement of the Parties.

16.2 In the event this Agreement is terminated for any reason prior to the end of the Clinical Trial, the Institution shall take all reasonable steps required by PPD, including communicating with the Subjects, to facilitate completion of the Clinical Trial at an alternative clinical site designated by PPD. In such event, PPD will (except where the termination was as a result of the breach by the Institution of its obligation under this Agreement) reimburse the Institution for its reasonable direct costs incurred in connection with such transfer, as well as for reasonable non-reimbursed costs incurred and non-cancellable commitments made prior to the receipt by the Institution that the Agreement will be terminated.

16.3 Termination of this Agreement by any Party shall not affect the rights and obligations of the Parties that have accrued prior to the effective date of the termination.

17. Effect of Termination

17.1 In the event of termination, the sum payable under this Agreement shall be limited to prorated fees based on actual Services performed pursuant to the Protocol as determined in accordance with **Exhibit A**.

17.2 Upon completion of the Clinical Trial or earlier termination thereof, Institution and/or Principal Investigator shall ensure that all data, information, reports and Clinical Trial results are properly recorded in eCRFs and submitted to PPD, and shall return to PPD all Information.

17.3 Upon completion of the Clinical Trial or early termination thereof, all unused Clinical Trial Product, and/or Materials furnished to Institution and/or Principal Investigator by or on behalf of GSK or PPD shall be returned to PPD or GSK, as described in Clause 3.

17.4 Immediately upon receipt of a notice of termination, Institution and Principal Investigator shall cease entering Subjects into the Clinical Trial, cease conducting procedures to the extent medically permissible on Subjects already entered into the Protocol, and refrain from incurring additional costs and expenses to the extent possible

17.5 All provisions of this Agreement that by their nature would be expected to survive termination of this Agreement shall survive such termination, including - but not limited to – Clauses 1, 2, 3, 4, 5, 7, 8, 9, 10, 11, 12, 14, 15, 16, 17, 18, 19 and 20.

18. Compliance with Laws and Human Rights

18.1 Each Party shall perform its obligations under this Agreement in a manner that complies with all applicable international, national and local laws in relation to, or otherwise relevant to, its obligations under this Agreement and shall promptly notify the other Parties if it receives a written allegation of non-compliance with any such law by any person which relates to its performance of such obligations.

18.2 Institution and the Principal Investigator (the "**Site**") agree to the terms of **Exhibit B**.

18.3 Each Party expressly agrees that this Agreement is the result of arms-length negotiations, and that neither Party has entered into this Agreement with a corrupt motive to obtain or retain business or to secure an unfair business advantage.

18.4 Each Party hereby warrants and undertake that they shall at all material times keep and maintain accurate and up to date accounting records to ensure that all transactions relating to this Agreement are sufficiently documented.

18.5 Respectful of its employees right to freedom of association, Institution represents and warrants, to the best of its knowledge, that in connection with this Agreement, it respects the human rights of its staff and does not employ child labor, forced labor, unsafe working conditions, discrimination of protected characteristic or cruel or abusive disciplinary practices in the workplace; and that it pays each employee at least the minimum wage, provides each employee with all legally mandated benefits, and complies with the Applicable Laws on working hours and employment rights in the countries in which it operates. Institution shall be respectful of its employee's right to freedom of association, and Institution shall encourage compliance with these standards by any supplier of goods or services that it uses in performing its obligations under this Agreement.

19. Applicable law and competent jurisdiction

19.1 This Agreement shall be governed by and interpreted in accordance with the laws of India.

19.2 The Parties, expressly waiving any other jurisdiction to which they might be entitled, agree to submit any disputes arising out or in connection with this Agreement (whether of a contractual or non-contractual nature) to the Courts of India.

20. Miscellaneous

20.1 Independent Contractor

The Institution, including its agents and employees, shall be an independent contractor at all times, and shall not be an agent of PPD or GSK and shall have no actual, apparent or implied authority to bind PPD or GSK in any manner or to any obligation whatsoever. The Principal Investigator shall not be or be deemed to be an employee of PPD or GSK and shall not be entitled to any benefits available to employees of PPD or GSK.

20.2 Assignment

Institution shall not assign this Agreement in whole or in part to any other Party and shall not appoint any other person as Principal Investigator without PPD's written consent. PPD may assign this Agreement in whole or in part, including to any corporate parent, affiliate or subsidiary of PPD, without the Principal Investigator's/Institution's consent.

This Agreement shall be binding upon the Parties, their legal representatives, successors and permitted assigns. Institution and Principal Investigator acknowledge and agree that GSK and each of its Affiliates is a third party beneficiary to this Agreement and shall be entitled to enforce all of the rights and benefits of this Agreement at all times as if it were a party to this Agreement.

20.3 Use of Name

No Party shall make (or have made on its behalf) any oral or written release of any statement, information, advertisement or publicity in connection with this Agreement which uses the other Parties names, symbols, or trademarks without the other Parties prior written approval.

20.4 Notices

(a) All notices under this Agreement shall be sent by registered or certified mail, postage prepaid, or by overnight courier service. Notices may be sent by facsimile or e-mail, if confirmed by also sending as described above.

(b) Notices pertaining to this Agreement shall be sent to:

If to Institution:
Attn.:**Dr. Rajendra Bohra**
Title: The Dean
Mahatma Gandhi Mission's Medical College & Hospital
N-6,Cidco,
Aurangabad,431003,Maharashtra,
India
Tel.:0240-2481437,0240-2482235
Fax: 0240-2482235
E-mail address:
mgmmca@themgmgroup.com

If to PPD:
Attn.: Rashmi Chitgupi
Title: Associate Director, Clinical Management
PPD Pharmaceutical Development India Private Limited
101, A-Wing, Fulcrum, Hiranandani Business Park, Sahar Road, Andheri (East), Mumbai-400099, Maharashtra, India
Tel.: +91 22 4247 2900
Fax: +91 22 4248 6900
E-mail address: Rashmi.Chitgupi@ppdi.com

If to the Principal Investigator:
Attn.: **Dr Syed Umar Quadri**
Mahatma Gandhi Mission's Medical College & Hospital
N-6,Cidco,
Aurangabad,431003,Maharashtra,
India
Tel.: 9923798702
Fax: 0240-2482235
E-mail address:
umarazmed@gmail.com

If to the SMO:
Attn.: Mr. Maruti Patil
Doclin Clinical Research Services
445,Maruti Galli,Main Road, Hangrage Mandoli Belagavi-590008 Karnataka
Tel.: 9591358733
E-mail :maruti.patil171@gmail.com

20.5 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 in any way be affected.

20.6 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 any Party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by any Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

20.7 Force Majeure

If any Party is delayed in performing an obligation under this Agreement by strike, lockout, or other labor troubles of a third party; by restrictive governmental or judicial order not directly related to this Agreement; or by riots, insurrection, war, inclement weather, or Acts of God; performance is excused for the period of such delay. The delayed Party shall promptly notify the other Parties in writing of the delaying event.

20.8 Entire Agreement

This Agreement and its exhibits constitute the entire agreement and understanding between the Parties with respect to the subject matter hereof and supersedes any prior agreement, understanding or arrangement between the Parties, whether oral or in writing. No representation, undertaking or promise shall be taken to have been given or be implied from

anything said or written in negotiations between the Parties prior to this Agreement except as expressly stated in this Agreement.

20.9 Miscellaneous

(a) For the purposes of this Agreement, "Affiliate" means any entity that controls, is controlled by, or is under common control with, a party to this Agreement. In this context, "control" shall mean (i) ownership by one entity, directly or indirectly, of at least forty percent (40%) of the voting stock of another entity; (ii) power of one entity to direct the management or policies of another entity, by contract or otherwise; or (iii) any other relationship between GSK or Institution and an entity which GSK and Institution have agreed in writing may be considered an "Affiliate" of GSK or Institution (as the case may be).

(b) PPD or GSK may provide supportive measures to strengthen the Institution's research capacity for the benefit of the community. PPD, GSK and the Institution agree that any of these measures that may be provided by PPD or GSK are not intended to be for the exclusive benefit of the Clinical Trial or of GSK studies generally, or to induce the Institution to participate in the Clinical Trial or to induce or reward any use, purchase, recommendation, or prescription of GSK products. GSK and the Institution also agree that any of these measures that may be provided by PPD or GSK are intended to be sustainable by the Institution and the local community following the Clinical Trial.

(c) GSK and/or PPD and the Institution have sought agreement with key interested external parties, including ethics committees, research investigators, national government, health ministry, local health authorities, ethics groups, non-governmental organisations, or representatives of the communities who might participate in the Clinical Trial, that it is appropriate to conduct the Clinical Trial at the Institution, including discussion of the standard of care to be provided during the Clinical Trial, the scientific rationale for interventions (including placebo), the provision of healthcare for subjects after the Clinical Trial, and the fate of any capacity built for the conduct of the Clinical Trial.

(d) The Institution agrees that any nationally-licensed medicinal products that are not the subject of the Clinical Trial but are required for the routine care of a Clinical Trial subject during and after the Clinical Trial for the disease or condition to which the Clinical Trial relates are expected to be available to the Clinical Trial Subject and funded through the usual operations of the local healthcare system independently from the Clinical Trial and without expectation of GSK support.

20.10 **Counterparts and Electronic Signatures.:** This Agreement and all associated amendments may be executed in counterparts, each of which shall be deemed an original and all of which together shall constitute one and the same instrument. Each party may execute this Agreement and all amendments by electronic signature (whatever form the electronic signature takes) or in Portable Document Format (or other file format) sent by electronic means. Signatures of authorized signatories of the parties completed by electronic signature or sent by electronic means in Portable Document Format shall have the same force and effect as manual signatures, shall be valid and binding, and, upon delivery, shall constitute due execution of this Agreement any amendments hereunder.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

FOR INSTITUTION – Mahatma Gandhi Mission's Medical College & Hospital

Name: Dr. Rajendra Bothra
Position: Dean
Date: 31 Jul 2020

DEAN
MGM'S MEDICAL COLLEGE
AURANGABAD

FOR PPD - PPD Pharmaceutical Development India Private Limited

Name:
Position:
Date:

BY PRINCIPAL INVESTIGATOR

Name: Dr. Sayed Umar Quadri
Position: Associate Professor
Date: 31st Jul 2020

Dr. SYED UMAR QUADRI
M.B.B.S. M.D. (MED.)
Asst. Prof. of Medicine
MGM Medical College & Hospital A'bad.
REG NO. 2005/02/0904

BY SMO- Doclin Clinical Research Services

Name: Mr. Maruti Patil
Position: Managing Director
Date: 27-Jul-2020

EXHIBIT A

BUDGET AND PAYMENT SCHEDULE

Payment by PPD shall be made payable to the payee and at the address indicated on the PAF form or other applicable form provided to PPD prior to the execution of this Agreement ("Payee") as follows:

Payee Name:	Doclin Clinical Research Services
Payee Address:	445, Maruti Galli, Main Road, Hangarge, Mandoli – Belagavi 590008 Karnataka India
Bank Information and Routing number as applicable:	Bank Name: Axis Bank, Nehrunagar Belagavi-590010 Karnataka India Account Number:919020049795418 IFSC Code- UTIB0001690 Swift Code: CHASUS33
GST Number:	29AZXPP8818R1ZP

Institution may request to revise the payee details provided herein during the course of the Study. In such cases, the parties agree that no amendment to this Agreement shall be required provided that Institution provides written notification to PPD with the revised payee details and, if applicable, a revised PAF(Payment Authorization Form). The parties further agree that PPD assumes no liability for incorrect payee details provided by Institution.

Cost per Subject: The amount to be paid to the Payee per completed subject is outlined on the Exhibit A-1, less ten percent (10%) withholding. Payments will be made on a quarterlybasis in Indian Rupees and will be based on completed visits, verified as applicable in the subject electronic case report forms (eCRFs).

Enrollment: Institution shall apply best efforts for enrollment in accordance with the Study subject eligibility criteria specified in the Protocol for up to a maximum of thirty (30) Study subjects. With the express, written pre-approval of the Sponsor, the Institution may enroll beyond these thirty (30) randomized subjects into the study

Study Start-Up Fee: A one-time non-refundable Start-Up Payment at the rate set forth in Exhibit A-1, for Study Start-Up Activities, will be payable to SMO based on full execution of this document, proper completion and submission to GSK or GSK designated vendor of all regulatory documents as defined by the GSK Study team for the Study, including, but not limited to, and financial disclosure documents as well as IRB submission. The receipt of a correct and itemized invoice must be received prior to payment.

Screen Failures: The Payee will be paid for twenty (20) screen fails (as defined below) without pre-approval from Sponsor and may be paid up to a maximum of thirty (30) with express pre-approval from Sponsor. Payee will be reimbursed in accordance with the rates set forth for the Screening visit in the Budget, as verified in the CRF. For purposes of this Agreement, a Screen Failure shall mean any subject, who initially appears to meet the criteria for pre-screening, signs the informed consent form, completes the pre-screening and/or screening visit but does not randomize into the Study.

IRB Fees: Central IRB is defined as the IRB selected and paid by the Sponsor. Local IRB Fees will be submitted to PPD by the Institution and reimbursed by PPD directly to the Payee upon the receipt of correct and itemized invoices.

Record Storage and Archiving: A one-time record storage and archiving fee at the rate set forth in Exhibit A-1 will be paid to the SMO for purposes of compliance with this Agreement. SMO will be paid

this fee upon execution of this Agreement, confirmation of IRB meeting and approval, and completion of pre-Study requirements as specified by Sponsor or PPD/its designee.

Pharmacy Start-Up Fees: Payee will receive a one-time fee at the rate set forth in Exhibit A-1 to cover set-up of the pharmacy services on this Study. The pharmacy start-up fees will be payable upon PPD's receipt of a correct and itemized invoice from Payee.

Unscheduled visits: An "Unscheduled Visit" shall be defined as a Study subject visit which is not expressly set forth in the Protocol, but is otherwise required for the Study. Unscheduled Visits will be paid at the rates set forth in Exhibit A-1 upon PPD's receipt of correct and itemized invoices.

Loaned Equipment: Loaned Equipment described as follows:
eConsent logpads will be provided to sites by vendor, DrugDev (IQVIA) and must be returned to vendor at Institution close out.

Invoices: All correct and itemized invoices pertaining to this Study should be addressed to PPD and submitted quarterly for reimbursement to the following:

PPD Pharmaceutical Development India Private Limited, Office 101, A-Wing, Fulcrum, Hiranandani Business Park
Sahar Road, Andheri (East)
Mumbai-400099, Maharashtra
INDIA
GSKROWInvestigatorPayments@ppdi.com

All invoices must include the following:

- Institution Name and Address
- Protocol Number
- Investigator Name
- Invoice Date
- Invoice Number
- Clear description of items being invoiced, subject numbers, date of service, and if applicable supporting documentation (including but not limited to receipts, to and from addresses, invoices from vendors, etc.)
    - NOTE! DO NOT include any subject identifiers, other than subject numbers, in the invoice or back-up details. Subject names, initials, addresses, phone numbers, ages, and birthdates will need to be redacted on back-up details, receipts, and vendor forms to ensure patient privacy before sending to PPD
- Correct amount listed for each invoiced item
- Total amount being invoiced
- Payee information including name and address for sending payment (this should match the payment information listed in this Agreement)

All invoices for Study payments, as outlined in this budget and payment schedule, must be submitted to PPD within ninety (90) days of the Institution's Study close-out visit. Invoices received after this time will not be reimbursed.

GST: All fees payable by PPD will be exclusive of GST and similar indirect taxes as per the existing rules in India. PPD will pay the vendor on receipt of a legal tax invoice raised according to the terms of this agreement and the indirect tax / GST laws applicable in India

Final Payment: The final payment, which corresponds to the remaining ten percent (10%) of costs, shall be made upon completion of the close-out visit and upon receipt of (i) all completed and corrected case report forms and queries, of (ii) all Study documentation, of (iii) all unused Study drug

has been accounted for and (iv) all study equipment and supplies returned as specified by PPD and Sponsor. PPD must be notified of any discrepancies within ninety (90) days from receipt of final payment.
If at the completion of the Study, PPD has advanced sums under the terms of this Agreement that exceed the earned amount for all Study subject visits completed, Payee shall reimburse PPD within sixty (60) days any amount by which amounts advanced by PPD exceed the fees earned.

No other additional funding requests will be considered without the prior written consent of GSK.

Exhibit A-1

Budget Information

Total Cost per Patient: 727,291.50

Location: India

Institution: MGM medical College and Hospital

Overhead Percent: 30.00%

PI: Dr.Syed Umar Quadri

Currency: INR - Indian Rupee

Procedures

Name	OH?	Selected Cost	Screening	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 15	Day 16	Day 17
Informed consent	Y	3,000.00	3,000.00																	
Eligibility assessment	Y	1,500.00	1,500.00																	
Thoracic CT scan or Chest X-Ray	Y	SOC	SOC																	
Demography	Y	900.00	900.00																	
Medical history	Y	SOC	SOC																	
Daily clinical features of COVID-19 (for non-mechanically ventilated participants)	Y	2,300.00		2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00
Initial Full physical examination	Y	SOC	SOC																	
Follow up Full physical examination	Y	SOC																		
12-lead ECG	Y	500.00	500.00	500.00																
Blood pressure and pulse	Y	SOC	SOC	SOC																
Respiratory Rate and temperture	Y	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC
SpO2 (for participants not on invasive mechanical ventilation)	Y	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC
Concentration of inspired oxygen (FiO2) and / or oxygen flow rate (L/min)	Y	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC
Ordinal scale	Y	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00
SOFA score (for ICU)	Y	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC
AE review	Y	1,000.00		1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00
Concomitant medication review	Y	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00
Survival follow-up	Y	2,000.00																		
Hematology	Y	500.00	500.00	500.00	500.00		500.00			500.00							500.00			
Chemistry	Y	3,000.00	3,000.00	3,000.00	3,000.00		3,000.00			3,000.00							3,000.00			
Lactate	Y	900.00	900.00	900.00	900.00		900.00			900.00							900.00			
Troponin	Y	1,200.00	1,200.00	1,200.00	1,200.00		1,200.00			1,200.00							1,200.00			
D-dimer	Y	1,400.00	1,400.00	1,400.00	1,400.00		1,400.00			1,400.00							1,400.00			
CRP	Y	1,103.00	1,103.00	1,103.00	1,103.00		1,103.00			1,103.00							1,103.00			
Ferritin	Y	2,800.00	2,800.00							2,800.00							2,800.00			
Procalcitonin	Y	2,378.00	2,378.00							2,378.00							2,378.00			
ESR	Y	519.00	519.00							519.00							519.00			
Coagulation	Y	1,355.00	1,355.00	1,355.00	1,355.00		1,355.00			1,355.00							1,355.00			
Pregnancy Test - Serum	Y	800.00	800.00																	
PD Sample (Cytokines)	Y	3,000.00	3,000.00		3,000.00		3,000.00			3,000.00										
PK sample	Y	3,000.00		3,000.00	3,000.00					3,000.00							3,000.00			
Spec Handling (simple)	Y	1,500.00		1,500.00	1,500.00					1,500.00							1,500.00			
IV dosing with otilimab or placebo	Y	9,000.00		9,000.00																
Per Patient Activity Totals:			27,555.00	29,458.00	22,958.00	6,000.00	18,458.00	6,000.00	6,000.00	28,655.00	6,000.00	6,000.00	6,000.00	6,000.00	6,000.00	6,000.00	25,655.00	6,000.00	6,000.00	6,000.00

Name	OH?	Selected Cost	Day 18	Day 19	Day 20	Day 21	Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28	Discharge/Early Withdrawal	Follow-up Phone call (Day 42)/ Early Withdrawal	Follow-up Phone call (Day 60)/ Early Withdrawal	Day 14 Phone Visit if Subject is discharged	Day 28 Phone Visit if Subject is discharged
Informed consent	Y	3,000.00																
Eligibility assessment	Y	1,500.00																
Thoracic CT scan or Chest X-Ray	Y	SOC																
Demography	Y	900.00																
Medical history	Y	SOC																
Daily clinical features of COVID-19 (for non-mechanically ventilated participants)	Y	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00	2,300.00
Initial Full physical examination	Y	SOC																
Follow up Full physical examination	Y	SOC												SOC				
12-lead ECG	Y	500.00												500.00				
Blood pressure and pulse	Y	SOC												SOC				
Respiratory Rate and temperture	Y	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC				
SpO2 (for participants not on invasive mechanical ventilation)	Y	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC				
Concentration of inspired oxygen (FiO2) and / or oxygen flow rate (L/min)	Y	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC				
Ordinal scale	Y	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00	2,000.00
SOFA score (for ICU)	Y	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC	SOC				
AE review	Y	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00	1,000.00
Concomitant medication review	Y	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00	700.00
Survival follow-up	Y	2,000.00												2,000.00	2,000.00	2,000.00	2,000.00	2,000.00
Hematology	Y	500.00											500.00	500.00				
Chemistry	Y	3,000.00											3,000.00	3,000.00				
Lactate	Y	900.00											900.00	900.00				
Troponin	Y	1,200.00											1,200.00	1,200.00				
D-dimer	Y	1,400.00											1,400.00	1,400.00				
CRP	Y	1,103.00											1,103.00	1,103.00				
Ferritin	Y	2,800.00																
Procalcitonin	Y	2,378.00																
ESR	Y	519.00																
Coagulation	Y	1,355.00											1,355.00	1,355.00				
Pregnancy Test - Serum	Y	800.00												800.00				
PD Sample (Cytokines)	Y	3,000.00																
PK sample	Y	3,000.00																
Spec Handling (simple)	Y	1,500.00																
IV dosing with otilimab or placebo	Y	9,000.00																
Per Patient Activity Totals:			6,000.00	6,000.00	6,000.00	6,000.00	6,000.00	6,000.00	6,000.00	6,000.00	6,000.00	6,000.00	15,458.00	18,758.00	8,000.00	8,000.00	8,000.00	8,000.00

Non Procedures

Name	OH?	Selected Cost	Screening	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 15	Day 16	Day 17
Physician's Fees without Exam Costs	Y	5,000.00	7,500.00	7,500.00	7,500.00	5,000.00	6,250.00	5,000.00	5,000.00	10,000.00	5,000.00	2,500.00	2,500.00	2,500.00	2,500.00	2,500.00	10,000.00	2,500.00	2,500.00	2,500.00
Study Coordinator Fee Per Visit	Y	3,000.00	4,500.00	4,500.00	4,500.00	3,000.00	4,500.00	3,750.00	3,000.00	6,000.00	3,000.00	1,500.00	1,500.00	1,500.00	1,500.00	1,500.00	6,000.00	1,500.00	1,500.00	1,500.00
Pharm Disp p/visit (use w/infusion)	Y	1,000.00		1,000.00																
Per Patient Other Direct Cost Totals:			12,000.00	13,000.00	12,000.00	8,000.00	10,750.00	8,750.00	8,000.00	16,000.00	8,000.00	4,000.00	4,000.00	4,000.00	4,000.00	4,000.00	16,000.00	4,000.00	4,000.00	4,000.00

Overall Patient Cost

	Screening	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment
	Screening	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10	Day 11	Day 12	Day 13	Day 14	Day 15	Day 16	Day 17
Costs Charged before overhead	39,555.00	42,458.00	34,958.00	14,000.00	29,208.00	14,750.00	14,000.00	44,655.00	14,000.00	10,000.00	10,000.00	10,000.00	10,000.00	10,000.00	41,655.00	10,000.00	10,000.00	10,000.00
Overhead at 30%	11,866.50	12,737.40	10,487.40	4,200.00	8,762.40	4,425.00	4,200.00	13,396.50	4,200.00	3,000.00	3,000.00	3,000.00	3,000.00	3,000.00	12,496.50	3,000.00	3,000.00	3,000.00
Selected Cost Per Visit	51,421.50	55,195.40	45,445.40	18,200.00	37,970.40	19,175.00	18,200.00	58,051.50	18,200.00	13,000.00	13,000.00	13,000.00	13,000.00	13,000.00	54,151.50	13,000.00	13,000.00	13,000.00

Non Procedures

Name	OH?	Selected Cost	Day 18	Day 19	Day 20	Day 21	Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28	Discharge/Early Withdrawal	Follow-up Phone call (Day 42)/ Early Withdrawal	Follow-up Phone call (Day 60)/ Early Withdrawal	Day 14 Phone Visit if Subject is discharged	Day 28 Phone Visit if Subject is discharged
Physician's Fees without Exam Costs	Y	5,000.00	2,500.00	2,500.00	2,500.00	2,500.00	2,500.00	2,500.00	2,500.00	2,500.00	2,500.00	2,500.00	6,250.00	6,250.00	6,250.00	6,250.00	5,000.00	5,000.00
Study Coordinator Fee Per Visit	Y	3,000.00	1,500.00	1,500.00	1,500.00	1,500.00	1,500.00	1,500.00	1,500.00	1,500.00	1,500.00	1,500.00	3,750.00	3,750.00	3,750.00	3,750.00	3,000.00	3,000.00
Pharm Disp p/visit (use w/infusion)	Y	1,000.00																
Per Patient Other Direct Cost Totals:			4,000.00	4,000.00	4,000.00	4,000.00	4,000.00	4,000.00	4,000.00	4,000.00	4,000.00	4,000.00	10,000.00	10,000.00	10,000.00	10,000.00	8,000.00	8,000.00

Overall Patient Cost

	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Treatment	Discontinuation	Follow Up	Follow Up	Treatment	Treatment
	Day 18	Day 19	Day 20	Day 21	Day 22	Day 23	Day 24	Day 25	Day 26	Day 27	Day 28	Discharge/Early Withdrawal	Follow-up Phone call (Day 42)/ Early Withdrawal	Follow-up Phone call (Day 60)/ Early Withdrawal	Day 14 Phone Visit if Subject is discharged	Day 28 Phone Visit if Subject is discharged
Costs Charged before overhead	10,000.00	10,000.00	10,000.00	10,000.00	10,000.00	10,000.00	10,000.00	10,000.00	10,000.00	10,000.00	25,458.00	28,758.00	18,000.00	18,000.00	16,000.00	16,000.00
Overhead at 30%	3,000.00	3,000.00	3,000.00	3,000.00	3,000.00	3,000.00	3,000.00	3,000.00	3,000.00	3,000.00	7,637.40	8,627.40	5,400.00	5,400.00	4,800.00	4,800.00
Selected Cost Per Visit	13,000.00	13,000.00	13,000.00	13,000.00	13,000.00	13,000.00	13,000.00	13,000.00	13,000.00	13,000.00	33,095.40	37,385.40	23,400.00	23,400.00	20,800.00	20,800.00
														727,291.50		

Site Level Other Direct Costs

Name	OH?	Selected Cost
Archiving/Document storage/per site	N	200,000.00
Pharmacy set-up fee	N	60,000.00
Site Start-up Costs	N	75,000.00

Invoiceable Procedures

Name	Selected cost	Overhead	Total incl OH
Re-consent Process, per patient	3,000.00	900.00	3,900.00
SAE Review	5,907.00	1,772.10	7,679.10
Pregnancy Test -Urine	500.00	150.00	650.00
Hospitalisation Fees(ICU)/day	9,000.00	2,700.00	11,700.00

EXHIBIT B

GSK ANTI-BRIBERY AND ANTI-CORRUPTION TERMS

1. Institution agrees that it shall comply fully at all times with all applicable laws and regulations, including but not limited to anti-corruption laws, and that it has not, and covenants that it will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorise, ratify or offer to make, or take any act in furtherance of any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting it or GSK in obtaining or retaining business, or in any way with the purpose or effect of public or commercial bribery, and warrants that it has taken reasonable measures to prevent subcontractors, agents or any other third parties, subject to its control or determining influence, from doing so. For the avoidance of doubt this includes facilitating payments, which are unofficial, improper, small payments or gifts offered or made to Government Officials to secure or expedite a routine or necessary action to which we are legally entitled.

2. Institution shall not contact, or otherwise knowingly meet with any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement, without the prior approval of GSK and, when requested by GSK, only in the presence of a GSK designated representative.

   For the purpose of this Agreement "Government Official" (where 'government' means all levels and subdivisions of governments, i.e. local, regional, national, administrative, legislative, executive, or judicial, and royal or ruling families) means: (a) any officer or employee of a government or any department, agency or instrumentality of a government (which includes public enterprises, and entities owned or controlled by the state); (b) any officer or employee of a public international organisation such as the World Bank or United Nations; (c) any officer or employee of a political party, or any candidate for public office; (d) any person defined as a government or public official under applicable local laws (including anti-bribery and corruption laws) and not already covered by any of the above; and/or; (e) any person acting in an official capacity for or on behalf of any of the above. "**Government Official**" shall include any person with close family members who are Government Officials (as defined above) with the capacity, actual or perceived, to influence or take official decisions affecting GSK business.

3. Institution shall inform GSK in writing, if, during the course of this Agreement, it is convicted of or pleads guilty to a criminal offense involving fraud or corruption or becomes the subject of any government investigation for such offenses, or is listed by any government agency as debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for government programs.

4. Institution represents and warrants that except as disclosed to GSK in writing prior to the commencement of this Agreement: a) none of their significant shareholders (>25% shareholding) or senior management have influence over GSK's business; (b) no significant shareholders (>25% shareholding), members of senior management team, members of the Board of Directors, or key individuals who will be responsible for the provision of goods / services are currently or have been in the past two years, a Government Official with actual or perceived influence which could affect GSK business; (c) it is not aware of any immediate relatives (e.g. spouse, parents, children or siblings) of the persons listed in the previous clause (b) having a public or private role which involves making decisions which could affect GSK business or providing services or products to, or on behalf of GSK; (d) it does not have any interest which directly or indirectly conflicts with its proper and ethical performance of this Agreement; and (e) it shall maintain arm's length relations with all third parties with which it deals for or on behalf of GSK in performance of this Agreement. Institution shall inform GSK in writing at the earliest possible opportunity of any conflict of interest as described in this subsection #4 that arises during the performance of this Agreement.

5. GSK shall have the right during the term of this Agreement to conduct an audit of Institution's activities under this Agreement to monitor compliance with the terms of this Agreement.

Institution shall cooperate fully with such audit, the scope, method, nature and duration of which shall be at the sole reasonable discretion of GSK.

6. Institution shall ensure that all transactions under the Agreement are properly and accurately recorded in all material respects on its books and records and each document upon which entries such books and records are based is complete and accurate in all material respects. Institution must maintain a system of internal accounting controls reasonably designed to ensure that it maintains no off-the-books accounts.

7. Institution agrees that in the event that GSK believes that there has been a possible violation of the terms of this **Exhibit B**, GSK may make full disclosure of such belief and related information at any time and for any reason to any competent government bodies and its agencies, and to whomsoever GSK determines in good faith has a legitimate need to know.

8. GSK shall be entitled to terminate the Agreement immediately on written notice to Institution, if Institution fails to perform its obligations in accordance with this **Exhibit B**. Institution shall have no claim against GSK for compensation for any loss of whatever nature by virtue of the termination of this Agreement in accordance with this **Exhibit B**.

EXHIBIT C

GLAXOSMITHKLINE'S – CLINICAL TRIAL COMPENSATION GUIDELINES

GlaxoSmithKline (GSK) will adhere to the following broad guidelines in the event of injury caused to the patient attributable to participation in the trial in question.

1. **Basic Principles**

1.1 Notwithstanding the absence of legal commitment, GSK will pay compensation to the patient-volunteers suffering Clinical Trial related injury (including death) in accordance with these guidelines.

1.2 Compensation will be paid when, on the balance of probabilities, the injury was attributable to the administration of a medicinal product under study or any clinical intervention or procedure provided for by the protocol that would not have occurred but for the inclusion of the Subject in the Clinical Trial.

1.3 Compensation will be paid to the child injured in utero through the participation of the Subject's mother in a clinical trial as if the child were a patient-volunteer with the full benefit of these guidelines.

1.4 Compensation will only be paid for the more serious injuries of an enduring and disabling character (including exacerbation of an existing condition) and not for temporary pain or discomfort or less serious or curable complaints.

1.5 Where there is an adverse reaction to a medicinal product under study and injury is caused by the procedure adopted to deal with the adverse reaction, compensation will be paid for such injury as if it were caused directly by the medicinal product under study.

1.6 Neither the fact that the adverse reaction causing the injury was foreseeable or predictable, nor the fact that the patient has freely consented (whether in writing or otherwise) to participate in the Clinical Trial should exclude a patient from consideration for compensation under these guidelines, although compensation may be abated or excluded in the light of the factors described in paragraph 4.2 below.

1.7 For the avoidance of doubt, compensation will be paid regardless of whether the Subject is able to prove that GSK has been negligent in relation to research or development of the medicinal product under study or that the product is defective and therefore, as the producer, GSK is subject to strict liability in relation of injuries caused by it.

2. **Types of Clinical Research Covered**

2.1 These guidelines apply to injury caused to patients involved in Phase II and Phase III trials, that is to say, patients under treatment and surveillance (usually in hospital) and suffering from the ailment which the medicinal product under trial is intended to treat but for which the product license does not exist or does not authorize supply for administration under the conditions of the trial.

2.2 These guidelines do not apply to injuries arising from studies in non-patient volunteers (Phase I), whether or not they are in hospital, for which separate guidelines for compensation already exist at the facility where the Clinical Trial is carried out

2.3 These guidelines do not apply to injury arising from clinical trials on marketed products (Phase IV) where a product licence exists authorising supply of administration under the conditions of the trial, except to the extent that the injury is caused to a patient as a direct result of procedures undertaken in accordance with the protocol (but not any product administered) to which the patient would not have been exposed had treatment been other than in the course of the trial. These guidelines do not apply to post-marketing surveillance and ancillary care.

2.4 These guidelines do not apply to clinical trials which have not been initiated or directly sponsored by GSK. Where trials of products are initiated independently by doctors, responsibility for the health and welfare of patients rests with the doctor alone (see also paragraph 5.2 below).

3. Limitations

3.1 Compensation will not be paid to research participants receiving placebo in consideration of its failure to provide a therapeutic benefit.

3.2 Compensation will not be paid for natural progression of an underlying disease.

3.3 Compensation will not be available for adverse effects due to concomitant medications allowed as per protocol/routine procedures as part of standard of care.

3.4 No compensation should be paid for the failure of a medicinal product to have its intended effect or to provide any other benefit to the patient.

3.5 No compensation should be paid for injury caused by other licensed medicinal products administered to the patient for the purpose of comparison with the product under trial.

3.6 No compensation should be paid (or it should be abated as the case may be) to the extent that the injury has arisen:

(a) through a significant departure from the agreed protocol;

(b) through a wrongful act or default of a third party, including a doctor's failure to deal adequately with an adverse reaction;

(c) through a contributory negligence by the patient.

3.7 Compensation may not be provided if it is determined (by the Investigator and the IEC) that the injury has arisen through:

(a) wrongful act or default of a third party;

(b) contributory negligence by the research participant (e.g. wilful or reckless non-adherence to protocol procedures/instructions by the research participants as described in the ICDs).

4. Assessment of Compensation

4.1 The amount of compensation paid should be appropriate to the nature, severity and persistence of the injury and should in general terms be consistent with the quantum of damages commonly awarded for similar injuries by the Indian Courts in cases where legal liability is admitted.

4.2 Compensation may be abated, or in certain circumstances excluded, in the light of the following factors (on which will depend the level of risk the patient can reasonably be expected to accept):

(a) the seriousness of the disease being treated, the degree of probability that adverse reaction will occur and any warnings given;

(b) the risks and benefits of established treatments relative to those known or suspected of the trial medicine.

This reflects the fact that flexibility is required given a particular patient's circumstances. As an extreme example, there may be patient suffering from a serious or life-threatening disease who is warned of a certain defined risk of adverse reaction. Participation in the trial is then based on an expectation that the benefit/risk ratio associated with participation may be better than that associated with alternative treatment. It is, therefore, reasonable that the patient accepts the high risk and should not expect compensation for the occurrence of the adverse reaction of which he or she was told.

4.3 In any case where GSK concedes that a payment should be made to a Subject but there exists a difference of opinion between GSK and patient as to the appropriate level of compensation, GSK shall seek at its own cost (and make available to the patient) the opinion of a mutually acceptable independent expert, and that his/her opinion should be given substantial weight by GSK in reaching its decision on the appropriate payment to be made.

5. **Miscellaneous**

5.1 Claims pursuant to the guidelines should be made by the Subject to GSK, preferably via the Principal Investigator, setting out details of the nature and background of the claim and, subject to the Subject providing on request an authority for GSK to review any medical records relevant to the claim. GSK should consider the claim expeditiously.

5.2 The undertaking given by GSK extends to injury arising (at whatever time) from all administration, clinical interventions or procedures occurring during the course of the Clinical Trial but not to treatment extended beyond the end of the Clinical Trial at the request of the Principal Investigator. The use of unlicensed products beyond the trial period is wholly the responsibility of the treating doctor.

5.3 The fact that GSK has agreed to abide by these guidelines in respect of a Clinical Trial does not affect the right of a Subject to pursue a legal remedy in respect of injury alleged to have been suffered as a result of participation. Nevertheless, patients will normally be asked to accept that any payment made under the guidelines will be in full settlement of their claims.

5.4 GSK should encourage the investigator to make clear to participating Subjects that the Clinical Trial is being conducted subject to GSK's guidelines relating to compensation for injury arising in the course of clinical trials and the copy of these guidelines should be made available to the participating Subjects.

EXHIBIT D
PAYMENT AUTHORIZATION FORM

All fields are **mandatory** unless indicated otherwise

NB **IF YOU HAVE COMPLETED THIS FORM BEFORE, YOU NEED ONLY COMPLETE IT AGAIN IF ANY OF YOUR DETAILS HAVE CHANGED**

Payee or Investigator Details

Description (CTMS Field) (Finance Field)	**Payee or Investigator Information**	Max Chars for Finance Field Incl. Spaces
Payee Name *(in terms of the provisions of the Statement of Agreement):*	**Doclin Clinical Research Services**	80
(To whom should the transfer be made payable to?) **N.B. This must be the exact payee as it appears on the bank account**		
Street Address of Payee (Address Line 1) (Address 1)	**445, Maruti Galli, Main Road, Hangarge, Mandoli**	30
Department Name (if applicable): (Address Line 2) (Address 2)	**NA**	30
Room / Floor (if applicable) (Address Line 3) (Address 3)	**NA**	30
Other Address Details (if applic.) (Address Line 4) (Address 4)	**NA**	30
Country (Country) (Country)	**India**	2 *ISO Code*
State / Province (if Applicable) (State / Province) (State or Province)	**Karnataka**	2
Town/City (City) (City or Address 5)	**Belagavi**	18
Postal Code (Zip/Postal Code) (Postal Code)	**590008**	10
Contact name for payee if different from above	**Mr. Maruti Patil**	30
Telephone	**+91-9591358733**	27
Fax	**NA**	27
E-mail	**Maruti.patil171@gmail.com**	60
Web page	**NA**	60

Service / VAT / Tax Withholding Details

(Please note that payments cannot be made without these fields being completed):

Service / VAT / Sales Tax

Are you GST Registered	**YES**		*Delete where applicable*
If no Reason			

If **YES**, please provide the following information

GST No,	29AZXPP8818R1ZP
At what % rate GST be charged?	18%

Tax Withholding

Is PPD required to withhold Tax from Payments?	**YES**		*Delete where applicable*

If **YES**, please provide the following information

PAN ID number Please provide a copy of the PAN Card. In case you are exempt from TDS please provide IT certificate	**AZXPP8818R** **Attached**

Payment Method required

What is your preferred payment method?	Bank transfer

If **Bank Transfer**, please complete the following details:

Preferred

Bank Account Number			
Sorting Code *(For UK only)*		**Branch number/Bank code**	**1690**
RTGS/NEFT code:	**UTIB0001690**		

Bank Details

Bank name:	**Axis Bank**		
Address:	**Nehru Nagar, Ratna Plaza, CTS No. 10593, Kolhapur Circle**		
City	**Belagavi**	**Postal Code**	**590010**
Country:	**India**	**Private or Public Bank Account**: *(Belgium and France only)*	

Declaration

I have provided the above details and confirm they are correct:

Investigator/Institutional Signatory	
Name in print	Dr. Sayed Umar Quadri
Date (dd/mmm/yyyy)	31st Jul 2020

Dr. SYED UMAR QUADRI
M.B.B.S. M.D. (MED.)
Asst. Prof. of Medicine
MGM Medical College & Hospital A'bad.
REG NO. 2005/02/0904

TO BE COMPLETED BY THE PPD CRA/CONTRACT SPECIALIST

Other Financial Data

PPD CRA/CONTRACT SPECIALIST name	**Kathrine Joy**
Location	**Mumbai**
Paying Country *(if in doubt, contact the Financial Analyst for the study)*	
In what currency is the Statement of Agreement defined	

CASCADE Interface Data

- If the Investigator is the payee, please enter the CASCADE **Contact** number.
- If the Hospital/R&D etc is the payee, please enter the CASCADE **Account** number.
- It may be that the Payee listed above already has a Vendor number (Contact/Account Screen and More Info View) and Remittance code (Contact/Account Screen and Addresses View).
- Please note that these fields are crucial to correct payments being made. Please confirm the correct numbers with your CASCADE Super User or the cascade business support team via the helpdesk.

NOTE: DO NOT USE THE CTMS SITE NUMBER HERE

CTMS Number *Contact/Account – More Info View*	**Vendor Number** *Contact/Account – Addresses View*	**Remittance Code** *Contact/Account – Addresses View*

If the Account or Contact has a vendor number, please identify the purpose of this form, if you are **certain** of the correct option.

New Vendor	☐	Amend Vendor	☐	New Remittance Address Required	☐	Amend Remittance Address	☐

Lawson Data

TO BE COMPLETED BY PPD FINANCE DEPARTMENT

Vendor Name *(used in Lawson)*			
Vendor Number:		**Vendor Location**	
Vendor Group		**Distribution Code**	
Vendor Class	INV	**Separate Payment**	Y
Search Name *(used in LAWSON):*			
Tax Code *(dependent on Service Tax / VAT Reg)*			
Cash Code *(dependent on country and currency)*			
Payment Code *(dependent on method of payment)*			
Next Available User Field *(AP10.1)*		CTMS	

No. BT/PR14641/MED/32/465/2015
GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY

Block 2, (6-8th Floors)
CGO Complex, Lodhi Road,
New Delhi- 110 003
Date:16.08.2019

RELEASE ORDER

In continuation of this Department's sanction order of even number dated Aug 08, 2016 sanction of the President is hereby accorded, under Rule18 of the Delegation of Financial Powers Rule, 1978, for the release of Rs. **423840.00** (Rupees Four Lakhs Twenty Three Thousand Eight Hundred and Fourty Only) being the third year release for the project entitled **"Development of a Powered Transtibial Prosthesis"**, being implemented by

Dr. Rajani Prashant Mullerpatan, MGM Institute of Health Sciences(Deemed University), Plot 1 & 2, Sector 1, Kamothe, Navi Mumbai - 410209, Maharashtra,

The detailed break-up is as given below:

SNo	Institute Name	Recurring						Total Release Amount (Rs)
		Manpower	Consumable	Travel	Contingency	Others	Overhead	
1	MGM Institute of Health Sciences(Deemed University)	396000.00	0.00	0.00	27840.00	0.00	0.00	423840.00
	Rs. 0.245 lakhs was re-appropriated to Travel head during 2nd release made on 06.09.2018 and Rs.0.22160 lakhs (0.0516 lakhs of interest earned + Rs. 0.17 balance available under consumables) is re-appropriated to Contingency. Accordingly, total amount available in Contingency is Rs. 0.50 lakhs							

2. The amount of Rs. **423840.00 /-(Rupees Four Lakhs Twenty Three Thousand Eight Hundred and Fourty Only)** will be directly credited by the Pay & Accounts Officer, DBT in the account as detailed below:

   The Director, MGM Institute of Health Sciences (Deemed University), N-6. CIDCO, Mumbai - 410209, Maharashtra

   Bank Name : State Bank of India
   Branch Name : Konkan Bhawan, Navi Mumbai
   A/c No. : 35732854178
   IFSC Code : SBIN0006240
   MICR Code : 400002109

3. The expenditure involved is debitable to:

Demand No. 85	Department of Biotechnology
3425	Other Scientific Research 2019-2020
3425.60	Others (Sub Major Head)
3425.60.200	Assistance to other Scientific Bodies (Minor Head)
3425.60.200.29	Biotechnology Research and Development
3425.60.200.29.17	Assistance for Research and Development
3425.60.200.29.17.31	Grants -in-Aid General

4. The Director, MGM Institute of Health Sciences (Deemed University), Mumbai, Maharashtra will submit audited utilization certificates and statements of expenditure in respect of the above-mentioned amount.
5. As per Rule 236 (1) of GFR 2017, the accounts of all Grantee Institutions or Organisations shall be open to inspection by the sanctioning authority and audit, both by the Comptroller and Auditor General of India under the provision of CAG (DPC) Act 1971 and internal audit by the Principal Accounts Office of the Ministry or Department, whenever the Institution or Organisation is called upon to do so.

6. No International Travel will be undertaken from the sanctioned project grant unless specified otherwise.
7. The Institute/Agency will keep the whole of the grant in a Bank Account earning interest, and the interest so earned should be reported to DBT in the Utilisation Certificate and Statement of Expenditure. The Interest so earned will be treated as created to the institute/Agency and shall be adjusted towards further instalment of the grant and or at the time of Final Settlement of Accounts.
8. Competent authority has also allowed to carry forward of Rs. 0.9866 lakhs to current FY 2019-20
   The other terms and conditions governing the financial sanction will remain unaltered.
9. The utilization certificate for the financial year 2018-19 is enclosed herewith.
10. This issues under the powers delegated to this Department and with the concurrence of IFD, DBT, vide their SAN No. **102/IFD/SAN/1314/2019-2020** dated **August, 14 2019**.
11. This sanction order has been noted at serial no. 11 in the Register of Grants.

(Dr. Kalaivani Ganesan)
Scientist 'E'
डॉ. कलैवाणी गणेसन/Dr. Kalaivani Ganesan
वैज्ञानिक 'ई'/Scientist 'E'
बायोटेक्नोलॉजी विभाग/Deptt. of Biotechnology
विज्ञान और प्रोद्यो. मंत्रालय/M/o Science & Tech.
भारत सरकार, नई दिल्ली/Govt. of India, N. Delhi

To,

The Pay & Accounts Officer,
Department of Biotechnology,
New Delhi – 110 003.

Copy to:

1 The Principal Director of Audit (Scientific Departments), DACR Building, New Delhi- 110 002.
2 Abhishek Gupta(Project Co-ordinator), Department of Mechanical Engineering, IIT Bombay, Powai, Mumbai - 400076
3 The Director, MGM Institute of Health Sciences(Deemed University), N-6. CIDCO, Mumbai - 410209, Maharashtra
4 The Registrar, INDIAN INSTITUTE OF TECHNOLOGY, BOMBAY, Powai, Mumbai - 400076, Maharashtra
5 Dr. Rajani Prashant Mullerpatan, Professor Director, Physiotherapy, MGM Institute of Health Sciences(Deemed University), Plot 1 & 2, Sector 1, Kamothe, Navi Mumbai - 410209, Maharashtra
6 Dr. Swagatika Mishra, Associate Professor, Prosthetic and Orthotic, MGM Institute of Health Sciences(Deemed University), Plot 1 & 2, Sector 1, Kamothe, Navi Mumbai - 410209, Maharashtra
7 Prof. Abhishek Gupta, Assistant Professor, Department of Mechanical Engineering, INDIAN INSTITUTE OF TECHNOLOGY, BOMBAY, Department of Mechanical Engineering, IIT Bombay, Powai, Mumbai - 400076, Maharashtra
8 Cash Section, DBT (2 copies).
9 Sanction Folder.
10 File Copy.

(Dr. Kalaivani Ganesan)
Scientist 'E'
डॉ. कलैवाणी गणेसन/Dr. Kalaivani Ganesan
वैज्ञानिक 'ई'/Scientist 'E'
बायोटेक्नोलॉजी विभाग/Deptt. of Biotechnology
विज्ञान और प्रोद्यो. मंत्रालय/M/o Science & Tech.
भारत सरकार, नई दिल्ली/Govt. of India, N. Delhi

MGM School of Physiotherapy
Sector-1,Kamothe,Navi Mumbai

Receipt Voucher

No. : **131** Dated : **21-Aug-2019**

Particulars	Amount
Account :	
Grant From DBT	**4,23,840.00**
Through :	
S.B.I..CBD Br.-35732854178	
On Account of :	
being received from DBT through NEFT for 3 rd grant against Project	
Amount (in words) :	
Indian Rupees Four Lakh Twenty Three Thousand Eight Hundred Forty Only	
	₹ 4,23,840.00

Authorised Signatory

MGM School of Physiotherapy NAVI MUMBAI

ICMR SCHOLARSHIP AWARD LETTER

भारतीय आयुर्विज्ञान अनुसंधान परिषद
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य और परिवार
कल्याण मंत्रालय, भारत सरकार

Indian Council of Medical Research
Department of Health Research, Ministry of Health
and Family Welfare, Government of India

Dr. N. C. Jain
Scientist- G & Head (HRD)

No.3/2/July-2019/PG-Thesis-HRD (14)
Dated: 30.07.2019

Dr. Kulkarni Noopur Sudhakar,
Dept of Community Medicine,
MGM Medical College,
Navi Mumbai, Maharashtra-410209
noopurdr@gmail.com

Dear Dr. Kulkarni Noopur Sudhakar,

This is with reference to your application seeking financial assistance from the ICMR for MD/MS/DM/Mch/MDS dissertation/thesis entitled **"A study of pattern of expenditure on utilization of health services related to maternal and child health in Tribal, Rural and Urban Slum population in Raigarh district of Maharashtra"**.

I am glad to inform you that Director General, ICMR, based on the recommendation of Expert Committee, has sanctioned a sum of **Rs. 50,000/- (Fifty thousand only)** which will be disbursed in two/three installments. Initial amount of **Rs. 30,000/-** will be released after receipt of the Undertaking as per the guidelines and remaining amount of **Rs. 20,000/-** on receipt of the electronic copy and summary of work done of your dissertation / thesis duly approved by the University/ Institute along with one publication in an indexed Journal. Mandatory requirement to avail this opportunity is to provide us with an Undertaking duly forwarded through the Guide, to the undersigned, enabling us to release the grant.

The amount will be released after submission of the UNDERTAKING as well as the MANDATE FORM (available on ICMR website) along with a photocopy of a Cancelled Cheque (Please ignore, if already submitted) WITHIN SIX WEEKS for receiving e-payment for purpose of verification of the concerned bank account where money is to be remitted.

Kind regards.

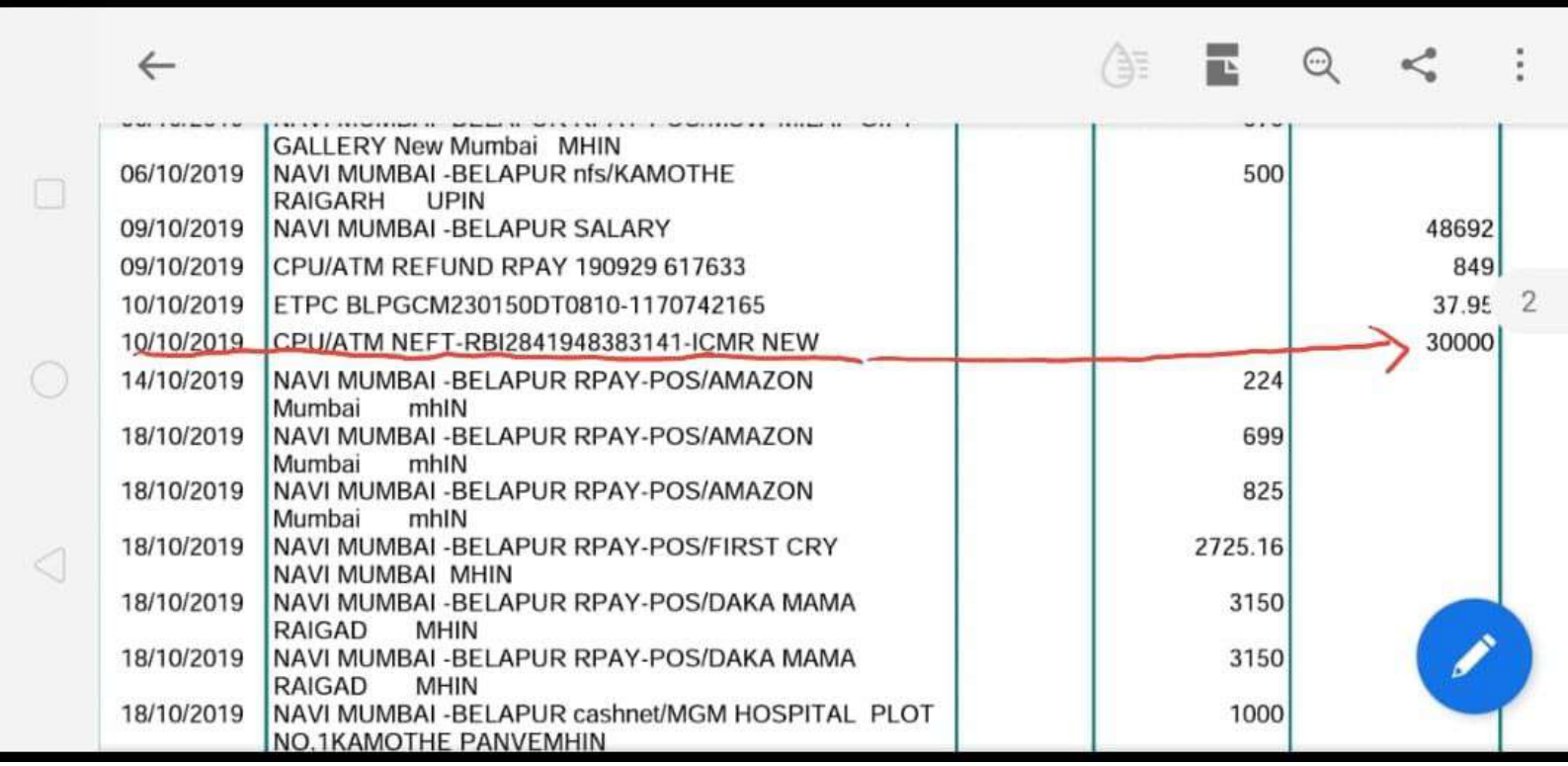
Yours sincerely,

(N. C. Jain)
011-26589258
drncejain@gmail.com

Copy to: **Dr. Prasad Waingankar, Professor and HOD, Department of Community Medicine, MGM Medical College, Navi Mumbai, Maharashtra-410209.**

वी. रामलिंगस्वामी भवन, पोस्ट बॉक्स नं 4911
अंसारी नगर, नई दिल्ली - 110 029, भारत
V. Ramalingaswami Bhawan, P.O. Box No. 4911,
Ansari Nagar, New Delhi - 110 029, India

Tel: +91-11-26588895 / 26588980 / 26589794
+91-11-26589336 / 26588707
Fax: +91-11-26588662 | icmr.nic.in



	GALLERY New Mumbai MHIN			
06/10/2019	NAVI MUMBAI -BELAPUR nfs/KAMOTHE RAIGARH UPIN		500	
09/10/2019	NAVI MUMBAI -BELAPUR SALARY			48692
09/10/2019	CPU/ATM REFUND RPAY 190929 617633			849
10/10/2019	ETPC BLPGCM230150DT0810-1170742165			37.95
10/10/2019	CPU/ATM NEFT-RBI2841948383141-ICMR NEW			30000
14/10/2019	NAVI MUMBAI -BELAPUR RPAY-POS/AMAZON Mumbai mhIN		224	
18/10/2019	NAVI MUMBAI -BELAPUR RPAY-POS/AMAZON Mumbai mhIN		699	
18/10/2019	NAVI MUMBAI -BELAPUR RPAY-POS/AMAZON Mumbai mhIN		825	
18/10/2019	NAVI MUMBAI -BELAPUR RPAY-POS/FIRST CRY NAVI MUMBAI MHIN		2725.16	
18/10/2019	NAVI MUMBAI -BELAPUR RPAY-POS/DAKA MAMA RAIGAD MHIN		3150	
18/10/2019	NAVI MUMBAI -BELAPUR RPAY-POS/DAKA MAMA RAIGAD MHIN		3150	
18/10/2019	NAVI MUMBAI -BELAPUR cashnet/MGM HOSPITAL PLOT NO.1KAMOTHE PANVEMHIN		1000	

भारतीय गैर न्यायिक

एक सौ रुपये

Rs. 100

रु. 100

ONE HUNDRED RUPEES

सत्यमेव जयते

भारत INDIA

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA ◐ 2019 ◐ WF 533555

जिल्हा कोषागार कार्यालय, ठाणे

- 9 JUN 2020

मुख्य प्रमुख लिपीक / लिपीक

जिल्हा कोषागार कार्यालय ठाणे

CLINICAL TRIAL SERVICES AGREEMENT

This Agreement is made and entered into this 02/SEP/2020 by and between:

Principal Investigator
Dr. Syed Umar Quadri
Mahatma Gandhi Mission's Medical College and Hospital
H-6 CIDCO, Aurangabad-431003, Maharashtra

And

Head of Institute
Dr. Rajendra Bohra
Mahatma Gandhi Mission's Medical College and Hospital

Protocol Number: MGC-006
Site: MGM- Aurangabad

N-6 CIDCO, Aurangabad-431003, Maharashtra

And

Professor & HOD of Pharmacology:
Dr. Deepak Bhosle
Professor and HOD of
pharmacology
Mahatma Gandhi Mission's Medical College and
Hospital N-6 CIDCO, Aurangabad-431003,
Maharashtra India.

And

CRO:
Biosphere Clinical Research Pvt.
Ltd., SB - 02, 03 & 04, Second Floor,
Highland Corporate Centre,
Kapurbawdi Junction, Thane (W)-400607,
Maharashtra, India.

For study titled **"A Phase II, controlled clinical study designed to evaluate the effect of ArtemiC in patients diagnosed with COVID-19."**

WHEREAS CRO is engaged in the business of clinical trials management as a Clinical Research Organization and intends to carry out the Phase III Clinical Study (here in after "the Study" / "Clinical trial") and is acting on behalf of MGC Pharmaceuticals.

WHEREAS, the CRO has represented that it has entered into an agreement with the SPONSOR whereby the terms and conditions governing the conduct of the clinical trial at the INSTITUTION have been incorporated.

Subject to the condition of obtaining the pertinent ethics committee approval and the regulatory authority's authorization, the parties intend to participate in the Study by rendering their services and agree to the following:

1. **INSTITUTION:** The CRO has approached the INSTITUTION on behalf of the SPONSOR, as the

   SPONSOR desires the INSTITUTION to perform the study in regards to the said Investigational Product in accordance with the following standards:

(a) The current World Medical Association Declaration of Helsinki titled "Ethical Principles for Medical Research involving Human Patients";

(b) The current ICH Harmonized Tripartite Guideline for Good clinical Practice (CPMP/ICH/135/95);

(c) The current Indian Ministry of health and Family Welfare Guidelines for good clinical

practice titled, "Good Clinical Practices for Clinical Research in India";

(d) The current Indian Council of Medical Research on Human Patients;

(e) New Drugs and Clinical Trials Rules, 2019

(f) The written requirements of all reviewing institutional ethics committees;

(g) The Principal Investigator requirements;

(h) All policies and procedures of the INSTITUTION;

(i) All current and applicable permission, licenses, approvals, federal wide assurance and certifications and (1) all current and applicable laws and regulations (such as standards set forth in Sections 2(a) – (i) collectively referred to hereafter as the Standards) and;

(j) In accordance with the final protocol, patient information sheet, informed consent documents and case report forms for the above-referenced clinical study (collectively, the Clinical Trial Protocol, a current version of which is attached hereto, which attachment shall be replaced in the final version and all amended versions, if any).It is understood and agreed that, in the event of a conflict among any of the standards, the most stringent standard shall apply.

2. PERFORMANCE:

a) Protocol and Standards: Principal investigator who will supervise and direct the work of the INSTITUTION and the Dean of the INSTITUTION, hereby confirm that they have read and understood the Clinical Trial Protocol for the Study to be conducted in 50 patients and further confirm that their research team is properly trained concerning the clinical trial Protocol and Standards. All amendments have also been read and understood. The Principal Investigator and the INSTITUTION agree to the final Clinical Trial Protocol and to perform the study in strict accordance with this Agreement.

b) Subcontracting: Services of Principal Investigator: The INSTITUTION shall not subcontract the performance of any or all of its obligations under this Agreement to any third party (including to any affiliate). The services of the Principal Investigator are considered essential for the performance of this Agreement. If for any reason the Principal Investigator becomes unavailable or otherwise unable to supervise and direct the activities under this Agreement, INSTITUTION shall promptly notify the CRO/SPONSOR. If a mutually acceptable successor is not promptly identified, this Agreement may be terminated by the CRO.

c) Study Duration: It is anticipated that the Clinical Study will commence upon execution of this Agreement, that subject enrollment will be completed approximately in four months from the date of Site Initiation Visit, and that the Clinical Study will be completed as per the study schedule, unless otherwise terminated in accordance with Section 7.

d) Recruitment: The Principal Investigator understands and agrees that the CRO/SPONSOR requires approximate 35 evaluable patients at the conclusion of the Study from site. hence it will be necessary for the INSTITUTION to enroll approximately 35 patients (considering a drop-out rate of 10%) to achieve the targeted number of patients who satisfy all enrollment criteria specified in the Clinical Trial Protocol, within a period of 1-2 months approximately after the SPONSOR authorizes commencement of the study.

e) Confidentiality:

i Definition: During the term of this agreement (period of five years thereafter), the INSTITUTION and Principal Investigator may have access to information, know-how, knowledge and data in oral, written, electronic, graphic or other tangible form, confidential or proprietary to SPONSOR or to SPONSOR's other collaborators (other than the INSTITUTION) and is, therefore of a confidential nature (confidential information). Confidential information shall include the Clinical Trial Protocol, SPONSOR's Investigator's Brochure concerning the Investigational Product data, all Study Data, all documents maintained in the Clinical Trial Record Binder (site documentation), any other data emerging out of the protocol, any other information supplied by SPONSOR/CRO during the course of the study and clinical development plan, except the information already existing in the public domain, and all results and reports obtained, collected, conceived, processed and developed pursuant to this Agreement.

ii Use: The INSTITUTION shall hold all confidential information and shall disclose confidential information only to its Principal Investigator, Co-Investigators, hospital staff and employees who have a need to know such confidential information for the purpose of this agreement and who agree in writing to keep such confidential information, confidential under terms substantially similar to those set forth herein. The INSTITUTION shall use confidential information for the sole purpose of providing services under this Agreement and shall not use confidential information for the INSTITUTION's own benefit at any time. No right or license under any patent application, trade secret or other proprietary right now or hereafter owned or controlled by the SPONSOR or other collaborators is granted to the INSTITUTION from the provision of confidential information hereunder. The INSTITUTION shall comply with the Study Data Confidentiality conditions.

ii. Provision to CRO/SPONSOR: The INSTITUTION agrees that, at any time upon CRO/SPONSOR's request, it shall promptly provide to the CRO/SPONSOR respectively, copies of all Confidential Information under this Agreement. The INSTITUTION further agrees that upon any termination or expiration of this Agreement, it shall at CRO/SPONSOR's election, return to the CRO/SPONSOR or destroy all copies of all Confidential Information; however, that the INSTITUTION may retain two (2) archival copies, with obligation to maintain the confidentiality of such confidential information.

f) Work Product:

i. Definition: The Parties agree that all work performed by the INSTITUTION hereunder including, without limitation, all study data, results, reports, inventions, discoveries, new uses or know-how obtained, collected, conceived, processed, developed, improved or reduced to practice by Principal Investigator or the INSTITUTION's other hospital staff or employees pursuant to this Agreement (collectively, work product) shall be the property of the SPONSOR.

ii. Disclosure, Assignment and Provision to CRO/SPONSOR: The parties agree that the INSTITUTION shall promptly disclose to the CRO/SPONSOR any and all work related to the product comprising inventions, discoveries, new uses or know-how obtained. As per the agreement, the CRO/SPONSOR can review and obtain copies of all work related to the product including and without limitation, all study data, in an agreed–upon format and with a complete glossary of terms used for such data.

ii. Materials: The study medication, blood samples from patients under the study and all other tangible material provided to or obtained by the INSTITUTION under this Agreement (Collectively the Materials) shall be the property of the SPONSOR and/or SPONSOR's other collaborators (other than the INSTITUTION). The INSTITUTION shall use the Materials for the sole purpose of providing services under this agreement and shall not use the materials for its own benefit at any time. No right or license, any patent, patent application, trade secret or other proprietary right now or hereafter owned or controlled by SPONSOR or SPONSOR's other collaborators is granted to the INSTITUTION from the provision of materials hereunder. Upon any remaining Investigational Product and other Materials received or obtained hereunder in accordance with the Protocol, standards and the directions of CRO/SPONSOR.

g) Human Patients: The INSTITUTION shall be responsible for safeguarding the rights and welfare of patients in the study. The INSTITUTION shall ensure (i) the rights and welfare of each such patient are protected, (ii) informed consent of each such patient is freely and knowledgeably given: (A) to participate in the study and (B) for the collection by, processing by and disclosure to and between the CRO representatives of SPONSOR, Principal Investigators and Researcher, Study Monitors, Study Laboratory Personnel, Study Data Analysts, members of the Independent Ethics Committees and representatives of governmental and inter-governmental agencies in India; (iii) the balance between risk and potential benefit from participating in the study has been assessed and deemed acceptable; and (iv) the SPONSOR/CRO has made appropriate arrangements to eliminate, mitigate and/or compensate for the consequences to such patients and their families in case of any death, injury or illness which has causal relationship with the patient diagnosed with Covid-19 for which the SPONSOR/CRO has agreed to assume liability. Such arrangements shall include medical treatment and financial relief as per the Policy provided by Sponsor.

h) Ethical Approval: The INSTITUTION shall petition for written certification of ethical approval of the Study from its Institutional Ethics Committee. The INSTITUTION shall

keep the CRO/SPONSOR fully advised of the progress of such submission and shall upon request, provide the CRO/SPONSOR with all correspondence relating to such submission. The INSTITUTION shall obtain such certification prior to screening any patients for the Study, annually after obtaining such certification, and prior to implementing any changes to the Clinical Trial Protocol. Upon receipt of such certification, the INSTITUTION shall promptly provide a copy to the CRO/SPONSOR.

i) Electronic Case Report Form Handling: The Principal Investigator shall be responsible for providing correct Electronic Case Report Forms ("eCRF") according to the following:

i. The main objective of the eCRF is to obtain those data required by the Protocol in a complete, accurate, legible and timely fashion. The data in the eCRF must be consistent with the relevant source documents, and they must be suitable for submission to authorities.

ii. The data recorded in the course of the Study shall be documented in the eCRFs and, as necessary, on the SAE report. They will then be forwarded to CRO/SPONSOR for data management and biometric analysis.

ii. The data in the eCRF shall be recorded, evaluated, and stored in anonymous form in accordance with data-protection regulations. The Principal Investigator shall ensure that patient names are not mentioned on any document, neither eCRFs nor other documents that will be forwarded to the CRO/SPONSOR.

iv. Wherever possible, all data obtained in the course of the Study must be recorded in the original patient files. Data to be recorded directly on the eCRFs and considered as source data will be identified as such. All data in the eCRFs must correspond exactly with data recorded in the source documents.

iv. If eCRFs are not complete the Principal Investigator shall be obliged to complete them on request of CRO/SPONSOR.

j) Drug Safety: The recording of Adverse Events (AEs) is an important aspect of study documentation. It is the Principal Investigator's responsibility to document all AEs according to the detailed guidelines of the Protocol. The Principal Investigator agrees to answer any questions of CRO/SPONSOR Medical Monitors concerning any AEs. According to the Protocol, the Principal Investigator will assess at each visit whether any Adverse Event (AE) including abnormal laboratory values has occurred. The details of all AEs, whether reported by the patient or observed by the Principal Investigator/Study personnel during the entire study, will be recorded onto the appropriate source document. Each adverse event must be recorded in the AE section of the electronic case report form (eCRF), regardless of the causal relationship. The Principal Investigator must immediately report all Serious Adverse Events (as defined in the Protocol), which occur during the course of the Study and up to the date of the patient's last visit, to the addressee given below. The SAE Report Form will be used for documentation and reporting. Initial and follow up SAE reports are to be sent to **CRO** for onward transmission to SPONSOR:

Name: Dr. Neeta Nargundkar
Telephone Numbers: (022) 41006794
E-mail: drneeta@biospherecro.com

If the event is unexpected and fatal or life threatening and is considered by the Principal Investigator possibly related to the study medication CRO shall be informed immediately by telephone and followed immediately by mail. CRO will be responsible to notify on-time the health authorities in India.

k) Source Data: The Principal Investigator shall be responsible for providing the Source Data according to the following regulations. Source data are the original patient records of all variables collected for the trial as well as the patient's medical history. Specifically, but not limited to they comprise:

i. Signed Informed Consent Form
ii. Patient hospital file and individual clinical notes
ii. Laboratory Reports
iv. Pharmacy Records
v. Study specific source documents
vi. Appropriate sections of the eCRF, where data are recorded directly onto specific forms
vi. Other reports and records of any procedure performed in accordance with the Protocol

l) The Principal Investigator shall safely maintain the original study documentation together with all source data for the maximum period of time permitted by the hospital, research institute or practice in question, but not less than 5 years after the clinical part of the trial has been completed. If archiving can no longer be maintained at site, the Principal Investigator will notify CRO/SPONSOR.

m) Investigator Study File and Archiving: The INVESTIGATOR shall prepare and maintain complete and accurate study documentation in compliance with ICH-GCP standards and local regulations. Therefore, an investigator study file shall be prepared which contains all relevant documents necessary for the conduct of the study:

i. Signed Protocol and Amendments
ii. Investigator's Brochure and Updates
ii. EC Composition, approval(s)/opinion correspondence/reporting
iv. Notifications of regulatory authorities
v. CVs and signature sheet for key study personnel (e.g. Investigators, Study Nurses)
vi. Signed study agreements including financial agreement.
vi. Trial Initiation Report
vii. Approved and signed Informed Consent Forms
ix. Patient Insurance Certificate
x. CRFs (Investigator's copy)
xi. Data Clarification Forms (copies)
xi. SAE documentation and related correspondence/reporting

xii. Shipping/accountability/destruction records for investigational product.
xiv. Certificate of Analysis
xv. Instructions for handling of investigational product.
xvi. Laboratory accreditation/certification and up-to-date reference ranges of normal values, Screening, enrollment and monitoring logs and subject identification code list
xvii. Appointment diaries
xvii. Study related correspondence with CRO/SPONSOR

n) Documentation and Material (Supplies): All supplies provided to the Principal Investigator for the purpose of carrying out the Study are supplied only for the purpose of the Study and must not be used for any other purpose whatsoever. The Principal Investigator, or a person(s) delegated by him, are responsible for the security and accountability of all supplies.

o) The inventory must be available for monitoring, auditing and inspection. When the study is completed, or if it is prematurely terminated, any supplies of unused material for the Study, supplied by the CRO/SPONSOR (except documentation required to be retained by the Principal Investigator), must be returned to the CRO/SPONSOR. In the latter case, the identification and quantity of each unit of study medication and the person in charge must be documented.

p) Monitoring, Quality Assurance and Inspection by Authorities: The Study will be monitored by the CRO. Its representatives (alone or together with representatives from SPONSOR) will be allowed access to all information resulting from this Study and SPONSOR will have an unrestricted right to use such information. CRO (alone or together with representatives from SPONSOR) will perform regular on-site monitoring and remote monitoring throughout the Study. The tasks of the monitor comprise the following:

i. to ensure Protocol adherence
ii. to verify the data in the eCRFs against source documents (SDV)
ii. to check progress of the study and to motivate, if necessary
iv. to review the eCRFs for complete and accurate capture of data, including laboratory test reports and other patient records
v. to check all data for possible SAEs and AEs
vi. to review signed informed consent forms for signatures and date of consent
vi. to ensure accurate record of drug accountability
vii. to ensure adequate storage of study supplies
ix. to check completed eCRFs
x. to discuss and help resolve any problems

q) Source Data Verification (SDV) shall be performed on 100% of key data such as informed consent, demographics, and inclusion/exclusion criteria, parameters for the evaluation of the main endpoints, safety evaluation and drug accountability.

The visits shall involve the Principal Investigator or his appointed representative(s) and any other staff, as required. The Principal Investigator shall ensure that sufficient time is allowed

for monitoring visits. Follow-up correspondence between the Site and the CRO relating to apparent inconsistencies or clarification of eCRF entries will be kept on file at both CRO and the Site.

r) Study Protocol, Patient Information Leaflet/Consent Forms, eCRF is well as each step of data recording, monitoring and processing shall be subject to the independent Quality Assurance at CRO.

s) This Study shall be audited on behalf of SPONSOR to assure GCP compliance as well as validity of the study data according to a study specific audit plan. The audits will be conducted in accordance with the SOPs of the CRO/SPONSOR.

t) For monitoring visits and in case of audits and inspections by authorities, the Principal Investigator must provide direct access to the complete study records including eCRFs, original source data, study documentation, and, if necessary, any additional background data. Furthermore, access to Study related facilities must be ensured.

u) Confidentiality of Patient Records: The INSTITUTION and the Principal Investigator must assure that Study patients' anonymity will be maintained, and that their identities will be protected from unauthorized parties. Documents stating patients' names must be kept in strict confidence by the Principal Investigator. On eCRFs or other documents removed from the INSTITUTION, patients must not be identified by their names, but by initials and patient identification number. The Principal Investigator is obliged to maintain a subject identification code list showing the patients' full name and date of birth together with the corresponding patient identification number to allow revealing identity of any subject.

v) The Principal Investigator agrees that representatives of CRO/SPONSOR, of the responsible IEC/IRB and of national or international regulatory authorities may inspect the patient records at the site for source data verification. SPONSOR and CRO guarantee for their representatives that patient data will be treated confidentially. Monitors and Auditors are further bound to secrecy.

4. **AMENDMENTS:** The CRO, on behalf of the SPONSOR, may from time to time, make changes to the Protocol. Changes in the Protocol must take the form of written amendments and shall be approved by all signatories of the final version of the Protocol. Any amendments to the Protocol which affect the patient (e.g. changes in procedures/assessments or matters relating to patient safety) require approval of the relevant ethics committee as well as further informed consent from each concerned patient prior to implementation. The Principal Investigator shall obtain such approval. Changes of purely administrative nature shall be notified to the committee by the Principal Investigator, but do not require formal approval.

5. **INSPECTIONS:**

a) By Representatives of CRO/SPONSOR: The INSTITUTION agrees that CRO/SPONSOR's representatives and clinical monitors for the Study will have free access to the INSTITUTION's facilities and all documents pertaining to the Study during

normal business hours, after provision of prior written notice, as is necessary to ensure that the Study is conducted in accordance with this Agreement. In the event any such representative or monitor observes non-compliance with this Agreement, incomplete, illegible or inaccurate recording of Study data, or other matters of concern relating to the Study, the INSTITUTION shall, in cooperation with such representative or monitor, promptly remedy such non-compliance, Study data recording problems or matters of concern and shall promptly notify such representative or monitor of such remedial actions taken.

b) By Governmental Representatives: The INSTITUTION agrees that representatives of the government will have access to its facilities and such documents pertaining to the study as may be legally requested by such representatives. The INSTITUTION shall not disclose individually- identifiable personal information, individually-identifiable health care information or other Confidential Information to such governmental representatives except as required by law, and if the INSTITUTION discloses such individually-identifiable information or other Confidential Information to such governmental representatives, the INSTITUTION shall seek an appropriate, written agreement of confidentiality from such governmental representatives prior to making such disclosure. The INSTITUTION shall promptly provide copies to the CRO/SPONSOR of any notices, correspondence and other documentation received or prepared by or on behalf of the INSTITUTION in connection with any governmental inspection, action; inquiry or correspondence relating to or that may affect the INSTITUTION's activities under the Study. The INSTITUTION shall take all actions necessary to remedy any non-compliance cited by governmental authorities and shall promptly notify CRO/SPONSOR of such remedial actions taken.

6. **WARRANTIES AND DISCLAIMER OF WARRANTIES:** INSTITUTION warrants that all services provided under this Agreement will be provided in a professional and workmanlike manner, in compliance with the Standards and the terms of this Agreement.

7. **AGREEMENT TERM AND TERMINATION:**

a) This Agreement is effective as of beginning of the study, and shall continue until 5 (five) years after completion of study, unless terminated sooner in accordance with this Article 7 or unless extended for a defined period by a signed written amendment in accordance with Article 14.

b) The Study and this Agreement may be terminated by written notice from the SPONSOR/CRO to the INSTITUTION for any of the following reasons:

i. Notification to CRO/SPONSOR from applicable regulatory authorities to terminate this Study.
ii. Determination by CRO/SPONSOR that the INSTITUTION is not performing the Study as required in the Agreement and/or is not meeting the agreed upon patient enrollment requirements set forth in Section 7(c) herein.
iii. Failure of the Principal Investigator and/or the INSTITUTION to provide access to the SPONSOR monitors or SPONSOR representatives to the INSTITUTION's

facilities and all original medical records and Study-related documents necessary to verify entries on Study electronic Case Report Forms and the INSTITUTION's compliance with this Agreement.

iv. Failure of the Principal Investigator or associated staff or any other person engaged in the Study (excluding patients) to be available, upon reasonable notice and by prior mutually convenient time appointment by CRO/SPONSOR, to meet with the CRO/SPONSOR monitors or CRO/SPONSOR representatives during the course of the Study as necessary to discuss information relevant to the Study.

v. Unauthorized replacement of Principal Investigator, in accordance with Section 7(b) herein.

vi. Determination by SPONSOR that business or scientific considerations require termination.

vii. Electronic Case Report Forms provided to the Principal Investigator by the CRO/SPONSOR for use in the Study are not completely, accurately and/or legibly completed and/or forwarded to the CRO/SPONSOR's designated representative, as appropriate, within one (1) week of each patient's visit date.

c) The INSTITUTION may terminate this Agreement by written notice from the INSTITUTION to the CRO/SPONSOR for any of following reasons:

i. SPONSOR does not comply with the Clinical Trial Protocol provisions related to supply of Investigational Product for the Study, or the CRO/SPONSOR does not supply other agreed-upon study related material.

ii. The Principal Investigator reasonably suspects an adverse reaction/adverse event related to the Study procedure and of serious nature, after informing the Institutional Ethics Committees and the CRO/SPONSOR.

d) In case of any termination or expiration of this Agreement:

i. Responsibility for treatment of enrolled patients will be as specified in the Standards;

ii. The INSTITUTION shall cooperate with the SPONSOR/CRO for an orderly wind-down of activities, with due regard for patient safety and welfare;

iii. The INSTITUTION shall return or destroy all Confidential Information to CRO/SPONSOR, at the CRO/SPONSOR's election, in accordance with Section 7(d)(iii) herein;

iv. The INSTITUTION shall promptly provide all Agreement deliverables due to the CRO/SPONSOR and, if requested by the CRO/SPONSOR, provide copies of all Work Product (including without limitation all Trial Data) to CRO/SPONSOR, in accordance with Section 7(d) (ii) herein;

v. The INSTITUTION shall return and/or dispose of all remaining Investigational Product or other Materials received or obtained hereunder, in accordance with the Protocol, Standards and the directions of CRO/SPONSOR, in accordance with Section 7(d) herein;

vi. The INSTITUTION shall, within thirty (30) days after such termination or expiration, provide a final invoice to the CRO; and

vii. The INSTITUTION shall, notwithstanding such termination or expiration, remain responsible for compliance with all Standards.

c) The provisions of Articles 5, 6, 7, 8, 9, 10, 12 and 13 herein shall survive any termination or expiration of this Agreement, as shall such other provisions as, by their context, are intended to survive such termination or expiration.

Effect of Termination

The Institution shall comply all the standard procedures required for study close out

8. **RECORDS:** The INSTITUTION shall maintain in the English language (a) all Work Product; and (b) complete, accurate and legible scientific and clinical documents, books and records pertaining to all activities performed and all Materials provided or obtained under this Agreement. The other Study materials will be archived at the INSTITUTION for the period set forth in the Clinical Trial Protocol and originals given to the CRO for the purposes of data analysis.

9. **PUBLICATION OF RESULTS:**

a) Both the INSTITUTION and CRO shall treat matters of authorship in a proper, collaborative spirit, giving credit where it is due and proceeding in a manner that fosters cooperation and communication.

b) It is hereby expressly made clear that all Intellectual Property Rights in the final test report as well as in the material generated during the process of Clinical trial will reside with the SPONSOR. CRO.

10. **FINANCE:**

a) The expenses of the Study, as set forth in the total projected budget, shall be paid by the CRO and are estimated not to exceed the amount mentioned in the total projected budget, in case it exceeds it will be mutually agreed upon on reasonable grounds and documented appropriately. The CRO's payment to INSTITUTION is contingent upon the CRO receiving payment from the SPONSOR. Funds shall be paid by the CRO to the INSTITUTION for the satisfactory and timely performance under this Agreement, as per the payment details, terms and conditions laid out in

b) ***Annexure A.***

All payments will be based on actual patient visits for every 2 months.

Method of payment

CRO, on behalf of the Sponsor shall pay the relevant cost and fee as set out in Annexure A to the Institution and Institution will pay Principal Investigator.

Details of Payee are: All the site payments including investigator and co-investigator fees, Subject travel reimbursement and Institutional overhead charge will be paid on below mentioned payee name

Payee Name	MGM Medical College, Aurangabad
Address	Mahatma Gandhi Mission's Medical College and Hospital N-6 CIDCO, Aurangabad-431003, Maharashtra
PAN Number	AAATM4256E
Bank Account Number	0376104000000107
Bank IFSC Code	IBKL0000376
GST NO	-
Name of the Bank	IDBI Bank

Note: All the payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws in the country and CRO will deduct the tax at the time of making payments unless a valid Certificate) from tax authority is made available.

g) An insurance policy, as relevant, for the participating patients covering any injury or illness suffered as a direct result of their participation in this Clinical Study shall be taken out by the SPONSOR/CRO. All participating patients will be informed by the Principal Investigator about the existence of the insurance policy and the extent of the coverage.

II. PUBLICITY, PRODUCT PROMOTING ACTIVITY AND COMMUNICATION GUIDELINES:

a) The SPONSOR shall not identify or use the names, trademarks, trade names or symbols of the institution, Principal Investigator or his research team under the study without the prior written permission of the Principal Investigator and head of the institution for claims, publicity or any product promoting activity. because the SPONSOR is a publicly funded organization that must maintain a certain level of transparency about its collaborations, SPONSOR may disclose the identity of the INSTITUTION, publicly available information about the INSTITUTION and the broad purpose of the collaboration under this Agreement to third parties such as a Court of Law, regulatory agencies, governmental or legal agencies, other collaborators, other investigators involved in the project and the organization (profit or non-profit) funding the development of the Investigational Product. Also such details can be shared in scientific forums and with other medical professionals, if questioned.

b) The INSTITUTION shall not identify or use the names, trademarks, trade names or symbols of the SPONSOR, the SPONSOR's employees or affiliates, SPONSOR, SPONSOR's employees, donors or affiliates or any other author of the primary collaborative publication described in Section 11(b) herein for publicity or product promoting activity.

c) Prior to the beginning of the Study, the CRO/SPONSOR shall develop external

communication guidelines for use by the INSTITUTION. The INSTITUTION agrees to comply with such guidelines. The INSTITUTION shall not issue any press release concerning the Study or this Agreement without the prior, express written approval of SPONSOR.

12. **LIMITATION OF LIABILITY:** The parties expressly agree that there shall be no limitation on either Party's liability for any claims, damages, losses or liabilities arising out of or related to this Agreement or the services performed hereunder. 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 PATIENT MATTER OF THIS AGREEMENT. THE PARTIES EXPRESSLY ACKNOWLEDGE THAT THE FOREGOING LIMITATIONS HAVE BEEN NEGOTIATED BY THE PARTIES AND REFLECT AFAIR ALLOCATION OF RISK. Any disputes that arise during the study between SPONSOR/CRO and Principal Investigator will be under the jurisdiction of Mumbai courts.

i. **APPLICABLE LAW AND ARBITRATION:** This Agreement is entered into and will be deemed for all purposes to have been made in Mumbai, India and shall be governed and construed in accordance with the laws of India applicable to contracts and agreements. The parties shall share equally the costs of the Arbitration unless determined otherwise.

13. **AMENDMENTS:** This Agreement may only be amended by and to such degree as specified by the mutual written consent of the parties hereto

14. **ENTIRE AGREEMENT:** This Agreement, contains the entire understanding of the parties with respect to the subject matter hereof and except as expressly set forth herein, all express or implied agreements, representations and understandings, either oral or written, made prior to this Agreement are hereby expressly superseded by this Agreement. In the event there is a conflict between the Clinical Trial Protocol and the terms in the body of this Agreement, the terms in the body of this Agreement will govern with respect to commercial and contract terms, but such Protocol will govern with respect to the conduct of the Study and with respect to serving the welfare of patients of the Study. This Agreement may only be amended by a written instrument executed by the parties hereto, and CRO must approve any such amendment in writing prior to such amendment becoming effective.

15. **SEVERABILITY:** The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision of this Agreement.

16. **ASSIGNMENT:** The Principal Investigator may not assign or transfer any of their rights or obligations under this Agreement without the prior written consent of the CRO. The CRO may assign this Agreement and all its rights and obligations hereunder to a successor or assignee of the business to which this Agreement relates.

Protocol Number: MGC-006
Site: MGM- Aurangabad

17. **WAIVER:** No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of the same term, provision or condition, or of any other term, provision or condition of this Agreement.

18. **NOTICE:** Any notice required or permitted hereunder shall be in writing and shall be deemed given as of the date it is (A) delivered by hand or (B) received by registered or certified mail, postage prepaid, return receipt requested, or received by facsimile and addressed to the party to receive such notice at the address set forth below, or such other address as is subsequently specified in writing

WHEREOF, the parties hereto have executed this Agreement in quadripartite by proper persons thereunto duly authorized.

If to Principal Investigator: Name of the principle investigator **Dr. Syed Umar Quadri** Mahatma Gandhi Mission's Medical College and Hospital N-6 CIDCO, Aurangabad-431003, Maharashtra	**If to INSTITUTION:** Name of the Institute Head **Dr. Rajendra Bohra** Mahatma Gandhi Mission's Medical College and Hospital N-6 CIDCO, Aurangabad-431003, Maharashtra
Professor& HOD of Pharmacology: **Dr. Deepak Bhosle** Professor and HOD of Pharmacology Mahatma Gandhi Mission's Medical College and Hospital N-6 CIDCO, Aurangabad-431003, Maharashtra	**If to CRO:** 02 SEP 2020 BIOSPHERE CLINICAL RESEARCH MUMBAI **Dr. Neeta Nargundkar** **Biosphere Clinical Research Pvt. Ltd.,** Highland Corporate Centre, SB 02,03 & 04, Second Floor, Near Kapurbawdi Junction, Thane (W)400 607.

Annexure A

Name of the Site: Mahatma Gandhi Mission's Medical College and Hospital N-6 CIDCO, Aurangabad- 431003, Maharashtra.

Principle Investigator and Site Payment-Per Patient cost is as follows:

Visit Number	Payments INR
Visit 1 –Screening Visit (Day 1)	4,500
Visit 2 –(Day 2)	4,500
Visit 3– Follow up visit (Day 3-14)	4,500
Visit 4 –End of study visit (Day 15)	4,500
Total	18,000 INR

Note 1: The above payments are inclusive of Investigator Fees, Sub-Investigator Fees, Subject Travel Reimbursement, and Institutional Overheads (30%).

Note 2: Lab Cost to be paid at actual.

Note 3: Clinical Research Site Coordinator Fees 10,000 INR/months will be paid from Site Initiation Visit till completion of study activities.

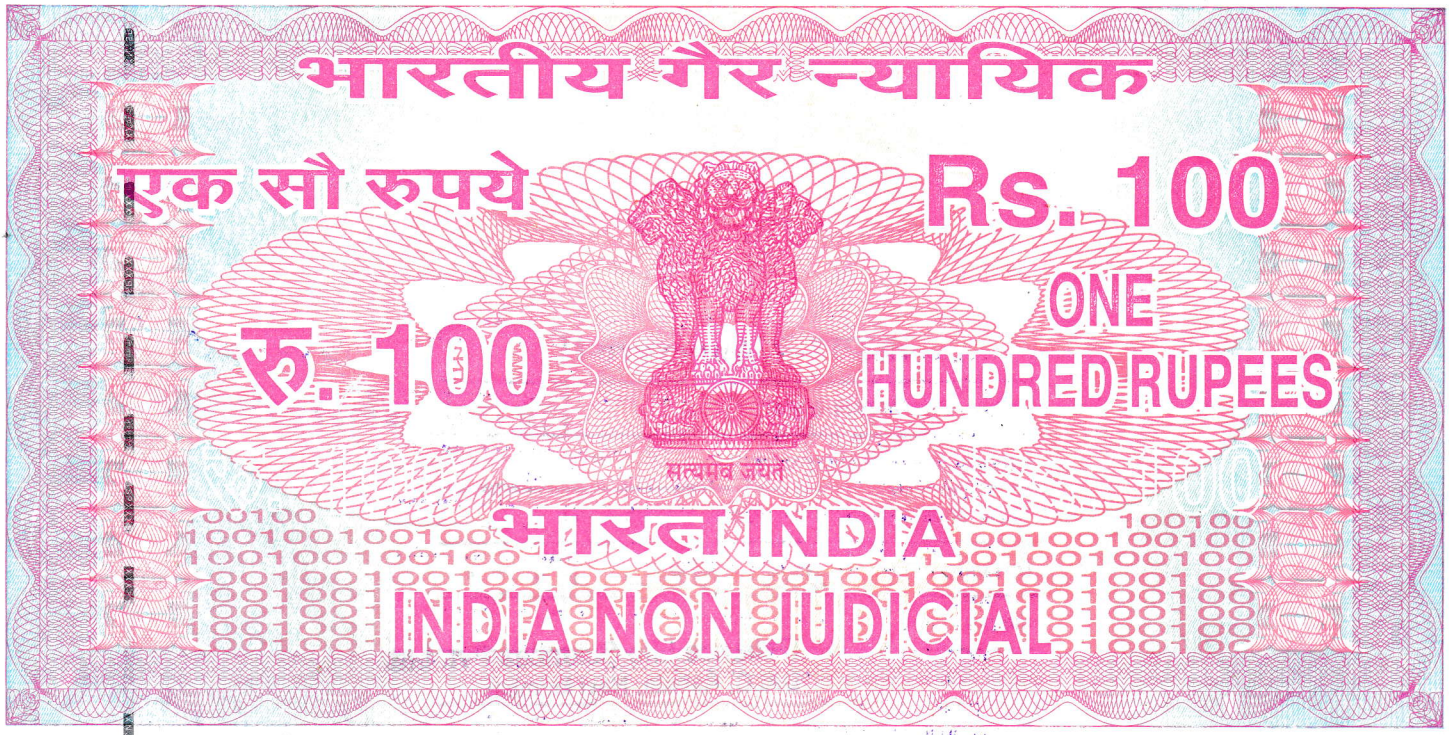
Note 4: Screen failure subjects will be paid only up to 10% of the total enrolled completed subjects at the site.

Note 5: For drop-out subject payment will be made as per completed visit on pro-rata basis.

Note 5: All the site payments will be released upon receipt of original invoice signed by authorized signatories.

Note 6: All the payments made to the payee are subject to Tax Deducted at Source (TDS) and Goods and Services Tax (GST) as per the applicable existing tax laws in the country and CRO will deduct the tax at the time of making the payments.

Note 7: Post study archival of the study documents will be done by the sponsor.



महाराष्ट्र MAHARASHTRA ◐ 2019 ◐ WA 589071

SUB-TREASURY OFFICE KALYAN
Sub-Treasury Officer
Kalyan

19 MAR 2020

CLINICAL TRIAL AGREEMENT

Between

Reliance Life Sciences Pvt. Ltd., ("Reliance")

AND

Dr.Ashish Deshmukh ("Investigator")

AND

MGM Medical College and Hospital, N-6, CIDCO, Aurangabad-431003 ("Institution")
AND

Grapecity Research Solutions LLP **("SMO")**

जोडपत्र-२/Annexure-II

दस्ताचा प्रकार/अनुच्छेद क्रमांक: Bond/Agreement

दस्त नोंदणी करणार आहेत का ? ——

नोंदणी होणार असल्यास दुय्यम निबंधक कार्यालयाचे नाव: ——

मिळकतीचे वर्णन: As per Doc.

मोबदला रक्कम:

मुद्रांक विकत घेणाऱ्याचे नाव: Reliance Life Sciences Pvt. Ltd. DALC, Rabale, Navi Mumbai

दुसऱ्या पक्षकाराचे नाव: Dr. Ashish Deshmukh, Aurangabad

हस्ते असल्यास त्यांचे नाव व पत्ता: Ashish R. Ghodke

मुद्रांक शुल्क रक्कम: 100/-

मुद्रांक विक्री नोंद वही अनु.क्रमांक: 28h28 दिनांक: 20 MAR 2020

मुद्रांक विकत घेणाऱ्याची सही:

20 MAR 2020

परवानाधारक मुद्रांक विक्रेत्याची सही तसेच मुद्रांक विक्रीचे ठिकाण

सौ. [illegible] देशमुख
मुद्रांक विक्रेता, ला. नं. १२०६०२१
कल्याण [illegible], कल्याण.

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

This Clinical Trial Agreement (the Agreement) is entered on the 26th_day of Jun 2020 by and between **1) Reliance Life Sciences Pvt. Ltd.; ("Reliance"),** with a registered office at Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701, India and . 2) **Dr.Ashish Deshmukh ("Investigator"), Dermatologist, MGM Medical College and Hospital, N-6, CIDCO, Aurangabad-431003, Maharashtra**, India. and **3) MGM Medical College and Hospital, N-6, CIDCO, Aurangabad-431003, Maharashtra, India** and **4)** Grapecity Research Solutions LLP **("SMO")** having its address at Shree Prasad, Block No. D-2, Prakash Housing Society, Kalewadi Phata, Thergaon, Pune 411033, Maharashtra, India

"Investigator", ''Institution", "SMO" and "Reliance" are hereinafter collectively referred to as 'Parties" and individually as a 'Party".

PROTOCOL NUMBER:	RLS/PMS/2016/08
PROTOCOL TITLE:	A prospective, multi-centre, open label, phase IV study to evaluate safety and efficacy profile of Infimab™ in patients with moderate to severe plaque psoriasis
STUDY PRODUCT:	Infimab™
SPONSOR	Reliance Life Sciences Pvt. Ltd.
INVESTIGATOR:	Dr.Ashish Deshmukh
INSTITUTION/SITE:	MGM Medical College and Hospital, N-6, CIDCO, Aurangabad-431003, Maharashtra, India.

WHEREAS, Reliance wishes to engage the Investigator, SMO & Institute to carry out Sponsor designated clinical study set out and described in protocol **RLS/PMS/2016/08** and the Investigator, SMO & Institute is able and willing to conduct a clinical trial (the "Study"), in accordance with the above-referenced Protocol (the "Protocol" and any subsequent amendments thereto) on the terms and conditions set forth in this Agreement. Reliance wishes to contract with the Investigator & Institute for conducting the Study at the Institution.

WHEREAS, the Investigator, SMO & Institute is willing to conduct the Study in accordance with the above-referenced Protocol and any subsequent amendments thereto; . The Institution and the Principal Investigator having each reviewed the Protocol for the Study and sufficient information regarding the Investigational Product to evaluate their interest in participating in the Study, wish to conduct in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study

WHEREAS the Institution has engaged Grapecity Research Solutions LLP **("SMO)** having its address at Shree Prasad, Block No. D-2, Prakash Housing Society, Kalewadi Phata, Thergaon, Pune 411033, Maharashtra, India authorized to facilitate the clinical trial study, on behalf of the Institution.

WHEREAS, the Parties wish to set forth certain the terms and conditions under which the Study shall be conducted;

CONFORMANCE WITH LAW AND GUIDELINES

The Institution and Principal Investigator shall carry out the Study in accordance with:

a) the Protocol as amended from time to time,
b) Good Clinical Practice;
c) the Declaration of Helsinki;
d) New Drug and Clinical Trial Rules, March 2019.
e) Ethical Guidelines for Biomedical Research on Human Subjects as prescribed by the Indian Council of Medical Research
f) any applicable direction received from a regulatory authority (DCGI) or ethics committee with jurisdiction over the Study;

NOW THEREFORE, the parties have agreed as follows:

A. Reliance hereby wishes to engage the Investigator to conduct the portion of the Study that is to be conducted at the Institution under the supervision and direction of the Investigator pursuant to this Agreement. The Institution warrants that the Principal Investigator, the SMO and the Institution's employees and collaborators involved in the Study will comply with all Applicable Laws.

B. The Study will be conducted at the Institution under the direction of the Investigator identified above. The Investigator, SMO and Institution will be responsible for performing the Study and for direct supervision of any individual performing any portion of the Study at the Institution. In the event the Investigator becomes unwilling or unable to perform the duties required for the Study conducted under this Agreement, the Institution, SMO and Reliance shall attempt to agree on a mutually agreeable replacement. In the event a mutually acceptable replacement is not available, then the Agreement may be terminated by Reliance hereto in accordance with Section 10 of this Agreement.

C. In consideration of conducting the Study hereunder, Reliance shall pay the Payee for the conduct of the Study, in accordance with the budget and payment schedule attached as Appendix A to this Agreement, with the last payment being made after the Investigator, SMO and Institution complete all obligations hereunder, including the return of any Confidential Information as defined herein, and after Reliance receives verification that all completed case report forms (CRF's) have been completed and data queries have been entered and resolved.

D. In the event that the Study does not start or is terminated prematurely by Reliance, Investigator/Institution shall be entitled reimbursement for all reasonable fees and expenses incurred by the Investigator/Institution/SMO up to the effective date of termination of the Study on the

production of bills to Reliance. The Investigator/Institution/SMO will not be paid for Study subjects who do not complete the Study unless the Study is terminated in accordance with Section 10

E. Reliance shall execute an agreement with Central Laboratory, to perform certain Study-related investigations for the Study. The Investigator agrees to cooperate with Central Laboratory and their designated representatives in performing Study-related investigations as specified in the Protocol.

F. Investigator's signature below evidences Investigator's agreement that, prior to commencement of the Study, she shall read and ensure that she understands all information in the Protocol and the Investigator's Brochure/ Package Insert, including the potential risks and side effects of the Study Product, and understands the Applicable Laws and Requirements.

TERMS AND CONDITIONS

1. Conduct of the Study.

1.1 Before Commencement of Study. Before the Study commences, the Investigator shall make necessary filings and obtain all necessary authorizations, approvals, favourable opinions and other regulatory documentation required by the Protocol and "Applicable Laws and Requirements" (defined below), including:

a. Written approval or favourable opinion from all relevant Institutional Ethics Committees or institutional review boards (the "Institutional Ethics Committee") regarding the conduct of the Study, the terms of the Protocol (including the informed consent template), recruitment procedures, and the other matters designated for their opinion under the Protocol or Applicable Laws and Requirements. Reliance will assist the Investigator in making applications to the Institutional Ethics Committee by providing relevant information and documentation

b. In addition, before participating in the Study, the Investigator shall sign and deliver to Reliance an Investigator's Study Undertaking in accordance with Table 4, covered under Third Schedule of GSR 227(E)of the New Drugs and Clinical Trials Rules, 2019, and such other applicable documents as may be required from Investigator pursuant to Applicable Laws and Requirements, and Institution and Investigator and shall cause any co-investigators or sub-investigators to submit such documentation to Reliance in a timely manner. .

c. The Investigator shall also, prior to commencement of the Study, provide to Reliance a copy of all (i) requests for review, requests for authorization, and requests for opinion, (ii) approvals, authorizations, favourable opinions and any other opinions given by the Ethics Committee, and (iii) any other documentation filed with and/or received from Ethics Committee or any Regulatory Authority related to the Study.

d. After the conditions precedent set forth in this Section 1.1 are satisfied, the Institution, and Investigator shall commence the Study, and shall comply with the conditions attached to the authorizations/approvals.

e. The Investigator will review and understand the information in the Package Insert/ Investigator's Brochure, shall ensure that all informed consent requirements as well as the procedures described in the Protocol in relation to each Study subject are met. Investigator will complete a Case Report Form)CRF) for each Study subject in accordance with the procedure set out in the Protocol. Investigator will review and sign each of the CRF's to confirm that they accurately reflect the data collected during the Study.

f. Upon completion of the Study, investigator shall inform the Institution, Institutional Ethics Committee and provide a summary of the Study report.

g. Investigator may appoint individuals and investigational staff as they may deem appropriate as sub-investigator and/or study coordinator/s (the "Sub-Investigators" and "Study Coordinators" respectively) to assist in the conduct of the Study. All Sub-Investigators, Study Coordinators and investigational staff will be adequately qualified, timely appointed and an updated list will be maintained. Investigator shall alone be responsible for hiring, leading, supervising and reimbursing such team of Sub-Investigators, Study Coordinator and investigational staff, who, in all respects, shall be bound by the same terms and conditions as the Investigator under this Agreement. The Investigator shall be responsible for the conduct of the clinical investigation in its entirety and the well-being of the study subjects ("Study Subjects").

1.2 Site Visits. The Institution , SMO and the Investigator shall permit Reliance and their representatives to visit the Study Site during normal business hours, with reasonable advance notice, to review personnel, procedures, and facilities; to discuss with Investigator the general obligations regarding the Study; to review Investigator's Study file and the forms used for data collection for completeness and adherence to the Protocol; and to ensure compliance with this Agreement and all Applicable Laws and Requirements. The Investigator will promptly and fully produce all data, records and information relating to the Study, to Reliance and their representatives and shall assist them in resolving any questions and in performing audits or reviews of original subject records, reports or data sources.

1.3 Study Product.

a. Upon the receipt by Reliance of the written approval of the Institution's Ethics Committee Reliance shall provide the Investigator, at no charge, with such quantities of the Study product as may be required for the Study. The Investigator, SMO and Institution shall have no liability for any failure to fulfill its obligations as a result of unavailability of the Study Product. The Investigator and the shall at their risks, costs and expenses ensure the safe receipt, handling, storage, use and administration of the Study Product and take all reasonable measures to ensure that it is kept secure. The Investigator and the shall not permit Study Product to be used for any purpose other than the conduct of the Study in

compliance with the Protocol. Upon completion or termination of the Study, Reliance may retrieve all unused Study Drug and Study materials (such as unused laboratory kits) and all Confidential Information (as defined below). The Investigator, SMO and Institution will keep full and accurate records of who dispenses the Study Product, the quantity dispensed and the quantity returned. The Investigator and Institution shall use the Study Product being tested in connection with the Study, solely for the purpose of properly completing the Study and shall maintain all Study Product and Study materials provided by Reliance in a locked, secured area at all times.

b. The Investigator shall be primarily responsible for the Study Product's accountability and will keep full and accurate records of the use and disposition of the Study Product, including the delivery of the Study Product to the Investigator's Site, the inventory at the Site, who dispenses the Study Product, the quantity dispensed, and the quantity returned to the Sponsor or disposed-off.

c. Institution, SMO and Investigator shall comply with all Applicable Laws and Requirements governing the disposition or destruction of Study Product and with instructions from the Reliance.

1.4 Adverse Events. The Investigator shall report all adverse events, adverse reactions, product problems and any other reportable events or product use errors to the Reliance immediately and within the timelines defined in the Protocol, and to report the same to the Ethics Committee in accordance with the Protocol and Applicable Laws and Requirements, and shall otherwise comply with all Applicable Laws and Requirements in connection therewith. Reliance shall ensure that an up-to-date Package Insert / Investigator's Brochure on the Study Product is available for dissemination to the Ethics Committee, as well as subsequent modifications, if any, to the Subject Information Sheet and informed consent form template.

1.5 New findings. Reliance will promptly report to the investigator any new findings that could affect the safety of participants and the willingness of participants to continue participation influence the conduct of the study or alter the EC's approval to continue the study. Those findings that could affect the safety or medical care of the participants will be communicated to the participants by the investigator. The investigator will also inform the participant when medical care is needed for an illness of which the investigator becomes aware.

2. Recruitment. Subject to all necessary approvals being obtained, the Investigator shall be responsible for the recruitment of Research Subjects in the Study. The Investigator shall use the Investigator's best efforts to ensure that Research Subjects fulfilling the Protocol criteria are recruited. Investigator shall ensure the unbiased selection of an adequate number of suitable subjects according to the Protocol, and shall use best efforts to enrol at least **20 suitable subjects** and shall limit enrolment of subjects to the maximum number specified by the Reliance from time to time. Investigator acknowledges that Reliance reserve the right to limit entry or enrolment of subjects at any time on written notice to Investigator. Investigator shall obtain the written approval of the Institutional Ethics Committee and Reliance to the text of any communication soliciting subjects for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail

pieces, Internet advertisements or communications, and newsletters, which communications must comply with Applicable Laws and Regulations.

3. Enrolment; Notices; Informed Consent; Authorization:

3.1 Prior to enrolling a Research Subject in the Study, Investigator shall obtain (a) the Research Subject's informed consent, as evidenced by a signed informed consent document evidencing the informed consent of Research Subjects for participation in the Study, in the form approved by the relevant Ethics Committee; (b) an Authorization (as defined and described below); and (c) such other consents as may be required by the Protocol or Applicable Laws and Requirements.

3.2 Institution, SMO and Investigator shall adhere to the principles of medical confidentiality and shall comply with all Applicable Laws and Requirements related to the personal data of Research Subjects, including data privacy or data protection laws of the country in which the data originated. Investigator shall obtain from each Research Subject and provide to Reliance a written consent and authorization valid under Applicable Laws and Requirements (each, an "Authorization") for the access, use, processing, storing, disclosure and transfer of the Research Subject's personal data by and to (a) Institution, SMO, Investigator, and their study team, (b) persons monitoring the Study and/or the Multi-Center Clinical Study or conducting an independent valuation of the Study and/or the Multi-Center Clinical Study, (c) the representatives of the Institutional Ethics Committee, (d) the Regulatory Authorities, and (e) Reliance and Central Lab and their representatives and agents, including third parties directly or indirectly performing services for Sponsor related to the Study and/or the Multi-Center Clinical Study.

3.3 The status of enrolment of the trial subjects shall be submitted by the Investigator/ Institution on a quarterly or more frequent basis as per the duration of treatment in accordance with the approved clinical trial protocol; such reports will be processed in accordance with Protocol and Applicable Laws and Requirements.

4. Confidential and Proprietary Information. All information (including, but not limited to, documents, descriptions, data, CRFs, photographs, videos and instructions), and materials (including, but not limited to, the Study Product), provided to the Investigator, SMO and Institution by Reliance or Sponsor or their agents (whether verbal, written or electronic), and all data, reports and information relating to the Study Product, the Study or its progress (hereinafter, the "Confidential Information") shall be the property of Sponsor. The Investigator, SMO and Institution will undertake to keep in strict confidence and not at any time to use other than in the Study or to disclose or permit to be disclosed to any third party the data and results of the Study and any information provided directly or indirectly by the Sponsor or Sponsors Representatives under this Agreement. The Investigator, SMO and Institution shall keep the Confidential Information strictly confidential and shall disclose it only to its employees involved in conducting the Study on a need-to-know basis. The Investigator, SMO and Institution shall ensure that the immediate members of the staff and any co-investigator who have access to Confidential Information are informed of its confidential nature and agree in writing to keep it strictly Confidential in accordance with the provisions of this Section 4. The obligations of non-disclosure stated in this Section shall be for a minimum period of fifteen (15) years after disclosure of said Confidential

Information to Investigator and /or Institution and /or SMO under consideration for the provisions of sub-section 4 (a) – (f) inclusive, and these confidentiality obligations shall continue after completion of the Study, but shall not apply to Confidential Information to the extent that it: a) is or becomes publicly available through no fault of the Investigator, SMO and Institution ; b) is disclosed to the Investigator by a third party not subject to any obligation of confidence; c) must be disclosed to ECs or applicable Regulatory Authorities; d) must be included in any Study subject's ICF; e) is published in accordance with Section 7 herein; or, f) is required to be disclosed by applicable law.

5. Intellectual Property Rights - All intellectual property rights existing prior to the date of this Agreement will belong to the Party that owned such rights immediately prior to the date of this Agreement. Neither Party will gain by virtue of this Agreement any rights in or ownership of copyrights, patents, trade secrets, trademarks or any other intellectual property rights owned by the other party. The Investigator, SMO and Institution hereby agree that the Sponsor shall own all intellectual property rights arising out of the Study and related to the Study Product, including any rights with respect to any discoveries, inventions, whether patentable or otherwise and which relates to the materials and arising as a result of the Study. The Investigator, SMO and Institution will, at Sponsor's expense, execute any documents and give any testimony necessary for Sponsor to effect the transfer of the title of such property, obtain patents in any country or to otherwise protect Sponsor's interests in such inventions. The Investigator, SMO and Institution shall have exclusive ownership of any inventions or discoveries conceived by the Investigator, SMO and Institution during the course of the that are wholly unrelated to the Study Drug and Protocol and do not arise in whole or in part from the Study or any Confidential Information, but the Investigator and Institution shall offer the Sponsor the right of first refusal as to any sales or licenses of such inventions. The Investigator, SMO and Institution agree to comply with any applicable data privacy or data protection legislation of the country in which the data originated.

6. Study Records

6.1 The Investigator shall prepare, maintain and retain complete, accurate, and legible source documents, regulatory documents, and other written records, accounts, notes, reports, and data relating to the Study (collectively, "Records"), including CRFs and including all documentation and records concerning the Study Site, the solicitation, screening, evaluation, enrollment and testing of subjects (including the relevant portions of other pertinent records concerning such subjects, all queries raised by the subject during the informed consent administration and the responses provided); the procedures, tests and other activities performed during the Study; results and interpretations, including statistical analyses, if required; and all financial transactions related to the Study. Further, the Investigator shall ensure that the data reported on the CRFs that is derived from source documents is consistent with the source documents, and discrepancies, if any, shall be explained. All original CRFs shall be made available to the Reliance in a timely manner throughout the performance of the Study. CRFs shall identify the Research Subjects by number/Code and/or screening number assigned to the subjects rather than by the subjects' name(s), personal identification informations and / or addresses. The Investigator shall retain the Records of the Study, including the original of all volunteer consent forms, for upto fifteen years from the date of the end of the study.

6.2 Investigator shall maintain, store and transmit any Records that are electronic records in a validated database and in accordance with Indian regulations, and any other Applicable Laws and Requirements. In no event shall Investigator remove any Records from the Study Site or destroy any Records without the prior written consent of Sponsor. Upon expiration of the applicable retention period, Sponsor shall, upon Institution or SMO or Investigator's request, direct that such Records be delivered to Sponsor or Sponsor's representative, be destroyed, or be retained by Institution//Investigator, and Institution//Investigator shall comply with Sponsor's directions.

7. Publication. The results of the Study including all obtained data will be the property of the Sponsor. The Investigator, SMO and Institution should not publish or communicate the data in public without written authorisation by the Reliance Unpublished data should not be disclosed to any third party by the Investigator, SMO and Institution without the written approval of the Sponsor. The Investigator and /or Institution and/or SMO may have access to the Study data resulting solely from her participation in the Study for purely scientific or educational purposes, but unless previously explicitly permitted in writing by the Reliance she may not use the data for any commercial purposes. Investigator may publish or otherwise disclose the results of the Study provided that Investigator provides a copy to Reliance, at least sixty (60) days prior to disclosure or submission to any third party, for review and comment. Within this sixty (60) days period, Sponsor shall review the proposed publication or release to determine whether it contains Confidential Information (as described in Section 4), whether Sponsor desires to file patent applications on subject matter contained in the proposed publication or release or to ensure the accuracy of the information contained in the publication or release. Upon receiving any notification from Sponsor requesting deletion of Confidential Information, requesting correction of inaccuracies, or requesting a delay in publication to allow the filing of patient applications before publication or release, Investigator shall take the requested action.

8. Subject Injury Reimbursement

8.1 Subject to Investigator and Institution's indemnification obligations under Section 11.2, if a properly enrolled Research Subject suffers a "Research Related Injury" as a direct result of taking part in the Study, Sponsor agrees to reimburse Institution and/or Investigator for the actual cost of diagnostic procedures, medical treatment necessary to treat a Trial Subject injury in accordance with the Protocol and provide financial compensation to the research subject as per the order of the licensing authority under rule 42 of New Drugs and Clinical Trial Rules [GSR 227(E), 19 March 2019 in case of Trial Subject's injury and/or death. Institution and Investigator agree to provide or arrange for prompt diagnosis and medical treatment of any medical injury experienced by a Trial Subject as a result of the Trial Subject's participation in the Trial. Institution, SMO and Investigator further agree to promptly notify Sponsor of any such medical injury. For purposes of this Agreement, the term "Research Related Injury" means physical injury or ill effect, disability whether temporary or permanent and serious or otherwise caused by the Products or procedures prescribed in the Protocols, which are different from the medical management the Research Subject would have received if he had not participated in the studies.

9. Inspection and Debarment.

9.1 Investigator, SMO and Institution shall cooperate with any government inspection or audit of the Study site or records. The Investigator, SMO and Institution agree to communicate in writing or contact by telephone or fax Reliance prior to any communication or meeting with any Regulatory Authority relating to the Study, and the Investigator, SMO and Institution would provide the Regulatory Authority only with information approved for disclosure by Reliance. The Investigator, SMO and Institution agree, upon reasonable notice, to disclose, from time to time, for inspection/audit by representatives of Reliance and/or national or international Regulatory Authorities, all such report forms and further documentation and information used and/or generated in the Study. The Investigator, SMO and Institution shall immediately notify Reliance of, and provide Reliance copies of, any inquiries, correspondence or communications to or from any governmental or Regulatory Authority relating to the Study, including, but not limited to, requests for inspection of the Institution's facilities, and the Investigator, SMO and Institution shall permit Reliance to attend any such inspections. The Investigator, SMO and Institution will make reasonable efforts to separate, and not disclose, all confidential materials that are not required to be disclosed during such inspections, except as required by law. The Investigator, SMO and Institution shall also arrange for access by such individuals to source data and shall be responsible for obtaining the informed consent of Study subjects to such disclosure of personal medical data and records, if required by law, and if not expressly granted by the subject in the signed Informed Consent Form.

9.2 The Investigator and/or Institution and/or SMO shall permit the representatives of Reliance to visit the premises on which the Study is being conducted and arrange/ grant access to laboratories and facilities used in connection with the Study, at periodic intervals at a mutually agreeable time.

9.3 The Investigator, SMO and Institution shall permit the Reliance to inspect and audit the study. The Investigator, SMO and Institution shall be responsible for maintaining essential Study documents for the time and in the manner specified by current ICH-GCP guidelines, Applicable Laws and Requirements, and Reliance requirements and shall take measures to prevent accidental or premature destruction of these documents. In the event the Investigator leaves an Institution or otherwise changes addresses, the Investigator, SMO and Institution shall promptly notify the same to Reliance.

9.4 The Investigator, SMO and Institution represents and warrant that neither the Investigator nor the Institution nor any of the employees, agents or other persons performing the Study under the Investigator's direction, has been debarred, disqualified or banned from conducting clinical trials or is under investigation by any Regulatory Authority for debarment or any similar regulatory action in any country, and the Investigator or Institution shall notify Reliance immediately if any such investigation, disqualification, debarment or ban occurs.

10. Study Term and Termination.

10.1 This Agreement shall be effective upon the date it is signed by all the parties and shall continue in effect till the completion of the Study as mentioned in the Protocol, unless terminated earlier by the parties as given below:

a. Reliance may terminate this Agreement with prior written notice of 30 days to the Investigator/ Institution for reasons including but not limited to any of the following occurrences:
   i) If no subjects are recruited by the Investigator within 30 days of the site initiation; or
   ii) No recruitment is done by the Investigator for a period of 45 consecutive days; or
   iii) If, no subjects have been enrolled or the Investigator subjects no patients or recruits such a low number (less than 2 in number) of subjects that it can be assumed that the agreed number of patients will not be reached during the planned recruitment phase;
   iv) Sponsor terminates the Study or the development of the Study product or the indication is discontinued;
   v) It is proved that the dosage used for the Study no longer seems to be justified;
   vi) A Regulatory Authority or other pertinent institution decides to terminate the Study in the Institution or as a whole;
   vii) The Investigator/ Institution/SMO fail to adhere to the conditions of the Protocol and the requirement to complete CRF data according to the Practice Applicable Laws and Requirements and the Study Protocol.

b. Should the Investigator/Institution/SMO recognize, with reasonable discretion, that continuation of the Study is no longer medically justified, due to (i) unexpected results (ii) the severity or prevalence of Serious Adverse eEvents or (iii) perceived insufficient efficacy of the treatment with Study Drug appears to be insufficient; then she will promptly notify Sponsor as well as the Ethics Committee in writing. Should Reliance or the Institutional Ethics Committee agree that continuation is not justifiable; the Investigator/Institution/SMO may arrange termination of the Study in accordance with Applicable Laws and Requirements and the Study Protocol..

c. Whichever party terminates the Study early shall provide the other parties with a written statement of its reasons for doing so. Reliance will notify Regulatory Authorities as appropriate of early termination, except that the Investigator will notify the Ethics Committee.

10.2 **Effect of Termination** Upon receipt of notice of termination, the Investigator shall immediately cease any patient recruitment, complete all outstanding Case Report Forms and return to Reliance all documents/equipment (if any) provided by the Reliance under this Agreement and following the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs. In the event of early termination Reliance shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in the Payment Schedule (Annexure A); provided, however, that ten percent (10%) of this final payment will be

withheld until final acceptance by Sponsor of all completed CRFs and all data clarifications issued and satisfaction of all other applicable conditions set forth in the Agreement.

10.3 Reliance shall not be responsible to the Investigator, SMO or the Institution or for any lost profits, lost opportunities, or other consequential damages arising out of this Agreement. If a material breach of this Agreement appears to have occurred and termination may be required, then, subject to subject safety, Reliance may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

11. Indemnification; Claims and Disclaimers.

11.1 Reliance agrees to indemnify, defend or cover costs of defense for, and hold harmless ("Indemnify") the, Principal Investigator; the Institution, SMO its officers, agents, and employees; and the IEC that approved the Trial (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities, expenses to the extent that it relates to the death of a Subject caused by: a) the administration of the Sponsor Drug and/or Comparator Drug; (b) by a properly-performed Protocol-required procedure;, provided, however, that Reliance will not indemnify or hold harmless the **Indemnified Parties** for any Liabilities arising from any injuries or damages that are a result of:

(i) the negligence or intentional misconduct of any of the **Indemnified Parties** and/or
(ii) any activities conducted contrary to the provisions of the Protocol or outside the scope of the Protocol; or information supplied by Sponsor and/or generally accepted medical standards and the applicable SOPs; and/or
(iii) any negligence, omission, or willful misconduct by any **Indemnified Parties** in the performance of their obligations under this Agreement and/or,
(iv) failure to have complied with all dosage and other specifications, directives and recommendations furnished by the Sponsor for the use and administration of the Study Product and/or
(v) failure to have complied with all applicable laws, rules, and regulations.

However, Reliance's indemnification obligations are subject to the following conditions:

a. The Research Subjects involved gave an adequate written informed consent and was provided prompt diagnosis and appropriate medical care following the occurrence of the injury;
b. The Reliance receives notice of the applicable, diagnosis, care initiated and care anticipated to be necessary and all appropriate follow-up reports; and Reliance are promptly notified in writing of any such claim or suit;.
c. Indemnified Parties reasonably cooperates with Sponsor and its legal representatives in the defense of any claim, suit, demand, action or other proceeding covered by this Agreement; and

d. Indemnified Parties permit Reliance to select and retain the right to defend any claim or suit in any manner it deems appropriate, including retaining a counsel to represent Indemnities parties and

e.. The indemnification obligations above shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the product.

Reliance's indemnification obligations do not apply to any complication of an underlying illness or any other injury that any Research Subjects may experience during the course of the studies that is not directly related to the Study Drug.

11.2 Investigator Institution and SMO shall indemnify, defend, and hold harmless Reliance and each of their respective affiliates, directors, officers, employees, contractors, and agents from and against any loss claim or demand arising from the following: (i) injuries or damages resulting from the negligent or willful misconduct of the Investigator, SMO and Institution or any of their respective affiliates, directors, officers, employees, contractors, and agents, including any co-investigators or sub-investigators performing the Study; or the failure of Institution and/or Investigator or any of their employees, contractors, and agents, including any co-investigators or sub-investigators, (i) to comply with the Protocol or written instructions of Reliance or any Applicable Laws and Requirements; or (ii) any breach by Institution, SMO or Investigator of any of their respective obligations under this Agreement, including but not limited to any failure to comply with the Protocol or any Applicable Laws and Requirements or (iii) any case in which the Investigator fails to obtain an informed consent form in compliance with the terms of this Agreement or otherwise fails to comply with Applicable Laws and Requirements provided:

a. Investigator, SMO and Institution promptly notified in writing of any such claim or suit;
b. Sponsor cooperate fully in the investigation and defense of any such claim or suit;
c. Investigator, SMO and Institution retain the right to defend any claim or suit in any manner it deems appropriate, including the right to retain counsel of its choice; and
d. Investigator, SMO and Institution shall have the sole right to settle the claim; provided, however, that Investigator shall not admit fault on Sponsor's behalf without Sponsor's advance written permission.

11.3 The Investigator, SMO and Institution shall promptly notify Reliance in writing of any claim of illness or injury actually or allegedly due to an adverse reaction to the Study Product and allow Reliance to handle such claim (including settlement negotiations), and shall cooperate fully with Sponsor in its handling of the claim.

11.4 Institution, SMO and Investigator acknowledge that the study product is experimental in nature, is not for commercial use, and is provided "as is" without any warranty, representation or undertaking whatsoever, express or implied, including, without limitation, any warranty of merchantability, fitness for a particular purpose, or non-infringement. Reliance shall not under any circumstances be responsible or liable under this

agreement for any indirect, incidental, or consequential damages (including without limitation damages for loss of profit, revenue, business, or data), even if the party has been informed of the possibility of such damages.

12. Financial Disclosure. Reliance may withhold payments if it does not receive a completed form from each such Investigator and sub-Investigator. The Investigator shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one year after its completion. The Investigator, SMO and Institution agree that the completed forms may be subject to review by governmental or regulatory agencies, Reliance and their agents and Institutional Ethics Committee. Whenever the investigator discloses a financial interest, the nature of financial disclosure will be reported to Reliance.

13. Insurance: Each party shall maintain types and levels of insurance or other adequate forms of protection consistent with industry standard and sufficient to satisfy its respective obligations under this Agreement. Each party shall provide the other party with a certificate of insurance upon request.

14. Shipping of Dangerous Goods and Infectious Materials. The handling, packaging and shipment of dangerous goods and infectious materials (including infectious specimens) are subject to local and national laws and regulations.

15. Publicity.

15.1 Solicitation of subject: Reliance and Ethics Committee shall approve in writing, the text of any communication soliciting subjects for the Study before placement, including, but not limited to newspaper or radio advertisements, direct mail, internet advertisements or communications, and newsletters. Such communication must comply with applicable laws and guidelines.

15.2 Press Releases: Reliance shall approve, in writing and all press statements by Investigator and Institution regarding the Study or the Study product before such statement is released. It is the Investigator's obligation to take such prior approval from Reliance.

15.3 Enquiries from media and financial analysts: During and after the Study, the Investigator, SMO and Institution may receive enquiries from reporters or financial analysts. Investigator and Institution must confer with Reliance authorised signatory to this Agreement named below or other named person in the same position of employment at that time at Reliance Life Sciences Pvt. Ltd. Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701 before responding to such enquiries.

15.4 Use of Name: Investigator, SMO and /or Institution or any of the Investigator and Institution's trained staff/employees, agents or other persons performing the Study under the Investigator's direction will not use Reliance's ' name or the names of Reliance employees in any advertising or sales promotional material or in any publication without the prior written permission of Reliance. Reliance shall not use the name of the

Investigator, SMO or Institution and their employees in any sales promotional material or in any publication without written permission from the Investigator, investigator and Institution. It is agreed that all Study Reports, Study Proposals, and notifications to Regulatory Agencies by Reliance may contain the name of the investigator and Institution.

16.0 Additional Contractual Provisions.

16.1 In conducting the Study, the Investigator, SMO and Institution shall be an independent contractor and shall not be considered the partner, agent, employee, or representative of Reliance and the Investigator and /or Institution and/or SMO has no authority to bind Reliance to any contract or commitment unless specifically authorized to do so in writing. This Agreement, including these terms and conditions, constitutes the sole and complete agreement between the Parties and replaces all other written and oral agreements relating to the Study.

16.2 The following provisions shall survive the termination or expiration of this Agreement; Section 4 (Confidential and Proprietary Information); Section 6 (Study Records); Section 7 (/Publication); Section 8 (Subject Injury Reimbursement); Section 11 (Indemnification; Claims and Disclaimers) and Section 15 (Publicity/Use of Names)

16.3 Amendments: No amendments or modifications to this Agreement shall be valid unless in writing and signed by all the Parties. Failure to enforce any term of this Agreement shall not constitute a waiver of such term. If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect. This Agreement shall be binding upon the Parties and their successors and assigns.

16.4 During the term of this Agreement, neither Investigator, nor Institution or SMO shall directly or indirectly conduct study related clinical trials as set out in the protocol no. **RLS/PMS/2016/08** and any subsequent amendments thereto or participate in the study, which is same or similar to Reliance designated study mentioned in this Agreement, without prior written approval of Reliance

16.5 Restrictions on Assignment: Neither Party will assign or transfer any rights or obligations under this Agreement without the prior written consent of the other Parties, which consent shall not be unreasonably withheld.

16.6 Conflict of interest: Investigator, SMO and Institution warrant and represent that the Investigator has no obligations, contractual or otherwise, that would conflict with its entering into this Agreement. Investigator, SMO and Institution further agree that subsequent to execution of this Agreement, the Investigator and /or Institution and/or SMO will undertake no obligations that would conflict or interfere with its performance hereunder.

16.7 Data Privacy: The Parties shall comply with all the Data Privacy related requirements prescribed by Applicable Laws and Requirements, and implement administrative, physical and technical safeguards to protect personal/sensitive personal information that are no less rigorous than accepted industry practices.

16.8 Force Majeure "Neither party of this agreement shall be liable for failure to perform if the failure is attributable to any cause which is reasonably beyond the party's control including:

(i) War (declared or undeclared), riot, political insurrection, rebellion or revolution.

(ii) Acts or order if, or legislation by government prohibiting the sale of the goods covered hereby, or imposing any restriction thereof.

(iii) Epidemics, pandemics or Quarantine restrictions.

(iv) Fire, flood, explosion, earthquake, tornadoes or other natural events: and

b) Any party claiming an event or force majeure shall promptly notify the other parties in writing and provide full particulars of the cause or event and the date of first occurrence thereof as soon as possible. If conditions of force majeure continue for a period of more than 60 days thereby affecting performance of the notifying parties, either party shall have an option to terminate this agreement by giving a 30 days' notice to the other party.

16.9 Notice: Any notices that either Party may be required to give the other shall be deemed to be duly given when mailed by certified or registered mail, postage prepaid, to the other Party at the addresses first given above or to such other addresses as the Parties may direct in writing. Any notice or other communication required or permitted under the Agreement shall be in writing and will be deemed given as of the date it is received by the receiving party.

16.10 Governing Language: The controlling language of this Agreement and all related documents, correspondence and notices shall be in English. This Agreement shall be governed by and construed in accordance with the laws of India without conflict of laws and principles.

16.11 Arbitration: Any dispute, controversy or misunderstanding between the Parties arising out of or related to this Agreement or any breach thereof shall be mutually settled by the Parties between their authorized representatives within a period of thirty days. In case, the dispute is not settled within a period of thirty days by the authorized representatives, the same shall be submitted to arbitration in accordance with Arbitration and Conciliation Act, 1996. Parties shall appoint a sole arbitrator, mutually agreed by the Parties. The place of Arbitration shall be at Mumbai and the language shall be in English. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs. Any award rendered by the arbitrators shall be in writing, shall be the final binding disposition on the merits, and shall not be appealable to any court in any jurisdiction. Judgment on an award rendered may be entered in any court of competent jurisdiction, or application may be made to any such court for a judicial acceptance of the award and an order of enforcement, as appropriate.

16.12 Counterparts: This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by facsimile or original, and a facsimile signature shall be deemed to be and shall be as effective as an original signature.

ACKNOWLEDGED AND AGREED BY RELIANCE LIFE SCIENCES PVT. LTD:

By: _____

Name: Dr. Pravin Ghadge
Title: Head, Clinical Research
Date: 26 JUN 2020

ACKNOWLEDGED AND AGREED BY INVESTIGATOR:

By: Ashis

Dr. A. R. Deshmukh
M.D., D.N.B.
Professor & HOD
Dept. of DVL
MGM Medical College & Hosp. A'bad
Reg. No. 56220

Name Dr.Ashish Deshmukh
Title: Associate professor and Head of Department of Dermatology, MGM Medical College and Hospital.
Date: 10-July-2020

ACKNOWLEDGED AND AGREED BY THE INSTITUTION:

By: _____

MGM's Medical College Aurangabad

Name: Dr Rajendra Bohra
Title: Dean, Dean, MGM Medical College and Hospital, Aurangabad
Date: 10 - July - 2020

ACKNOWLEDGED AND AGREED BY SMO:

By: _____

Name: Dr Sunil Chaudhary

Title: Director

Date: _____

Appendix A to Clinical Trial Agreement

Payee:

Investigator and Institution have designated "Grapecity Research Solutions LLP" as a Payee to receive all the payments under this Agreement. The details of the Payee designated to receive all of the payments for the services performed under this Agreement

PAYEE NAME:	Grapecity Research Solutions LLP
PAYEE ADDRESS:	Shree Prasad, Block No. D-2, Prakash Housing Society, Kalewadi Phata, Thergaon, Pune 411033, Maharashtra, India
TAX ID NUMBER (PAN Number)	AAPFG8186L
GSTIN number	27AAPFG8186L1ZH

The payments will be made by account payee Cheque in favor of the Payee "Grapecity Research Solutions LLP" in Indian Rupees.

The Parties agree that the payee designated herein is the proper payee for this Agreement, and that payments under this Agreement will be made only to the designated payee ("Payee").

Agreement Clauses

1) For the amount designated as per-subject budget, the Payee will receive payment only for the actual number of visits and procedures performed in accordance with agreed upon procedure fees outlined in the financial agreement; such compensation is limited to payment for the number of subjects who have completed these visits as per the Protocol, unless Reliance has given the Payee written approval to enroll additional Study subjects or extend the enrollment period.

2) To be eligible for payment, the procedures must be performed in full compliance with the Protocol and the Agreement, and the data submitted must be complete and correct. For data to be complete and correct each Study subject must have signed an EC-approved ICF document, and all procedures designated in the Protocol must be carried out on a best effort basis; omissions must be satisfactorily explained.

3) Reliance will reimburse the Payee, in accordance with the attached budget and payment schedule. The final payment will be made by Reliance to the Payee upon final acceptance by Reliance of all completed CRFs, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by Reliance, the return of all unused supplies to Reliance, and upon satisfaction of all other applicable conditions set forth in the Agreement.

4) Other than the final payment, Reliance shall not issue any payment for a total amount less than Rs.1000/- If the amount due in any given period is less than Rs.1000/-, such amount shall carry over without payment to the next payment period.

5) Major, disqualifying Protocol violations are not payable under this Agreement.

6) Matters in dispute shall be payable upon mutual resolution of dispute.

7) SMO needs to make payment to the Investigator and Institution within 15 days upon receipt of payment from Sponsor. Sponsor to be notified about the same by the Investigator regarding receipt of payment from SMO.

If Reliance requests the Investigator's attendance at a Study-start up meeting or other meeting necessary to provide the Investigator with information regarding the Study or Study Product, Reliance shall reimburse the amount of reasonable and necessary travel and lodging expenses that may be incurred to attend such meeting(s) and that have been specifically approved in advance by Reliance. Reliance shall make such reimbursements within thirty (30) days of receiving acceptable detailed documentation of such expenses provided that Reliance receives such documentation within sixty (60) days of the date that the expenses were incurred.

Payments shall be made as described in Appendix A and the rates agreed to between the Parties, as per the milestones described in the budget and payment schedule. Original invoices must be submitted to Reliance at the following address for reimbursement:

Reliance Life Sciences Pvt. Ltd.,
Dhirubhai Ambani Life Sciences Centre,
Plot no. R-282, TTC Area of MIDC,
Thane Belapur Road,
Rabale, Navi Mumbai 400 701
Attn: Sachin Singh , Tel: 022- 35338269,

The Payee will have 30 days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

Taxes
All payments shall be made net of income tax as per the Income tax act applicable at the time of payment. The TDS certificates for the income tax deducted will be provided in accordance with Income Tax Act.

Annexure A:
A.1. FINANCIAL SUMMARY (Unit Cost/Visit):

SITE BUDGET SHEET			
Project Code:	**K079**		
Protocol Number	**RLS/PMS/2016/08**		
Investigational Product	**Infimab™**		
No of patients in study	200		
No of patients	20		
No of visit per patient	5		
Site Related Costs (A)	**Unit Cost**	**Unit**	**Amount (INR)**
Principal Investigator Fees	18000	20	3,60,000
Clinical Research Coordinator Fees	5000	20	1,00,000
Administration Charges (20% of PI+CRC fees)	4600	20	92,000
Travel reimbursement	2500	20	50,000
Sub-Total site related cost (A)			**6,02,000**
Local Laboratory Testing Charges (B)			
Tuberculin Test	250	20	5,000
Chest X ray	450	20	9,000
Sub Total Laboratory Testing Charges (B)			**14,000**
Total (A) + (B)			**6,16,000**
Per Subject without GST			**30,800**
Applicable GST (18%)			**1,10,880**
Total Site Budget			**7,26,880**
Per Subject Budget including GST 18%			**36,344**

- The archival of the study documents after the close-out visit will be the responsibility of **MGM Medical College and Hospital, N-6, CIDCO, Aurangabad-431003, Maharashtra, India**. One time Archival charges will be paid at the rate of Rs. 75000 for 15 year. The archived documents will not be destroyed without prior notification and permission of Reliance Life sciences

A.2 Per Visit Payment schedule:

Assessment	Screening (V1)	Day 0 (V2)	Week 2 D 14(V3)	Week 6 D 42 (V4)	EOD day 98 Week 14 (V5)	Total (INR)
Principal Investigator Fees	3600	3600	3600	3600	3600	18000
Clinical Research Coordinator Fees	1000	1000	1000	1000	1000	5000
Institute Overhead- 20% on PI +CRC fees	920	920	920	920	920	4600
Travel Reimbursment @ INR 500 per visit	500	500	500	500	500	2500
Mantoux Test	250					250
Chest X ray	450					450
Per Visit Cost	6720	6020	6020	6020	6020	30800
GST (18%)	1209.6	1083.6	1083.6	1083.6	1083.6	5544
Per Visit Cost Including 18% GST	7929.6	7103.6	7103.6	7103.6	7103.6	36344
Per Subject Budget including GST 18%						36344

Note:

* Subject related expenses (investigation, travel expense etc will be released as per actual number of visits completed by subjects after monitor's verification and as per the statement provided by the investigator on the letterhead of the Investigator/Institute (not exceeding the cost specified above for each patient per visit).

- It is expected that the site will enroll at least 20 subjects.
- Reliance will reimburse only the cost of investigations performed locally for screen failure subjects (ESR, Chest X-ray and Mantoux test).
- Ethics Committee protocol review fee will be paid as per actuals.
- Procedure and Non-procedure cost for unscheduled visit and SAE or conditional procedures will be reimbursed upon receipt of invoices as per A.1 & A.2 Payment schedule under this Agreement. However, Reliance's prior approval should be taken for such visits and procedures (on a case to case basis).
- Payment related to Local lab investigations would be done upon receipt of actual from sites where approval for the same has been provided from Reliance.

Please note the following:

- The per visit activity cost will be paid on the completion of the corresponding activity and the completion of the corresponding CRF.
- Payments are calculated according to the above schedules payable on confirmation by Reliance.
- Early Discontinuations will be paid through last completed "visit".
- The investigator must present a statement on letterhead for claiming any above mentioned payment under section A.1 & A.2 as per tax-compliant formats.
- If the study is prematurely terminated, the total payment to the payee will be made for those evaluable subjects enrolled by the investigator in accordance with study visits completed at the time of the termination notice and upon receipt by Reliance of completed Case Report Form. The Investigator agrees agree to refund any excess amount previously paid, and Reliance agree to promptly pay any amount owing based to the receipt of acceptable CRFs at Reliance and the resolution of all queries/questions relating to the data.
- Permission to enroll additional subjects must be obtained from Reliance. The total grant will increase according to the per subject cost for the increased number of subjects.
- The archival of the study documents after the close-out visit will be the responsibility of MGM Medical College and Hospital, N-6, CIDCO, Aurangabad-431003, Maharashtra, India. One time Archival charges will be paid at the rate of Rs.75000 for 15 year. The archived documents will not be destroyed without prior notification and permission of Reliance Life sciences
- Reliance will reserve the right to re-allocate subject budget originally reserved for this site to the other sites if site is having difficulty in enrolling and qualifying subjects.
- GST will be paid as per prevailing rates. All other taxes are included in the budget cost. TDS shall be deducted as applicable.

CLINICAL TRIAL AGREEMENT

THIS CLINICAL TRIAL AGREEMENT ("Agreement") is made and entered into as of 04 day of SEP 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.** a company incorporated under Companies Act, 1956 having its registered office at 212/2, Off Soli Poonawalla Road, Hadapsar, Pune 411028, India. (hereinafter "Sponsor");

Dr. Tayade Deepak Narayan, MGM Medical College and Hospital, N-6, CIDCO, Aurangabad 431003, Maharashtra, India hereinafter referred to as the 'Principal Investigator' or 'Investigator'; AND

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) acting through its authorized signatory, Dr. Rajendra Bohra, Dean_being authorised to sign this Agreement (hereinafter referred to as the **"Institution"** which expression shall mean and include unless repugnant to the context, its successors and permitted assigns).

The Sponsor, the CRO, the Investigator, and the Institution shall hereinafter be referred to individually as "*Party*" and collectively as "*Parties*".

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: **An Open label, Randomized, Active-controlled, Multi-centric phase II/III Study in Indian Toddlers and Infants to Assess the Immunogenicity and Safety of SIIPL HEXASIIL™ (DTwP-HepB-IPV-Hib) Vaccine in Comparison to SIIPL Pentavac (DTwP-HepB-Hib) + Poliovac (IPV) vaccines Administered as Separate Injections**. Protocol no. – SII-wHEXA/IN-02, Version 2.0, dated 26th Jun 2020 or such other version as may be mutually agreed and finalized by the Parties to the Agreement("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-wHEXA/IN-02**,** 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 (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.

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) 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. 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 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 estimated as mentioned in Schedule C.

1.3 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.

1.4 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.

1.5 The Study shall be carried out at the Institution under the review of its Ethics Committee/Institutional Review Board or an appropriate independent review committee of scientists and other qualified individuals as set forth in the Declaration of Helsinki (any such Board, body or committee to be referred to hereinafter as "IRB"), in compliance with the applicable local regulation, 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 (and any subsequently approved Protocol amendments), and the terms of this Agreement and under the supervision of the Investigator.

1.6 Before commencing the Study, 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. 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;

1.7 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.

1.8 Institution and Investigator 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.

1.9 Institution and Investigator 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.

1.10 The Investigator hereby warrants that he/she has received a copy of the Investigator Brochure and has read and understood its contents.

1.11 Any change, amendment or modification to this Agreement or any Schedule hereto must be authorized in writing 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.

1.12 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.

1.13 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.

1.14 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 without the express written authorization of the CRO. 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.

1.15 The Institution and the Investigator shall comply with ICH/GCP, the Protocol and all applicable laws, rules, regulations and documentation of the Study (hereinafter "Regulatory Requirements") in the performance and documentation of the Study. Without in any way limiting the foregoing, these obligations shall include the following:

(a) The Institution and the Investigator shall, as the same may be required of them by Regulatory Requirements, or specific instruction of CRO 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").

(b) The Institution and Investigator 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 as directed / instructed by the Sponsor (e.g., completion of shipment forms, ensure the relevant shipment procedure);

(c)The Institution and Investigator 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 included in the Protocol.

(d) Upon reasonable notice and at reasonable times during the term of this Agreement, Institution and the Investigator shall permit representatives of the CRO and/or the Sponsor to examine their 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.

(e) The Investigator will keep appropriate records of Study Vaccine received, dispensed, used, and returned to pharmacy/storage (and returned to CRO/Sponsor in accordance with Regulatory Requirements.

1.16 Institution and Investigator 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.

1.17 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.

1.18 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.

1.19 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 any cost from CRO and/or Sponsor.

1.20 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.

Article 2 – Compensation

2.1 Recruitment for this Study will be through competitive enrolment, and Institution and Investigator may enroll more or less Study subjects, depending on the enrolment of Study subjects at other sites, which shall be coordinated by the Sponsor and the CRO. 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.

2.2 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 schedule annexed to this Agreement or any additional period that may be granted by CRO/Sponsor by written communication in writing which is agreed by both the Institution and Investigator, in writing. 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 agreed deliverables called for under this Agreement, including any technical report and financial statement.

2.3 In full and complete consideration of Investigator's and Institution's participation in the Study and of their covenants and obligations hereunder, and to cover their respective costs connected with the conduct of the Study, CRO shall pay amount as set forth in Schedule B hereto. 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 as agreed in the schedule of attached to this Agreement.

2.4 Institution agrees to apply all funds received from CRO, including all interest ccrued 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.

2.5. 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.

2.6 For all subjects who fail to get enrolled (Screen failure), the amount payable will be Rs. 3000 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.

2.7 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.

2.8 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.

2.9 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. As the sponsor has SEZ status and operates out of SEZ, CRO agrees to supply the services without charging GST. Supply of goods or services or both made to SEZ developer or unit are Zero rated under Section 16 (1) (b) of GST Act 2017. CRO shall clearly mention in its all invoices "Supply to SEZ without charging IGST against Letter of Undertaking (LUT) no.

2.10 The payments represent all Study costs, and no other money will be payable by CRO.

2.11 The Parties hereby agree and covenant that Investigator / Institution will raise invoices in the name of Sponsor which will be submitted to and 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 sent to CRO at the following addresses:

DiagnoSearch Life Sciences Pvt. Ltd.

702, Dosti Pinnacle, Wagle Estate

Thane – 400 604, India

2.12 All amounts payable to the Investigator / Institution will be subject to Tax Deduction at source as required by the relevant tax provisions

2.13 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 Authorized Operations under Bond or Legal Undertaking without payment of Integrated Tax."** Every such invoice must also mention the GSTIN No. 27AABCS4225M2Z6 of our SEZ unit.

(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 Authorized 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.

2.14 Cheques should be drawn and made payable to MGM Medical college ,Aurangabad and delivered to the following address:

MGM Medical College & Hospital,
N-6, CIDCO, Aurangabad – 431003

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 engaged for effective performance and execution of the Trial.

3.4 During the term of the Agreement, Institution and Investigator agree to permit representatives of the CRO and the Sponsor to examine at any reasonable time during normal business hours the facilities where the Study is being conducted, the Study data including original patient records and any other relevant information necessary to confirm that the Study is being conducted in conformance with the Protocol and in compliance with applicable laws and regulations. Institution and / or Investigator shall notify Sponsor / CRO in writing within three (3) business days of becoming aware of any FDA or other government inspection or inquiry concerning the Study or within twenty four (24) hours of any surprise government inspection or inquiry concerning the Study. Investigator and Institution agrees to promptly take any reasonable actions requested by CRO/Sponsor to cure deficiencies noted during an inspection or audit.

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 periodicity 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 generated hereunder shall become the property 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 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.

4.5 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 three (3) 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.

4.6 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;

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.

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 amount of compensation to be paid by the Sponsor / CRO shall be mutually agreed between the Parties before filing any application. 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

6.1 Press Releases. Except for publications pursuant to Article 6.2, in the event a Party wishes to issue a press release or other public announcement (collectively, "Press Release") regarding this Agreement, the Study, or the termination of or other information related to the Study, such Party will submit the intended Press Release to the designated officials of other Party for review at least thirty (30) days in advance of the date of the intended release. In the event a Party does not approve the intended Press Release in writing, the non-approving party shall discuss in good faith modifications to the Press Release with the Party proposing the Press Release, but neither Institution nor Investigator shall release a Press Release without the prior written approval of Sponsor, such approval not to be unreasonably withheld or delayed. The requirements of this Article 6.1 shall not apply to the extent that a Party is required to disclose information by applicable laws and Requirements or order of a governmental agency or a court of competent jurisdiction; provided, however, that the Party required to make such a disclosure will (i) provide prior written notice thereof to other Party before such disclosure, (ii) consult in good faith with other Party with respect to such disclosure, and (iii) provide other Party sufficient opportunity to, and cooperate with any reasonable request of other Party to object to any such disclosure or request confidential treatment thereof.

6.2 Investigator Publications; Publications by the Parties. The Parties shall undertake to make or coordinate a joint publication or presentation of the Study results ("Joint Publication"). And such Joint Publication shall comply with the obligations of ICMJE (International Committee of Medical Journal Editors), including matters of authorship. Any decision to make or coordinate a Joint Publication or presentation of the Study results shall be discussed and agreed by the Parties before implementing the same, and the content of such Joint Publication shall be reviewed and agreed by the Parties.

6.2.1 Each Party may also publish or orally present the Study results (a "Sole Publication"), consistent with high scientific standards and in an appropriate scientific forum, provided that such Sole Publication does not also disclose any other Party's Confidential Information other than the Study results. The Parties agree that any Sole Publication shall be made only after the Joint Publication and shall refer to such Joint Publication, provided that the Joint Publication is published or presented within twelve (12) months after the last subject's visit.

6.2.2 In the case of a Sole Publication by a Party, the Party seeking to publish or present will submit to the other Party each such proposed publication, written presentation, or summary of each proposed oral presentation, as the case may be, related to the Study, and the other Parties must receive such proposed publication, presentation, or summary, as applicable, at least thirty (30) days before the time of submission to any third party, and in any case no less than forty-five (45) days prior to the proposed date of the publication or presentation. Such other Parties will have at least thirty (30) days from receipt in which to review each proposed publication, presentation or summary of proposed oral presentation, as the case may be. Upon such review a Party may require a delay in any publication or presentation for up to one hundred twenty (120) days from the date of such request in order to file patent applications relating to an Invention.

6.2.3 A Party may require the removal of its Confidential Information contained in any proposed publication or presentation, and any Party may require (i) the deletion of that Party's name or the name of any of its respective Affiliates and (ii) the deletion or correction of any information that may, in such Party's view, be inaccurate, misleading, or inappropriate; provided, for the avoidance of doubt, that a Party may publish or orally present Study results in accordance with the requirements as set forth in Article 10.2. Notwithstanding the foregoing, a Party may not require the removal of any information from the proposed Investigator publication that would prevent Investigator from presenting in such publication or presentation a full and fair description of the Study results. Once any information has been so reviewed and approved by each of the Parties and Investigator, as applicable, for publication or presentation, a Party may include such information in subsequent publications, presentations or submissions without the need to re-submit such information to the other Parties for pre-review.

6.2.4 The rights and obligations of Article 6.2 shall continue in effect until five (5) years following the expiration or any termination of this Agreement.

6.3 License to Investigator Publications. Sponsor and institution shall have a royalty-free, nonexclusive, and irrevocable license to reproduce, translate, display, publish, use, and distribute Investigator publications and to authorize others to do so with the consent of the Investigator.

6.4 Authorship, Patent Protection and Notification of Funding. Any oral presentation of the Study will acknowledge any publication by a Party regarding the Study and will state that the Study sponsored by Sponsor was carried out in collaboration with the Parties.

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) any information that is appropriate to include in an Institution Publication made in accordance with this Agreement or

(v) 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.

7.5If 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 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.

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 CRO/Sponsor, 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 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.

9.4 The Institution is also entitled to terminate the present agreement for any breach of the terms of the agreement by the Sponsor, by issuing 30 days notice to it, in case such breaches are not cured by it within stipulated period.

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 notified vide Gazette dated 30th January 2013, G.S.R 53 (E), rule 122 DAB, 12th December 2014, G.S.R. 889 (E), and any amendment or new pronouncement notified by the Competent Authority

Notwithstanding clause 10.3 above, 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:

(a) not use child labor in circumstances that could cause physical or emotional impairment to the child;

(b) not use forced labor (prison, indentured, bonded or otherwise);

(c) provide a safe and healthy workplace; safe housing (if housing is provided by Institution to its employees); and access to clean water, food, and emergency healthcare in the event of accidents in the workplace;

(d) not discriminate against employees on any grounds (including race, religion, disability or gender);

(e) not use corporal punishment or cruel or abusive disciplinary practices;

(f) pay at least the minimum wage and provide any legally mandated benefits;

(g) comply with laws on working hours and employment rights;

(h) respect employees' right to join and form independent trade unions;

(i) encourage subcontractors under this Agreement to comply with these standards;

(j) maintain a complaints process to address any breach of these standards.

Article 14 - Anti-Bribery and Anti-Corruption

14.1 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")

14.2 The Institution and its affiliates has established and continues to maintain reasonable internal controls and procedures intended to ensure compliance with the Anticorruption Laws including controls and procedures designed to ensure that the Investigator or its employees or Sub-investigators do not make payments in violation of the 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 – Record keeping 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 three (3) 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 a pplicable 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 3 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 t rial 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 t rial s ite 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.

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 21, 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 The Institution and Investigator understand and agree that SPONSOR is a third party beneficiary to this Agreement and, in this capacity, can enforce any terms as if it were a Party hereto.

24.4 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.

24.5 Failure by either Party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by either Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

24.6 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:	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:	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: DiagnoSearch Life Sciences Pvt. Ltd
702, Dosti Pinnacle, Plot No. E-7, Road No. 22, Wagle Industrial Estate, Thane- 400604, Maharashtra, India

If to the Sponsor, to: Serum Institute of India Private Limited 212/2 Hadapsar, Pune 411 028, India
Facsimile: 91-20-26993921

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

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.

24.7 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 4th SEP 2020
Name: Dr. Tayade Deepak Narayan
Title: Principal Investigator

FOR AND ON BEHALF OF:
MGM Medical College and Hospital

By: Date 04/9/2020
Name: Dr. Rajendra Bohra
Title: Dean

FOR AND ON BEHALF OF:
DiagnoSearch Life Sciences Pvt. Ltd.

By: Date 12th Aug 2020
Name: Gajendra Sharma
Title: Controller Finance and Accounts

FOR AND ON BEHALF OF:
Serum Institute of India Pvt. Ltd.

By: Date 12/08/2020
Name: Dr. Hitt Sharma
Title: Additional Medical Director

SCHEDULE A
PROTOCOL NUMBER: SII-wHEXA/IN-02
CLINICAL TRIAL PROTOCOL SYNOPSIS

STUDY TITLE	An Open label, Randomized, Active-controlled, Multi-centric Phase-II/III Study in Indian Toddlers and Infants to Assess the Immunogenicity and Safety of SIIPL HEXASIIL™ (DTwP-HepB-IPV-Hib) Vaccine in Comparison with SIIPL Pentavac (DTwP-HepB-Hib) + Poliovac (IPV) Vaccines, Administered as Separate Injections.
SPONSOR	Serum Institute of India Pvt. Ltd.
CLINICAL RESEARCH ORGANIZATION (CRO)	DiagnoSearch Life Sciences Pvt. Ltd.
PROTOCOL ID	SII-wHEXA/IN-02
CLINICAL DEVELOPMENT PHASE	Phase II/ III
INDICATION	Active immunization against Diphtheria, Tetanus, Pertussis, Hepatitis B, Poliovirus type 1, 2 & 3 and *Haemophilus Influenzae* type b. Recommended schedule for primary immunization in infants is three doses with an interval of 4 weeks between doses, starting at 6 weeks of age. A booster dose is recommended in the second year of life.
NUMBER OF SITES	The study will be conducted at approximately 8 sites across India.
STUDY POPULATION	
PART I	222 healthy male and female toddlers aged 12-24 months who have completed 3 doses of primary immunization series at least 6 months prior to enrolment
PART II	1260 healthy male and female infants aged 6-8 weeks at enrolment
DURATION OF TODDLER/INFANT PARTICIPATION	
PART I	The maximum duration of participation of each toddler is approximately 42 days
PART II	The study duration is as follows: • Primary vaccination period (3-dose primary vaccination series) ~2 months • Follow-up post completion of 3-dose primary vaccination series ~1

	month • Post completion of 1-month follow-up period after primary vaccination series, the subjects will be further followed up for booster dose which may occur between 12-24 months of age. Post-booster dose, the subjects will be followed up for 1 month.
EXPECTED DURATION OF STUDY	
PART I	Approximately 3 months
PART II	Primary Vaccination Series: Approximately 12 months Total duration including Primary Vaccination Series and Booster Dosing Period: Approximately 32 months
STUDY RATIONALE	Vaccination of infants against diphtheria, tetanus, pertussis, hepatitis B polio and *Haemophilus influenzae* type b has been recommended by the World Health Organization (WHO) for several decades and is well established in most countries around the world. Immunization is simplified using combined vaccine presentations. Inactivated polio vaccine (IPV)-containing hexavalent vaccine represents one potential approach to global IPV access. A hexavalent combination vaccine containing diphtheria, tetanus, pertussis, hepatitis B, the three IPV antigens and *Haemophilus influenzae* type b could further simplify complex pediatric routine immunization schedules, improve compliance, and reduce delivery costs. Hexavalent vaccines are considered logically and scientifically sound drivers of such a strategy and are touted to be the ultimate combination vaccine for routine immunization. Serum Institute of India Pvt. Ltd. (SIIPL) has developed a fully liquid hexavalent vaccine (HEXASIIL™) containing diphtheria toxoid (D), tetanus toxoid (T), whole cell pertussis (wP), hepatitis B antigen (Hep B), inactivated poliovirus type 1, 2, 3 (IPV) and *Haemophilus influenzae* type b (Hib) conjugate (adsorbed). The vaccine can be a part of primary and booster vaccination of infants from 6 weeks of age against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis and *Haemophilus influenzae* type b. The preclinical animal toxicity studies and Phase I study in healthy toddlers, for this vaccine are successfully completed. The objective of the current study is to evaluate the safety and immunogenicity of HEXASIIL™ when administered as a booster dose

<table>
<tr><td></td><td>in toddlers aged 12-24 months and as a 3-dose primary vaccination series in infants aged 6-8 weeks, compared to already licensed SIIPL Pentavac + Poliovac vaccines.</td></tr>
<tr><td>INVESTIGATIONAL VACCINE</td><td>HEXASIIL™ (DTwP-HepB-IPV-Hib)
HEXASIIL™ vaccine is available as a fully liquid vaccine to be administered intramuscularly as a 0.5 mL dose. Each dose of 0.5 mL of HEXASIIL™ vaccine contains:
<table>
<tr><td>Ingredient</td><td colspan="2"></td></tr>
<tr><td colspan="3">Active Ingredients</td></tr>
<tr><td>Diphtheria Toxoid</td><td colspan="2">≥ 30 IU</td></tr>
<tr><td>Tetanus Toxoid</td><td colspan="2">≥ 40 IU</td></tr>
<tr><td>B. pertussis (whole cell)</td><td colspan="2">≥ 4 IU</td></tr>
<tr><td>HBsAg (rDNA)</td><td colspan="2">≥ 10 mcg</td></tr>
<tr><td rowspan="3">Inactivated Polio Vaccine
(Salk strains grown on vero cells)</td><td>Type- 1</td><td>40 DU</td></tr>
<tr><td>Type- 2</td><td>8 DU</td></tr>
<tr><td>Type- 3</td><td>32 DU</td></tr>
<tr><td>Hib conjugate (PRP-TT)</td><td colspan="2">10 mcg</td></tr>
<tr><td colspan="3">Inactive Ingredients</td></tr>
<tr><td>Aluminium content Al (3^{+}) (as Aluminium Phosphate gel)</td><td colspan="2">0.28 mg</td></tr>
<tr><td>2-Phenoxyethanol</td><td colspan="2">0.5%</td></tr>
</table></td></tr>
<tr><td>COMPARATOR VACCINE</td><td>SIIPL PENTAVAC (DTwP-HepB-Hib) + POLIOVAC (IPV) (hereafter referred to as SIIPL Pentavac + Poliovac in the document).
SIIPL PENTAVAC vaccine is available as a liquid vaccine to be administered intramuscularly as 0.5 mL dose. Each dose of 0.5 mL Pentavac vaccine contains:
<table>
<tr><td>Ingredient</td><td></td></tr>
<tr><td colspan="2">Active Ingredients</td></tr>
<tr><td>Diphtheria Toxoid</td><td>≤ 25 Lf (≥ 30 IU)</td></tr>
<tr><td>Tetanus Toxoid</td><td>≥ 2.5 Lf (≥ 40 IU)</td></tr>
<tr><td>B. pertussis (whole cell)</td><td>≤ 16 OU (≥ 4 IU)</td></tr>
<tr><td>HBsAg (rDNA)</td><td>≥ 10 mcg</td></tr>
<tr><td>Purified capsular Hib Polysaccharide (PRP) conjugated to Tetanus Toxoid (carrier protein)</td><td>10 mcg</td></tr>
<tr><td colspan="2">Inactive Ingredients</td></tr>
</table></td></tr>
</table>

	Adsorbed on Aluminium Phosphate, Al $^{+++}$ ≤ 1.25 mg Thiomersal 0.005% SIIPL POLIOVAC vaccine is available as a liquid vaccine to be administered intramuscularly as 0.5 mL dose. Each dose of 0.5 mL Poliovac vaccine contains: **Ingredient** **Active Ingredients** Poliomyelitis virus Type 1, Mahoney strain* 40 D antigen units Poliomyelitis virus Type 2, MEF-I strain* 8 D antigen units Poliomyelitis virus Type 3, Saukett strain* 32 D antigen units **Inactive Ingredients** 2-phenoxyethanol 2.5 mg Formaldehyde 12.5 mcg * Cultivated on Vero cells.
PRIMARY OBJECTIVE	
PART I	• To assess and compare the safety and reactogenicity of HEXASIIL™ vaccine with the comparator vaccine *viz*., SIIPL Pentavac + Poliovac when administered as a booster dose in toddlers aged 12-24 months.
PART II	• To demonstrate non-inferiority (NI) of HEXASIIL™ vaccine in comparison with SIIPL Pentavac + Poliovac in terms of seroprotection rate for diphtheria, tetanus, hepatitis B, and *Haemophilus Influenzae* type b and seroconversion rate for pertussis and polio, 28 days post completion of a 3-dose primary vaccination series in infants aged 6-8 weeks.
SECONDARY OBJECTIVE(S)	
PART I	• To assess and compare the immunogenicity of HEXASIIL™ vaccine with the comparator vaccine *viz*., SIIPL Pentavac + Poliovac when administered as a booster dose in toddlers aged 12-24 months.
PART II	• To assess and compare the safety and reactogenicity of HEXASIIL™ vaccine with the comparator vaccine *viz*., SIIPL Pentavac + Poliovac in infants aged 6-8 weeks. • To assess and compare the immune responses to HEXASIIL™ vaccine with the comparator vaccine *viz*., SIIPL Pentavac +

	Poliovac in terms of geometric mean concentration or geometric mean titre (GMC/GMT), 28 days post completion of a 3-dose primary vaccination series in infants aged 6-8 weeks. • To demonstrate equivalence of immunogenicity of 3 lots of HEXASIIL™ vaccine post completion of a 3-dose primary vaccination series in infants aged 6-8 weeks.
EXPLORATORY OBJECTIVE	
PART II	• To assess the post-booster dose safety of HEXASIIL™ and SIIPL Pentavac + Poliovac vaccine at 12-24 months, in subjects who have received three doses of primary vaccination series in this study. • To assess and compare the pre- and post-booster immunogenicity of HEXASIIL™ vaccine with the comparator vaccine *viz*., SIIPL Pentavac + Poliovac at 12-24 months, in subjects who have received three doses of primary vaccination series in this study.
PRIMARY ENDPOINTS	
PART I	• Occurrence, severity, and relationship of local and systemic solicited adverse events (AE) occurring up to 7 days following vaccination. • Occurrence, severity and relationship of unsolicited AEs occurring up to 28 days following vaccination. • Occurrence, severity and relationship of serious adverse events (SAE) occurring up to 28 days following vaccination.
PART II	• Percentage of infants achieving seroprotection for diphtheria, tetanus, hepatitis B, *Haemophilus influenzae* type b and seroconversion for poliovirus types 1 & 3 and pertussis, 28 days post completion of a 3-dose primary vaccination series.
SECONDARY ENDPOINTS	
PART I	• Percentage of toddlers achieving seroprotection for diphtheria, tetanus, hepatitis B, *Haemophilus influenzae* type b and seroconversion for poliovirus types 1 & 3 and pertussis, 28 days following vaccination. • Geometric mean concentrations/titres (GMCs/GMTs) for anti-diphtheria, anti-tetanus, anti-pertussis, anti-HBsAg (Hepatitis B

	surface antigen), anti-PRP (polyribosyl ribitol phosphate) and anti-polio types 1 & 3 antibodies, 28 days following vaccination.
PART II	**Safety Endpoints** • Occurrence, severity, and relationship of local and systemic solicited AEs occurring up to 7 days following each of the three vaccine doses. • Occurrence, severity and relationship of unsolicited AEs up to 28 days post completion of a 3-dose primary vaccination series. • Occurrence, severity and relationship of SAEs up to 28 days post completion of a 3-dose primary vaccination series. **Immunogenicity Endpoints** • Geometric mean concentrations/titres (GMCs/GMTs) for anti-diphtheria, anti-tetanus, anti-pertussis, anti-HBsAg, anti-PRP and anti-polio types 1 & 3 antibodies, 28 days post completion of the 3-dose primary vaccination series in infants. • Geometric mean concentrations/titres (GMCs/GMTs) for anti-diphtheria, anti-tetanus, anti-pertussis, anti-HBsAg, anti-PRP and anti-polio types 1 & 3 antibodies, among 3 lots of HEXASIIL™ vaccine, 28 days post completion of the 3-dose primary vaccination series in infants.
EXPLORATORY ENDPOINTS	
PART II	**Safety Endpoints** • Occurrence, severity, and relationship of local and systemic solicited AEs reported up to 7 days following the booster vaccination. • Occurrence, severity and relationship of unsolicited AEs occurring up to 28 days following the booster vaccination. • Occurrence, severity and relationship of SAEs occurring up to 28 days following the booster vaccination. **Immunogenicity Endpoints** Pre- and post-booster immunogenicity of HEXASIIL™ vaccine and comparator vaccine *viz*., SIIPL Pentavac + Poliovac in subjects who have completed the 3-dose primary vaccination series and receive a booster dose at 12-24 months of age as part of the study.

	• Percentage of toddlers achieving seroprotection for diphtheria, tetanus, hepatitis B, *Haemophilus influenzae* type b and seroconversion for poliovirus types 1 & 3 and pertussis, prior to booster dose and 28 days after a booster dose. • Geometric mean concentrations/titres (GMCs/GMTs) for anti-diphtheria, anti-tetanus, anti-pertussis, anti-HBsAg, anti-PRP and anti-polio types 1 & 3 antibodies, prior to booster dose and 28 days after a booster dose.
STUDY DESIGN This is an open label, randomized, active-controlled, multi-centric study to be conducted in two parts in healthy Indian toddlers and infants to assess the immunogenicity and safety of HEXASIIL™ vaccine in comparison with the licensed and commercially available SIIPL Pentavac + Poliovac vaccines.	
PART I	In Part I of the study, 222 toddlers, aged 12-24 months (365 to 730 days, both inclusive), who have completed primary immunization series at least 6 months prior to enrolment, will be randomized in a 1:1 ratio, to receive a booster dose of HEXASIIL™ vaccine or the comparator *viz*., SIIPL Pentavac + Poliovac. Toddlers will be followed up for 28 days post-vaccination for safety and immunogenicity. An external Data and Safety Monitoring Board (DSMB) comprising of independent Pediatrician, Physician, Pharmacologist and Biostatistician will be appointed to assess any safety concerns. The DSMB will review safety data of all participating toddlers post completion of Visit 2 (7 days following vaccination) and Visit 3 (28 days following vaccination). Part II of the study in infants, will be initiated only after obtaining recommendation of DSMB on the overall safety data of Part I of the study. The DSMB recommendation letter will be notified to DCGI for information only.
PART II	In Part II of the study, 1260 infants aged 6-8 weeks (42 to 56 days, both days inclusive) will be randomized in a 2:1 ratio (840:420), to receive a 3-dose primary vaccination series followed by a booster dose of HEXASIIL™ or the comparator *viz*., SIIPL Pentavac + Poliovac. In the HEXASIIL™ vaccine group, infants will receive the vaccine from one of the three different lots (n= 280 each). Among the 3 lots, the vaccine presentation will be single dose vial in the first lot, single dose pre-filled syringe (PFS) in the second lot and multi-dose vial in the third

	lot.
METHODOLOGY	
PART I	After signing an informed consent and post-confirmation of study eligibility status, toddlers will be randomized, in a 1:1 ratio, to receive either study vaccines. All toddlers randomized to the HEXASIIL™ vaccine group will receive a booster dose of 0.5 mL hexavalent vaccine administered intramuscularly in the upper anterolateral aspect of the thigh. Toddlers randomized to SIIPL Pentavac + Poliovac group will receive 0.5 mL Pentavac and Poliovac each, administered as two intramuscular (IM) injections at separate sites (upper anterolateral aspect of right and left thighs). Following vaccination, all toddlers will be observed at the site for minimum 30 (+15) minutes for any Immediate Adverse Events (IAE). Solicited AEs will be actively collected for 7 days post vaccination. Unsolicited AEs and SAEs will be collected throughout the study from the time of signing informed consent till 28 days post vaccination. All the SAEs will be reported to the regulatory authority as per applicable regulatory guidelines based on the knowledge of the events. Complete physical examination, vital sign and prior/concomitant medications assessments will be performed at Visit 1, Visit 2 and Visit 3. Additional targeted physical examination (if indicated) and vital sign measurements will be done 30 (+15) minutes after vaccination. Blood samples for immunogenicity assessment will be obtained from all participating toddlers at Visit 1 and at Visit 3.
PART II	**Primary Vaccination Series and Follow-up** Post signing informed consent and post-confirmation of study eligibility status, all infants will be randomized to receive a 3-dose primary vaccination series at 6, 10 and 14 weeks of age*. Infants in the HEXASIIL™ vaccine group will receive 0.5 mL hexavalent vaccine administered intramuscularly in the upper anterolateral aspect of the thigh while infants randomized to SIIPL Pentavac + Poliovac group will receive 0.5 mL Pentavac and 0.5 mL of Poliovac each, administered as two separate IM injections at separate sites (upper anterolateral aspect of right and left thighs). Following each vaccination, all infants will be observed at the site for minimum 30 (+15) minutes for any IAEs. Active follow up for solicited AEs will be conducted over the 7-day period after

	each vaccination. Unsolicited AE/SAEs will be collected from signing of informed consent till Visit 7. All the SAEs will be reported to the regulatory authority as per applicable regulatory guidelines based on the knowledge of the events. Complete physical examination, vital sign and prior/concomitant medication assessment will be performed at Visit 1 and at Visit 3, Visit 5 and Visit 7. Additional targeted physical examination (if indicated) and vital sign measurements will also be done 30 (+15) minutes after each vaccination and additionally during any other clinic visits. Targeted physical examination and vital sign evaluation will also be performed at Visits 2, 4 and 6 whenever it is a clinic visit. Blood samples for immunogenicity assessment will be obtained from all participating infants at Visit 1 and at Visit 7. The safety and immunogenicity data of Part I and Part II (up to 28 days post completion of a 3-dose primary vaccination series) shall be submitted together in the clinical study report (CSR) to DCGI for licensure. *Due to the current COVID-19 situation, subjects may not be able to visit the site and receive the vaccines as per scheduled timepoints. For subjects who are unable to visit the site at scheduled timepoints, all attempts should be made to administer all 3-doses of the primary vaccination series before the subject completes 6 months of age (≤6 months of age) ensuring a minimum gap of at least 4 weeks between any two vaccines doses in the primary series. This is in line with WHO recommendation for interrupted and delayed vaccination which states that a primary series of 3 doses of DTP-containing vaccine is recommended, with the first dose administered as early as 6 weeks of age and subsequent doses should be given with an interval of at least 4 weeks between doses. The third dose of the primary series should be completed by 6 months of age if possible [Error! Reference source not found.]. **Pre-booster Follow-up Assessment** Subjects who complete the primary vaccination series will be followed up further for booster dose. After Visit 7 (i.e. 28 days following completion of primary vaccination series) subjects will continue to be followed up for safety every 3 months starting from the age of 6 months (i.e. at 6, 9, 12, 15, 18, and 21 months of age) until they receive the

	booster dose. All such pre-booster safety follow-up visits will be considered as additional follow-up visits. For subjects whose primary vaccine is delayed because of COVID situation, the follow-up visits will be adjusted accordingly. Considering that the maximum age at which the third dose of primary series may be administered is 6 months of age, the pre-booster follow-up assessment for such subjects will not be applicable at 6th month. However, the pre-booster follow-up visits from 9th month should be followed as per schedule. Visit 8 is considered as the visit when booster dose will be administered and may occur anytime between 12-24 months (365 to 730 days, both inclusive) of age. The subject will receive a booster dose of HEXASIIL™ vaccine or the comparator *viz*., SIIPL Pentavac + Poliovac vaccine at Visit 8. During pre-booster safety follow-up period, all the reported unsolicited AE/SAE data will be collected and all SAEs will be reported to the regulatory authority based on knowledge of the events as per applicable regulatory guidelines. Targeted physical examination and vital sign evaluation will also be performed during pre-booster follow-up visits, whenever it is a clinic visit. Blood samples for immunogenicity will be collected just prior to booster administration at Visit 8. **Booster Dose Administration and Follow-up** Subjects will be called for booster vaccination between 12-24 months of age (Visit 8). After re-assessment of eligibility, subject will receive booster dose of same vaccine (HEXASIIL™ or SIIPL Pentavac + Poliovac vaccine) which they had received during primary vaccination series. Following vaccination, all subjects will be observed at the site for minimum 30 (+15) minutes for any IAEs. Solicited AEs will be actively collected for 7 days post vaccination. Unsolicited AEs/SAEs will be collected till Visit 10 i.e. 28 days post vaccination. All the SAEs will be reported to the regulatory authority as per applicable guidelines based on the knowledge of the events. Complete physical examination and vital sign evaluations will be performed at Visits 8 and 10. Additional targeted physical examination (if indicated) and vital sign measurements will be done 30 (+15) minutes after booster vaccination. Blood samples will also be collected from all subjects at Visit 10 i.e. 28

	days following the booster administration to assess the post-booster immunogenicity.
STUDY EVALUATIONS (PART I/PART II)	
IMMUNOGENICITY	Anti-diphtheria, anti-tetanus, anti-pertussis, anti-HBsAg and anti-PRP antibody titres will be measured by Enzyme Linked Immunosorbent Assays (ELISA). Anti-polio type 1 & 3 antibody titres will be measured by Neutralization assay. In addition, anti-pertussis toxoid (anti-PT) will also be measured by ELISA. Below are the thresholds for seroprotection/seroconversion for immunogenicity assessment in the study: Seroprotection for diphtheria, tetanus, hepatitis B and *Haemophilus influenzae* type b are defined as: • Anti-diphtheria antibody ≥ 0.1 IU/mL • Anti-tetanus antibody ≥ 0.1 IU/mL • Anti-HBsAg antibody ≥ 10 mIU/mL • Anti-PRP antibody ≥ 0.15 µg/mL Seroconversion for Polio is defined as: • Anti-poliovirus Type1 antibodies ≥ 8 (1/dilution) • Anti-poliovirus Type 3 antibodies ≥ 8 (1/dilution) Seroconversion for Pertussis is defined as: • In subjects with no quantifiable antibody - below the lower limit of quantitation (LLOQ) prior to vaccination, seroconversion is defined as achieving a quantifiable antibody level post-vaccination. • In subjects with quantifiable antibody prior to vaccination, seroconversion is defined by a 4-fold-increase in antibody titres from pre- to post-vaccination.
SAFETY	Subjects will be evaluated for IAEs for minimum 30 (+15) minutes following each vaccination, solicited AEs for 7-days post each vaccination, unsolicited AEs and SAEs during the defined time-periods. The solicited local AEs include injection site pain/tenderness, injection site erythema/redness and injection site swelling. The solicited systemic AEs include fever (defined as a body temperature ≥ 38°C/100.4°F as

	measured by axillary route), irritability, abnormal crying, drowsiness, vomiting and loss of appetite. The parent(s) will be given a digital thermometer to record axillary temperature, a measuring scale to record injection site erythema/redness & swelling and a subject diary card to record details of solicited and unsolicited AEs and to capture medication details. The parents will bring the filled subject diary cards to the site at the scheduled visits. The study Investigators will review the subject diary cards for its correctness and completeness and the clinical staff will be responsible for continuous close safety monitoring of all study subjects. All solicited and unsolicited AEs will be graded as per the grading scale detailed in Section 6.3.2.3 of the protocol and as per the clinical judgment of the Investigator considering information provided by subjects' parent(s). SAEs irrespective of the causality and expectedness will be reported to the DCGI, as per the regulatory requirements.
STUDY ELIGIBILITY CRITERIA	
PART I	**Inclusion Criteria** 1. Male or female toddlers aged between 12-24 months at the time of vaccination. 2. Toddlers with a good health, as determined by the medical history, physical examination and clinical judgment of the Investigator. 3. Toddlers who have completed primary immunization series against diphtheria, tetanus, pertussis, hepatitis B, poliomyelitis [oral polio vaccine (OPV) and/or IPV] and *Haemophilus Influenzae* type b at least 6 months prior to enrolment and have not received the booster dose for the above-mentioned vaccines scheduled at 12-24 months of age. 4. Informed consent form (ICF) signed by at least one parent. 5. The weight-for-length z-score for the toddler is ≥ -2 Standard Deviation (SD) at the time of enrolment. **6.** Willingness of subjects' parent to comply with the requirements of the protocol. **Exclusion Criteria** 1. History of diphtheria/tetanus/pertussis/hepatitis B/*Haemophilus*

	Influenzae type b/poliomyelitis infection(s) (confirmed either clinically, serologically or microbiologically). 2. Fever ≥ 38°C/100.4°F and/or any evidence of acute illness and/or receipt of antibiotics in the past 3 days. 3. Administration of any vaccine (except OPV during government immunization campaign) in the 4 weeks preceding the trial vaccination or planned receipt of any non-study vaccine during the study period. 4. History of major congenital defects or illness that require medical therapy, as determined by medical history or clinical assessment. 5. History of any clinically significant chronic disease that in the opinion of the Investigator, might interfere with the evaluation of the study objectives. 6. History of anaphylaxis, or any serious vaccine reaction, or hypersensitivity/allergy to any vaccine or components of study vaccine. 7. Presence of evolving or changing neurological disorder or toddler with a history of seizures and/or encephalopathy. 8. Toddlers with known or suspected impairment of the immune function, or those receiving immunosuppressive therapy such as anti-cancer chemotherapy or radiation therapy or received immunosuppressive therapy within 3 months prior to study entry (For corticosteroids, this will mean prednisone ≥ 0.5 mg/kg/day or equivalent for more than 2 consecutive weeks. Inhaled or topical steroids are allowed). 9. Known thrombocytopenia or a bleeding disorder. 10. Known personal or maternal history of Human Immunodeficiency Virus (HIV), Hepatitis B or Hepatitis C seropositivity. 11. Planned surgery during the study. 12. Receipt of blood or blood-derived products or immunoglobulins in the past 3 months, current or planned administration during the study period. 13. Participation in another clinical trial 4 weeks preceding the trial enrolment or planned participation during the present trial period in another clinical trial. 14. Toddlers whose families are planning to leave the area of the study

	site before the end of the study period.
PART II	**Inclusion Criteria** 1. Male or female infants aged 6-8 weeks (42 to 56 days, both days inclusive) at the time of first vaccination. 2. Infants with a good health, as determined by the medical history, physical examination and clinical judgment of the Investigator. 3. Infants who have received the birth doses of OPV and BCG at least 4 weeks before the first trial vaccination. 4. Informed consent form signed by at least one parent. 5. Infants born at full term pregnancy (≥ 37 weeks). 6. Infants with weight-for-length z-score ≥ -2 SD at the time of enrolment. 7. Willingness of subjects' parent to comply with the requirements of the protocol. **Exclusion Criteria** 1. History of diphtheria/tetanus/pertussis/hepatitis B/*Haemophilus Influenzae* type b/poliomyelitis infection(s) (confirmed either clinically, serologically or microbiologically). 2. Fever ≥ 38°C/100.4°F and/or any evidence of acute illness and/or receipt of antibiotics in the past 3 days. 3. Previous vaccination or planned receipt of any vaccine against diphtheria, tetanus, pertussis, hepatitis B (except birth dose), poliomyelitis (except OPV) or *Haemophilus Influenzae* type b infection apart from trial vaccines during the study period. 4. Administration of any vaccine (except OPV during government immunization campaign) in the 4 weeks preceding the first trial vaccination. 5. History of major congenital defects or illness that require medical therapy, as determined by medical history or clinical assessment. 6. History of any clinically significant chronic disease that in the opinion of the Investigator, might interfere with the evaluation of the study objectives. 7. History of anaphylaxis, or any serious vaccine reaction, or hypersensitivity/allergy to any vaccine or components of study vaccine.

	8. Infants with known or suspected impairment of the immune function, or those receiving immunosuppressive therapy such as anti-cancer chemotherapy or radiation therapy or received immunosuppressive therapy prior to study entry (For corticosteroids, this will mean prednisone ≥ 0.5 mg/kg/day or equivalent for more than 2 consecutive weeks. Inhaled or topical steroids are allowed). 9. Presence of evolving or changing neurological disorder or infant with a history of seizures and/or encephalopathy. 10. Known thrombocytopenia or a bleeding disorder. 11. Known personal or maternal history of HIV, Hepatitis B or Hepatitis C seropositivity. 12. Planned surgery during the study. 13. Receipt of blood or blood-derived products or immunoglobulins or planned administration during the trial which might interfere with the assessment of the immune response. 14. Participation in another clinical trial 4 weeks preceding the trial enrolment or planned participation during the present trial period in another clinical trial. 15. Infants whose families are planning to leave the area of the study site before the end of the study period.
REASSESSMENT OF ELIGIBILITY PRIOR TO BOOSTER DOSE FOR PART II	**Inclusion Criteria** 1. Male or female subjects aged between 12-24 months of age at the time of vaccination. 2. Subjects with a good health, as determined by the medical history, physical examination and clinical judgment of the Investigator. 3. Subjects who have received 3 doses of HEXASIIL™ or comparator vaccine *viz*., SIIPL Pentavac + Poliovac as part of primary immunization series in same study and have not received the booster dose in the second year of life (a minimum 6 months gap should be maintained between the last dose of primary series and the booster dose). **Exclusion Criteria** 1. History of diphtheria/tetanus/pertussis/hepatitis B/*Haemophilus Influenzae* type b/poliomyelitis infection(s) (confirmed either

	clinically, serologically or microbiologically). 2. Fever ≥ 38°C/100.4°F and/or any evidence of acute illness and/or receipt of antibiotics in the past 3 days. 3. Administration of any vaccine (except OPV during government immunization campaign) in the 4 weeks preceding booster vaccination or planned receipt of any non-study vaccine 4 weeks post booster vaccination. 4. History of any clinically significant chronic disease such that in the opinion of the Investigator may interfere with the evaluation of the study objectives. 5. History of anaphylaxis, or any serious vaccine reaction, or hypersensitivity/allergy to any vaccine or components of study vaccine. 6. Presence of evolving or changing neurological disorder or subject with a history of seizures and/or encephalopathy. 7. Subjects with known or suspected impairment of the immune function, or those receiving immunosuppressive therapy such as anti-cancer chemotherapy or radiation therapy or received immunosuppressive therapy within 3 months prior to booster dose (For corticosteroids, this will mean prednisone ≥ 0.5 mg/kg/day or equivalent for more than 2 consecutive weeks. Inhaled or topical steroids are allowed). 8. Known thrombocytopenia or a bleeding disorder. 9. Known personal or maternal history of HIV, Hepatitis B or Hepatitis C seropositivity. 10. Planned surgery during the study. 11. Receipt of blood or blood-derived products or immunoglobulins in the past 3 months, current or planned administration during the trial. 12. Participation in another clinical trial during the study period.
STATISTICAL CONSIDERATIONS	
SAMPLE SIZE JUSTIFICATION	
PART I	**Safety** No formal sample size calculation is performed for Part I of the study as this is Phase II descriptive study to assess mainly safety in toddlers. In

	terms of safety, the planned sample size will allow identification of common AEs. With a sample size of 111 vaccinated subjects per group, this study design allows a greater than 90% chance of observing at least one AE if true incidence rate is 2.08%. Conversely, if no AEs are observed in 111 vaccinated subjects then the study will be able to rule out AEs occurring at a rate of approximately 3.3% or above based on the upper bound of the two-sided 95% confidence interval (CI). **Immunogenicity** Assuming the SD of log10-transformed immunoglobulin G (IgG) concentration is ≤ 0.65, with a sample size of 100 evaluable subjects and a dropout rate of 10% per group (111 randomized subjects per group), the study has power of at least 90% for each antigen/serotype, to detect at least 0.5 of GMC/GMT ratio between HEXASIIL™ and the Comparator (SIIPL Pentavac + Poliovac) vaccine groups.
PART II	The Part II of the study is designed to have at least 90% power to meet one primary objective and one secondary objective. Testing primary objective of NI will have ~ 95% power and testing secondary objective of Lot-to-lot (LTL) consistency have at least 96% power at two-sided α of 0.05. To preserve α at 0.05 and to maintain at least 90% power for the study a fixed sequence statistical strategy is used. This strategy will test primary objective hypothesis of NI and secondary objective hypothesis of LTL consistency at same significance level of 0.05 by testing two hypotheses in predefined fixed sequential order i.e. primary endpoint related to NI will be tested first with two-sided α as 0.05 and if we get evidence of statistical significance for NI testing only then the secondary endpoint related to LTL consistency will be tested with same two-sided α as 0.05. The study will be declared successful if at least NI is demonstrated irrespective whether LTL consistency may or may not be achieved. However, if NI is not demonstrated then we will not be able to test hypothesis related to LTL consistency. Non-inferiority and LTL consistency (if allowed) will be demonstrated if NI and equivalence hypotheses are proved for all antigens/serotypes analyzed. Here for all comparisons instead of adjusting level of significance α, high power is assumed for individual comparison of each antigen/serotype. The sample size was chosen in an iterative, trial-and-error fashion to give the desired power of at least 90%. We first derived sample size for

	LTL consistency and then adjusted with respect to NI for 2:1 allocation ratio [HEXASIIL™: Comparator (SIIPL Pentavac + Poliovac) vaccine]. Thus, the plan is to randomize 1260 subjects: 840 subjects to receive HEXASIIL™ (280 in each of 3 lots) and 420 to receive Comparator (SIIPL Pentavac + Poliovac) group for testing the primary objective of NI. The sample size for testing the secondary objective of LTL consistency will be 840 (280 in each of 3 lots). Due to the unanticipated current COVID-19 situation and subsequent lockdown, some subjects could not visit the study site and complete the primary vaccination series as per schedule or even within ≤ 6 months of age. Further, some subjects received the primary immunization outside the study. These are considered Major protocol deviations and such subjects will not be considered for primary and secondary analysis using PP Population. In order to bridge this gap and to maintain the power of the study to 90%, few additional subjects may be enrolled in Phase III part of the study.
IMMUNOGENICITY ANALYSIS	
PART I & PART II	Comparisons for immunogenicity will be based on the different antigen/serotype-specific concentrations/titres of IgG antibody 4 weeks after one dose of vaccination in toddlers in Part I and 4 weeks after the 3-dose primary vaccination series in Part II, measured by ELISA for all antigens and Neutralization Assay for poliovirus types 1 & 3. Comparisons for immunogenicity objective for Part II will be based on the antigen/serotype-specific IgG concentration/titre, 4 weeks after the 3-dose primary vaccination series. Immunogenicity will also be evaluated 4 weeks after the booster dose as an exploratory objective for Part II. The details of threshold for each antigen/serotype are provided in below table. **Threshold for defining Seroresponse (Seroprotection/ Seroconversion) to Study Vaccination for each Antigen/Serotype for IgG Antibody Concentration /Titre**

S.No.	Antibody	Threshold (Criteria for Evaluation)
1.	Anti-Diphtheria [Seroprotection]	≥ 0.1 IU/mL
2.	Anti-Tetanus [Seroprotection]	≥ 0.1 IU/mL

3.	Anti-PRP [Seroprotection]	≥ 0.15 µg/mL
4.	Anti-HBsAg (Hep B) [Seroprotection]	≥ 10 mIU/mL
5.	Pertussis IgG [Seroconversion]	In subjects with no quantifiable antibody - below LLOQ -prior to vaccination, seroconversion is defined as achieving a quantifiable antibody level post-vaccination. In subjects with quantifiable antibody prior to vaccination, seroconversion is defined by a 4-fold-increase in antibody titres from pre- to post-vaccination.
6.	Anti-Polio Type 1 [Seroconversion]	≥ 8 (1/dilution)
7.	Anti-Polio Type 3 [Seroconversion]	≥ 8 (1/dilution)

For each of the antigen/serotype in HEXASIIL™, the distributions of IgG concentration/titre will be displayed in tabular form (e.g. number of observations, number of responders, percentage responding, geometric mean and its 95% CI) and graphically by reverse cumulative distribution (RCD) curves. These curves will allow visual comparison of percentiles (e.g. median, 25th and 75th percentiles) for each antigen/serotype in HEXASIIL™. Summaries will include percentage of seroresponders (Seroprotection/seroconversion responders), GMC/GMT and ratio of GMCs or GMTs for HEXASIIL™ to those for Comparator (SIIPL Pentavac + Poliovac) vaccine.

Non-inferiority comparisons will be based on a two-sided 95% CI for the difference in proportions calculated by a Farrington and Manning method and LTL comparisons will be based on the two-sided 95% CI for a ratio of GMCs/GMTs calculated by exponentiating the limits of a CI for the difference in means of log10 (concentration/titres), which will be calculated assuming a normal distribution for log10 (concentration/titres) and for finding GMC ratio and corresponding CIs will be back-transformed considering base 10 of log transformed data.

If NI is demonstrated, then primary objective of NI of HEXASIIL™ is supposed to be met and then study will be considered successful. The secondary objective of LTL consistency will be tested only after the success of the primary objective else hypotheses testing with respect to LTL consistency (equivalence) will be stopped, as we are following fixed-order sequential testing approach.

SAFETY ANALYSIS	
PART I & PART II	Unsolicited AEs and SAEs will be summarized by SOC and PT using the MedDRA as “n (%), E” where n represents the number of subjects who experienced any particular AE at least once; % represents percentage of subjects who experienced that particular AE and E represents frequency (count) of that AE. Adverse events and SAEs will also be summarized by severity and relationship to vaccine “n (%), E”. Occurrence of local and systemic AEs within 7 days after vaccination will be reported for both HEXASIIL™ and Comparator (SIIPL Pentavac + Poliovac) vaccine. For solicited AEs, two-sided 95% exact CIs for each of the proportions will be provided, as well as two-sided 95% CIs for the difference between the proportions in subjects from HEXASIIL™ and Comparator (SIIPL Pentavac + Poliovac) vaccine group.
ANALYSIS POPULATIONS	
PART I & PART II	**Enrolled Population** The Enrolled Population includes all screened subjects whose parent(s) provide informed consent, regardless of whether the subject is randomized to receive a study vaccine. This population will be used only to provide summary for subject disposition, starting with the informed consent. The enrolled population will not be used for analyses. **Randomized Population** The Randomized Population includes all eligible subjects who are randomized in the study, regardless of whether the subject received a study vaccination. This population will be used to provide summary for subject disposition as per randomization and vaccination status. **Full Analysis Set** **Part I** The Full Analysis Set (FAS) includes subjects in the enrolled population who were randomized, received study vaccination and have pre- and post-vaccination immunogenicity measurement(s) 4 weeks i.e. 28 days post vaccination. **Part II** The FAS includes subjects in the enrolled population who were randomized, received three doses of primary vaccination series of study

	vaccination and have pre- and post-vaccination immunogenicity measurement(s) 4 weeks i.e. 28 days from third dose of the primary vaccination series, available for subjects. Analysis for Part I and Part II will be according to the treatment group assigned at the time of randomization, regardless of whether subjects receive any study vaccine different from that to which they were randomized. The analysis based on this population will serve as supportive results for the immunogenicity objectives. **Safety Population** The Safety Population includes all subjects who were randomized and received at least one dose. Vaccine groups for safety analyses will be assigned according to the actual vaccine received at Dose 1. **Per Protocol Population** The Per Protocol Population (PP) includes subjects from FAS population who received all study vaccines as per the assigned vaccine group and have pre- and post-dose immunogenicity measurement(s) with no major protocol deviations that were determined to potentially interfere with immune response to the study vaccine. This population will serve as the primary analysis population for the immunogenicity objectives. The criteria for exclusion of subjects from the PP Population will be established prior to review and analysis of protocol deviations that occur in the study. Based on this, PP population will be finalized before database lock.

SCHEDULE B
STUDY BUDGET- PART- II

PART II Study Budget														
Heading	**Visit 1**	**Visit 2**	**Visit 3**	**Visit 4**	**Visit 5**	**Visit 6**	**Visit 7**	**Pre-booster Follow up visit (Month 6, 9, 12,)**	**Visit 8**	**Visit 9**	**Visit 10**	**Total**	**No. of Subjects randomized**	**Total per study**
Day	06 to 08 weeks	V1+07 days	10 to 12 weeks	V3+07 days	14-16 weeks	V5+07 days	18 to 20 weeks		Age 12-24 months	V8+07 days	V8+28 days			
Informed Consent	700	-	-									700	100	70,000
Medical History, Reviews of AE/SAE/Concomitant Medications	500	500	500	500	500	500	500	1,500	500	500	500	6,500		650,000
Physical Examination	600	600	600	600	600	600	600	1,800	600	600	600	7,800		780,000
I/E Criteria	600	-	-									600		60,000
Randomization	500	-	-									500		50,000
Study Vaccination	400		400		400				400			1,600		160,000

Review of Diary Cards	-	300	300	300	300	300	300	900	300	300	300	3,600		360,000
Blood Sample for Immunogenicity	500	-					500		500		500	2,000		200,000
Follow up FRA Cost		250	250	250	250	250	250	750	250	250	250	3,000		300,000
Total (A)	**3,800**	**1,650**	**2,050**	**1,650**	**2,050**	**1,650**	**2,150**	**4,950**	**2,550**	**1,650**	**2,150**	**26,300**		**2,630,000**
Screen Failure (Assumption: 10% of randomized)... **(B)**														
Screening Process	3,000												10	**30,000**
TOTAL (A+B+C)														
Institute Overhead 25% .....(D)	**0.25**											**-**		**665,000**
Total (A+B+C)												**-**		**3,325,000**
Subject visit reimbursement	500	500	500	500	500	500	500	1,500	500	500	500	**6,500**		650,000
Screen Failure visit Reimbursement	500												10	5,000
Total Subject reimbursement cost .....(E)														**655,000**
Archival Charges* ** One time charges .....(F)*	75,000													**75,000.00**
Total Cost														

														4,055,000.00
Total per Subject Cost														**40,550.00**

Notes:
● Subject visit (quarterly) post 12 month till receipt of Booster dose will be reimbursed as per the actual visit conducted.
● Period of recruitment is 3 months.
● Maximum number of screen failures for which Investigator to be compensated shall not exceed 10% of total randomized subjects at the site.
● INR 500/- will be paid as a screening visit travel reimbursement for screen failures not exceeding 10% of the total randomized subject at the site.
● The study recruitment will be a competetive, and there will be no upper limit to actual number of subjects enrolled. The final costs will be based on the actual number of subjects enrolled and actual number of visits completed. The final calculation will be done on prorated basis.
● Outpatient cost, if occur, would be reimbursed at actuals.

PAYMENT SCHEDULE

In connection with the Study, Sponsor will pay in accordance with the terms set forth in the Budget (schedule B):

1. 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.

2. 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

3. Payment will be pro-rata based on the actual no. of visits completed by the subject.

4. Screen failures would be paid at 3000 INR per subject and payment would be made at end of study. Notwithstanding the foregoing, the maximum number of screen failures for which Investigator shall be compensated shall not exceed 10% of randomized subjects at site.

5. 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

SCHEDULE C

STUDY TIMEFRAME

Recruitment:

PART II: Approx. 110 subjects. Total recruitment in 3 months

Case Record Form Completion:

General:

Data entry: 5 working days from completion of subject visit
Query resolution: 2 – 3 working days from query raised

For PSRT, DSMB meetings & data base lock:

Data entry: 2 workings days from the completion of subject visit (as per the announced dates)
Query resolution: within 1 working day from query raised

Source Documents:
Source documents must be maintained real time as and when subject visit is completed

Serious Adverse Event Notification:
SAE must be identified and reported as per the timeframe laid in New Drugs and Clinical Trial Rules, 2019 (GSR 227E).

Archival Period: 10 years post study completion

MGM INSTITUTE OF HEALTH SCIENCES
(Deemed University u/s 3 of UGC Act, 1956)
Grade 'A' Accredited by NAAC
Sector-01, Kamothe, Navi Mumbai - 410 209
Tel 022-27432471, 022-27432994, Fax 022 - 27431094
E-mail : research@mgmuhs.com | Website : www.mgmuhs.com

Research project in collaboration with All India Institute of Medical Sciences, Nagpur and MGM Medical College & Hospital, Kamothe, Navi Mumbai.

Research Project entitled " **A randomized, double blind, placebo controlled study to evaluate the efficacy and safety of Cordyceps Capsules (Food supplement) as an add-on therapy in patients with mild to moderate COVID -19 infection**" ethics Committee approval from MGMIHS on 15th September, 2020.

Principal Investigator	:	Dr. Siddharth P Dubhashi, Professor & Head, Department of Surgery, AIIMS, Nagpur.
Co-PI	:	Dr. Sagar Sinha, Asst. Prof., Department of Emergency Medicine, MGM Medical College & Hospital, Kamothe, Navi Mumbai.
Co-Investigator	:	Dr. Jaishree Ghanekar, Prof. & Head, Department of Medicine, MGM Medical College & Hospital, Kamothe, Navi Mumbai.
Co-Investigator	:	Dr. Sameer Kadam, Prof. & Head, Department of Surgery, MGM Medical College & Hospital, Kamothe, Navi Mumbai.
Co-Investigator	:	Dr. Parineeta Samant, Prof. & Head, Department of Biochemistry, MGM Medical College & Hospital, Kamothe, Navi Mumbai.

Total Amount received from sponsor M/s. Ambosia Food Farm Co., Uttrakhand Rs. 14,72,00.00 on 13.10.2020 by MGM Institute of Health Sciences, Kamothe, Navi Mumbai towards the expenses for the clinical trial.

Dr. Sabita M Ram
Director (Research)
13/10/2020

MGM Institute of Health Sciences (HO)

Head Office-3rd Floor, MGM Education Complex,
Plot No-1 & 2, Sect-1, Kamothe, Navi Mumbai

AMBROSIA FOOD FARM CO.

Ledger Account

1-Apr-2020 to 14-May-2021

Date		Particulars	Vch Type	Vch No.	Debit	Page Cred
13-10-2020	Dr	**IDBI Bank A/c - 0183104000132763** *bEING RECD. AGAINST RESEARCH GRANT FOR CHEMICALS PARINITA MADAM DUBHASHI SIR FROM AMBROSIA FOOD FARM CO.*	IDBI Receipt	500		14,72,000.(
9-3-2021	Cr	**IDBI Bank A/c - 0183104000132763** *Ch.no.: 018745 Being 100% advane paid against PI No. 0001 dated 11/02/2021 to Noble Surgical towards purchase of Lab Chemicals for Investigation of Covid (Bill No. 524 dated: 09/04/2021 bill received)*	IDBI Payment	1118	4,24,352.00	
7-3-2021	Cr	**IDBI Bank A/c - 0183104000132763** *Ch.No.: 018757 Being Bill.No. R/3304 Dated : 03/03/2021 of B.H. Agency towards purchase of Lab Kits for the project of Ambrosia Project*	IDBI Payment	1142	1,18,366.00	
31-3-2021	Cr	**IDBI Bank A/c - 0183104000132763** *Ch.No.: 018809 Being Bill.No. 20212583 Dated : 23/03/2021 of Calyx Wellness Pvt Ltd towards purchase of Lab Kits for the project of Ambrosia Project*	IDBI Payment	1213	1,36,220.00	
	Cr	**IDBI Bank A/c - 0183104000132763** *Ch.No.: 018825 Being Bill.No. 20212665 Dated : 30/03/2021 of Calyx Wellness Pvt Ltd towards purchase of Lab Kits for the project of Ambrosia Project*	IDBI Payment	1214	52,500.00	
	Cr	**Closing Balance**			7,31,438.00 7,40,562.00	14,72,000.00
					14,72,000.00	**14,72,000.00**

CLINICAL STUDY AGREEMENT

This Agreement is made on **25th August 2020** at Navi Mumbai BY and BETWEEN

Ambrosia Food Farm Co., a Company incorporated under the Companies Act, 1956 having its registered office at **Rehar Road, Bhowali, Nainital, Uttrakhand India, Pin Code 263156** hereinafter referred to as **"Sponsor"**

AND

Dr. Siddharth P. Dubhashi, Professor and Head, Department of Surgery, All India Institute of Medical Sciences (AIIMS), Nagpur, an Institute having its office at **Nagpur,** hereinafter referred to as "**The Institute**"

AND

Dr. Sagar Sinha, Asst Professor, Department of Emergency Medicine, MGM Medical College and Hospital, Navi Mumbai, an Institute having its office at **Navi Mumbai,** hereinafter referred to as "**The Institute**", to conduct a clinical study and evaluation of Study. Institutions and Sponsor agrees as follows.

1. PROTOCOL AND STUDY CONDUCT

1.1 Institution agrees to use its best efforts to conduct the Study, as an independent contractor, in accordance with Institutional policy, applicable laws and regulations and the Protocol, "An Open Label, Randomized, Parallel Group Comparative Study to evaluate the Efficacy, Safety of Cordyceps Capsules as an Add-On Therapy in patients with moderate COVID 19 Infection", Protocol Number: Cordyceps-2001, which is attached hereto as Exhibit A for reference purposes only. The Study will be supervised by Dr. Siddharth P. Dubhashi, ("Principal Investigator"), at Institution Department of Surgery, All India Institute of Medical Sciences (AIIMS), Nagpur,, with assistance from associates and colleagues as required. The Institute will primarily obtain Ethics committee approval as required and data entry in to eCRF

1.2 Sponsor agrees to engage the services of Institution to conduct the Study and further agrees to provide at no cost to Institution the drug, materials and/or equipment as applicable for the conduct of the Study. Sponsor will provide financial and logistic support and coordinate and oversee the execution and will perform the clinical monitoring as required by the GCP guidance, Sponsor will take insurance for trial participants as per the regulatory requirements, Sponsor will register this study on CTRI as required by the Ethics committee.

1.3 Nothing in this Agreement will limit or prohibit Institution or any of its personnel, including the Principal Investigator, from conducting any research or for performing research for or with any entity or person, including any other outside sponsors. Sponsor acknowledges that this provision is intended to preserve the academic freedom and integrity of Institution and its faculty and to ensure that Institution and its faculty are not regarded as captive researchers for Sponsor.

2. AWARD

2.1 In consideration for performance of the Study by Institution, Sponsor shall support Institution for the clinical study. This amount, shown by approximate category of expense in Exhibit B attached hereto for information only.

2.2 Sponsor shall make payments to Institution at the following address referencing the Principal Investigator's name and protocol number.

Site details for Payment

Bank Name: IDBI Bank
Bank Address: 39-41, Sector – 11, C.B.D. Belapur, Navi Mumbai - 400614
Account Number: 0183104000132763
IFS Code: IBKL0000183
Account Holder Name: MGM Institute of Health Sciences
Co-Investigator Name: Dr. Sagar Sinha
Protocol Number: Cordyceps-2001, Version: 1, date 20 August 2020

2.3 Institution shall send invoices for payment to the attention of Mr. Gourvendra Gangwar, at following email address: gourvendra@ambrosiafoodfarm.com.

3. TERM

3.1 This Agreement shall continue in force till completion of the study from the Effective Date set forth above; provided, however, that either party may terminate the Agreement by giving thirty (30) days advance notice to the other. The parties may extend the term of this Agreement only if mutually agreed to in writing by authorized signatories representing each party.

3.2 Upon early termination of this Agreement, Sponsor shall be liable for all reasonable costs incurred or obligated by Institution at the time of such termination, subject to the maximum amount specified in Article 2. Sponsor shall pay Institution for such costs within thirty (30) days of receipt of an invoice for same.

3.3 Upon termination of this Agreement, Institution shall return Sponsor's materials and equipment to Sponsor.

3.4 Each Party reserves the right to terminate this Agreement at any time effective immediately (i) if the authorization and approval to conduct the Study is withdrawn by the Ministry of Ayush, IRB, or other regulatory authority, or (ii) for safety or efficacy concerns.

4. INDEMNIFICATION

4.1 Sponsor shall indemnify and hold harmless System, Institution, their Regents, officers, agents and employees from any liability or loss resulting from judgments or claims against them arising out of

the activities to be carried out pursuant to the obligations of this Agreement, including but not limited to, the use by Sponsor of the results of the Study; provided, however, that the following is excluded from Sponsor's obligation to indemnify and hold harmless:

a. the negligent failure of Institution to comply with any applicable governmental requirements or to adhere to the terms of the Protocol; or

b. the negligence or willful malfeasance by a Regent, officer, agent, or employee of Institution or System.

5. PUBLICATION AND CONFIDENTIALITY

5.1 Institution reserves the right to publish the results of the Study. Institution will, however, notify Sponsor and will submit a draft of the manuscript to Sponsor for comments at least forty-five (45) days prior to submission for publication or oral presentation. Sponsor shall notify Institution in writing within forty-five (45) days of receipt of such draft whether such draft contains information deemed to be confidential under the provisions of this Section 5, or information that if published within forty-five (45) days would have an adverse effect on a patent application in which Sponsor owns full or part interest, or intends to obtain an interest from Institution pursuant to this Agreement. In the latter case Sponsor has the right to request a delay and Institution agrees to delay said publication for a period not exceeding ninety (90) days. In any such notification, Sponsor shall indicate with specificity to what manner and degree Institution may disclose said information and Sponsor shall be permitted to advise as to the implications of timing of the publication if the same clinical trials set forth in Protocol are still in progress at other sites. Proper recognition of Sponsor shall be made in any publication. Subject to this clause 5.1, Institution shall have the final authority to determine the scope and content of any publication, provided that such authority shall be exercised with reasonable regard for the commercial interests of Sponsor. It is the intent of the parties that no publication will contain any of Confidential Information (defined below) disclosed by Sponsor without Sponsor's prior written permission. Information related to Sponsor's experimental drugs will not be transmitted to nonscientific journals, newspapers, radio or television without Sponsor's written consent.

Notwithstanding the foregoing, Institution agrees that if the Study is part of a multi-center study, the first publication of the results of the Study shall be made in conjunction with the results from the principal investigators at the other study centers. The manner in which the publication will be generated will be negotiated between Sponsor and the principal investigators prior to initiation of Study. However, in the event no publication of the multi-center study has been made within one year of the completion of the study at all centers, then Institution will be free to publish its own results.

5.2 Except as otherwise required by law or regulation, neither party shall release or distribute any materials or information containing the name of the other party or any of its employees without prior written approval by an authorized representative of the non-releasing party, but such approval shall not be unreasonably withheld.

5.3 The parties may wish, from time to time, in connection with work contemplated under this Agreement, to disclose confidential information to each other ("Confidential Information"). Each party will use reasonable efforts to prevent the disclosure of any of the other party's Confidential

Information to third parties till completion of the study from receipt thereof, provided that the recipient party's obligation shall not apply to information that:

a. is not disclosed in writing or reduced to writing and so marked with an appropriate confidentiality legend within thirty (30) days of disclosure;

b. is already in the recipient party's possession at the time of disclosure thereof;

c. is or later becomes part of the public domain through no fault of the recipient party;

d. is received from a third party having no obligations of confidentiality to the disclosing party;

e. is independently developed by the recipient party;

f. is required by law or regulation to be disclosed;

g. is necessary to disclose in order to file a patent application or enforce a patent related to this Agreement;

h. is communicated to the Institution's scientific and/or institutional review committees; or

i. is required to be disclosed in order to obtain informed consent from patients or subjects who may wish to enroll in the Study, provided, however, that the information will be disclosed only to the extent necessary and Confidential Information will not be provided in answer to unsolicited inquiries by telephone or to individuals who are not eligible Study candidates.

In the event that information is required to be disclosed pursuant to subsection f., the party required to make disclosure shall notify the other to allow that party to assert whatever exclusions or exemptions may be available to it under such law or regulation.

6. INTELLECTUAL PROPERTY RIGHTS

6.1 It is recognized and understood that certain inventions and technologies owned by Institution or Sponsor and existing at the date when this Agreement becomes effective are the separate property of Sponsor or Institution respectively, and are not affected by this Agreement, and neither party shall have any claims to or rights in such separate inventions and technologies of the other party. All the new inventions, developments, or discoveries, including patent applications or patents issued thereon, resulting from the Study ("Inventions") shall be promptly disclosed in writing to Company. Institution shall not obtain or attempt to obtain patent coverage on the Study Drug except as set forth herein

6.2 "Invention" shall mean any discovery, concept, or idea, whether or not patentable, made during the conduct of the study, and arising from the performance of the study, including but not limited to processes, methods, software, tangible research products, formulas and techniques, improvements thereto, and know-how related thereto.

6.3 Institution agrees that the Principal Investigator will promptly disclose to its Intellectual Property Committee and to Sponsor any Inventions made by the Institution and/or the Principal

Investigator. It is agreed that all Inventions and any information with respect thereto shall be subject to confidentiality obligations commensurate with those set forth in Section 5.3 herein.

6.4 Any Inventions that originate solely with the Principal Investigator, or any other Institution agent or employee associated with this study (jointly or severally referred to as "Inventor") shall be the property of Institution. If Inventor is a co-inventor with Sponsor, its agents or employees, Institution and Sponsor shall jointly own the Invention. Any Inventions that originate solely with any agent or employee of Sponsor shall be the property of Sponsor. To the extent that Institution owns the rights of sole or joint title in any Invention, Company is hereby granted, without option fee other than consideration of the Study sponsored herein and the reimbursement to Institution for patent expenses incurred prior to or during the option period, an option to acquire an exclusive, worldwide, royalty-bearing license to Institution's rights to any Invention, which option shall extend for ninety (90) days after Company's receipt of an Invention disclosure. Upon Company's exercise of the option, the parties shall promptly negotiate a license agreement in good faith. In addition, notwithstanding the above, Institution shall grant to Company a fully paid up, world-wide, royalty-free, non-exclusive license to the Inventions claiming the composition, use or derivative of the Study Drug, including the Inventions that directly relate to the Study drug, and such license shall be of sufficient scope to allow Company to make, have made, use, sell, import and export the Study Drug including a right to sub-license to Company's development partners, out-licensing partners as well as buyer of the rights in the Study Drug.

6.5 If Sponsor and Institution fail to enter into an agreement during that period of time, Sponsor shall have a right of first refusal with respect to any terms generally more favorable offered by Institution to a third party for a period of one (1) year thereafter. In the event Sponsor elects to exercise its option to negotiate a license in accordance with the procedures detailed above, it shall be obligated to pay all expenses, including attorney's fees, incurred in searching prior art, obtaining search opinions, preparing applications, filing, prosecuting, enforcing or maintaining a patent or patent application with respect to the licensed invention in any country in which the patent or application is filed.

6.6 If any third party claims ownership or rights in any invention in which Sponsor has an interest under this Agreement (a "Conflicting IP Claim"), then Institution may elect not to be involved in any dispute resolution process regarding the Conflicting IP Claim, and if Institution makes such election, Sponsor will not name or include as parties the Institution or System or their Regents, officers, or employees in any arbitration or litigation concerning the Conflicting IP Claim. In addition, if Institution makes the foregoing election, the Conflicting IP Claim must be resolved pursuant to binding arbitration under the then-current procedures of the American Arbitration Association or such other procedure upon which the parties mutually agree, provided, however, that this requirement will not apply if the other party claiming ownership or rights in the invention is not required to submit or does not agree to submit to binding arbitration.

7. BIOLOGICAL SAMPLES

7.1 "Biological Samples" include, without limitation, blood, serum, fluid and tissue biopsy samples collected from subjects enrolled in the Study. Biological Samples further include, without limitation, any tangible material directly or indirectly derived from such blood, fluid or tissue samples, such as: genes, gene fragments, gene sequences, proteins, protein fragments, protein sequences, probes, DNA, RNA, cDNA libraries, plasmids, vectors, expression systems, cells, cell lines, organisms, antibodies or other biological substances; and any constituents, progeny,

mutants, variants, derivatives, replications, reagents or chemical compounds thereof or derived therefrom.

7.2 Institution's Collection, Retention and Use of Biological Samples. Institution will collect, retain and use Biological Samples in accordance with the Protocol. Institution may collect and/or reserve additional quantities of Biological Samples ("secondary Biological Samples") for use in research not described in the Protocol ("non-Protocol research"), provided that (a) such collection complies with all applicable laws, regulations and acceptable clinical trial practices, including, but not limited to, patient privacy and informed consent laws in the country in which the Study is being conducted, and (b) no Confidential Information or any other information which links the secondary Biological Samples to any Confidential Information is available to investigator(s) for such non-Protocol research (for example, without limitation, Institution may annotate such secondary Biological Samples with Study subject demographic information (e.g., age, gender and clinical diagnosis), but not with information related to administration of, or response to, or adverse events associated with, a Study Drug).

7.3 Sponsor's Receipt and Use of Biological Samples. Sponsor may receive pre-determined quantities of Biological Samples from Institution, as set forth in the Protocol, for use in research as described in the Protocol, provided that such research complies with all applicable laws and regulations, including, but not limited to, patient privacy and informed consent laws in the country in which Biological Samples were collected.

Sponsor will disclose to the Principal Investigator all raw data generated by Sponsor from its research using such Biological Samples ("Biological Samples Raw Data"). Sponsor reserves the right to withhold any such Biological Samples Raw Data on any such genes which are pre-obligated and/or encumbered in some manner. Such Biological Samples Raw Data (i) shall be treated by Institution as Confidential Information under this Agreement, (ii) the Principal Investigator may use such Biological Samples Raw Data for the purpose of generating for non-commercial purposes, a manuscript to be published in a scientific peer-reviewed journal, and (iii) may use such Biological Samples Raw Data for non-commercial research and academic purposes, either within Institution or, with prior written notice to Sponsor, may disclose such Biological Samples Raw Data to academic investigators outside Institution; provided that the Institution provides written notice to the recipient of such Biological Samples Raw Data (with a copy to Sponsor) that such Biological Samples Raw Data is Sponsor's Confidential Information.

7.4 In the event that Principal Investigator desires to conduct further research in collaboration with Sponsor with respect to such Biological Samples Raw Data, Sponsor agrees to consider any such request. Any such further research agreed upon by Sponsor shall be subject to the terms of a separate research agreement.

8. GENERAL

8.1 This Agreement constitutes the entire and only Agreement between the parties relating to the Study, and all prior negotiations, representations, agreements, and understandings are superseded hereby. No agreements altering or supplementing the terms hereof, including the exhibits attached hereto, may be made except by a written document signed by the duly authorized representatives of the parties.

8.2 Sponsor and Institution will seek to resolve complaints or grievances arising between them through informal discussion. If a dispute arises out of this Agreement that the parties cannot resolve by informal discussion, the parties will submit the matter to non-binding, advisory arbitration. The arbitration process will be initiated by notice to the other party and will proceed

in accordance with the applicable, or such other procedure upon which the parties mutually agree. The arbitration proceedings will be advisory and will not bind either party. Any costs of arbitration will be shared equally by both parties, without regard to the ultimate disposition of the matter, except for the separately incurred expenses of either party in preparation for the arbitration. The arbitration process itself and any information or disclosure revealed by either party to the arbitrator or to the other party during the arbitration process will be confidential and may not be referred to in any testimony or evidence offered in any subsequent proceeding. The advisory arbitration proceedings will conclude with the arbitrator's issuance of written findings of fact. If Sponsor and Institution are willing to accept the arbitrator's decision, then Sponsor and Institution will execute a settlement agreement that will reflect the arbitrator's decision and which will provide for releases of the claims (i) by Institution to Sponsor and Sponsor's officers, directors and employees, and (ii) by Sponsor to Institution and System and their Regents, officers, and employees.

8.3 Parties agree to remain silent on governing law.

8.4 Any conflicts between the Protocol and this Agreement are controlled by this Agreement.

8.5 This Agreement anticipates educational training and may involve health science postgraduates and other students of the Institution.

8.6 Principal Investigator and Sponsor may be parties to a consulting agreement or other outside agreement to which Institution is not a party. Sponsor acknowledges and agrees that Institution has no involvement with or responsibility for these consulting or outside agreements.

8.7 This Agreement is subject to, and the parties will comply with, all applicable local, state, federal, national and international laws, statutes, rules and regulations. Any provision of any law, statute, rule or regulation that invalidates any provision of this Agreement, that is inconsistent with any provision of this Agreement, or that would cause one or any of the parties hereto to be in violation of law will be deemed to have superseded the terms of this Agreement. The parties, however, will use all reasonable endeavors to accommodate the terms and intent of this Agreement to the greatest extent possible consistent with the requirements of the law and will negotiate in good faith toward amendment of this Agreement in such respect. If the parties cannot reach agreement on an appropriate amendment, then this Agreement may be immediately terminated by either party.

8.8 Notwithstanding any other provision of this Agreement, it is understood that the parties are subject to, and shall comply with, applicable laws, regulations, and governmental requirements and restrictions controlling the export of technology, technical data, computer software, laboratory prototypes, and other commodities, information and items (individually and collectively, "Technology and Items"), including without limitation, and sanctions regulations, all as amended from time to time ("Restrictions") and that the parties' obligations hereunder are contingent on compliance with applicable Restrictions

IN WITNESS WHEREOF, Institution and Sponsor hereby enter into this Agreement, effective as of the date first set forth above, and execute two (2) original counterparts.

Sponsor

BY: **Gourvendra Gangwar**

Ambrosia Food Farm Co.,

BY: **Shailendra Singh**

Ambrosia Food Farm Co.,

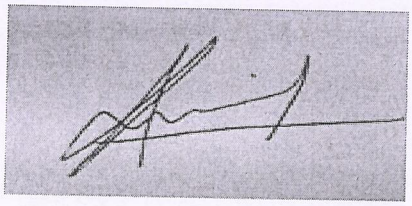
Institution

BY:

Dr. Siddharth P. Dubhashi, AIIMS Nagpur

I acknowledge that I have read this Agreement in its entirety and that I shall use reasonable efforts to uphold my individual obligations and responsibilities set forth herein:

BY:



Dr. Sagar Sinha
MGM Medical College and Hospital, Navi Mumbai, MGMIHS

BY: _____

I acknowledge that I have read this Agreement in its entirety and that I shall use reasonable efforts to uphold my individual obligations and responsibilities set forth herein:

BY: _____

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital

N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS

(CLINICAL RESEARCH UNIT)

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: pharmacolgy@mgmmcha.org

To,

Date: 31 Oct 2020

Dean,
MGM Medical College and Hospital.
N-6, CIDCO, Aurangabad -431003.

Protocol Number: LUF-44-001

Protocol Title: Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study.

Subject: Submission of Study Procedural Fees of Sub no.012019 to Sub no. 012020, Professional Fees of Sub no.012019 to Sub no.012020 and Institutional Overhead Charges for Protocol LUF-44-001.

Respected Sir,
With Reference to above Subject Here by I am submitting 02 cheque towards procedural fees, professional fees and Institutional overhead charges.

Payment Details:

Sr.No	Payment	Cheque No	Amount Rs.	7.5%TDS deducted	Payable Amount
01	**Procedural Fees** of Subject No. 012019 & Subject No. 012020	037177	21,845	NA	21,845

Sr.No	Payment	Cheque No	Amount Rs.	7.5%TDS deducted	Payable Amount
02	**Professional Fees** of Subject No. 012019 & Subject No. 012020	037178	75,465	5,660	69,805

11.12.20

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital

N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS

(CLINICAL RESEARCH UNIT)

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: pharmacolgy@mgmmcha.org

Sr.No	Payment	Cheque No	Amount Rs.	7.5%TDS deducted	Payable Amount
03	**Institutional Overheads**	037178	29,025	2,177	26,848

Kindly acknowledge the receipt of the same by signing the box below and attesting the stamp of the Institute Dean.

With best regards,

Dr. Shivaji Pole
Principal Investigator
Mahtama Gandhi Mission's Medical College and Hospital.
N-6, Cidco .Aurangabad-431003.

Name	Designation	Signature
Dr. Rajendra Bohra	Dean of Institute	

यूनियन बैंक ऑफ इंडिया Union Bank of India

केरेगांव पार्कपुणे – 411 001
Koregaon Park Pune - 411 001
IFS Code : UBIN0564460

VALID FOR 3 MONTHS FROM THE DATE OF ISSUE

दिनांक DATE 28 10 2020
D D M M Y Y Y Y

1SN99

PAY M. G.M. Medical college.

या धारक को OR BEARER

रुपये RUPEES Twenty One Thousand Eight hundred and forty Five only/ अदा करें। ₹ 21,845/-

08/03/20

खाता सं. A/c No. 438901010036758

चेक क्रं. Cheque No. 12037177

For ARDENT CLINICAL RESEARCH SERVICES

AuthorisedSignatory

PLEASE SIGN ABOVE THIS LINE

भारत की हमारी सभी शाखाओं में सममूल्य पर देय
PAYABLE AT PAR AT ALL OUR BRANCHES IN INDIA

"037177" 411026051: 644612" 29

यूनियन बैंक ऑफ इंडिया Union Bank of India

केरेगांव पार्कपुणे – 411 001
Koregaon Park Pune - 411 001
IFS Code : UBIN0564460

VALID FOR 3 MONTHS FROM THE DATE OF ISSUE

दिनांक DATE 28 10 2020
D D M M Y Y

1JK13

PAY M.G.M. Medical college.

या धारक को OR BEARER

रुपये RUPEES Ninety Six Thousand Six hundred and Fifty Three. अदा करें। ₹ 96,653/-

08/03/20

खाता सं. A/c No. 438901010036758

चेक क्रं. Cheque No. 12037178

For ARDENT CLINICAL RESEARCH SERVICES

AuthorisedSignatory

PLEASE SIGN ABOVE THIS LINE

भारत की हमारी सभी शाखाओं में सममूल्य पर देय
PAYABLE AT PAR AT ALL OUR BRANCHES IN INDIA

"037178" 411026051: 644612" 29

R

Dr 15/12/2020

MAHATMA GANDHI MISSION
Mahatma Gandhi Mission's Medical College & Hospital
N-6 CIDCO, Aurangabad - 431003
DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)
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

Date: 30 Nov 2020

To,

The Dean,

MGM Medical College and Hospital

N-6 CIDCO, Aurangabad-431003.

Protocol No: - GPL/CT/2020/004/III

Protocol Title :- A randomized open-label study to evaluate the efficacy and safety of favipiravir and umifenovir as compared to favipiravir alone in moderate hospitalized adult Indian COVID-19 patients.

Subject: - Submission of Study Payments includes institutional overhead charges.

Respected Sir,

With reference to above subject, Here by I am submitting cheque details towards the study payment.

Payment Details:-

Sr. No	Payment	Cheque No.	Amount Rs
01	Study Payment	000815	5,67,820 /-

Kindly the receipt of the same by signing in the box below

Thanking You,

Dr.Deepak Bhosale
Professor & HOD
Clinical Research Unit &Department of Pharmacology,
Mahatma Gandhi Mission's Medical College & Hospital,
N-6, CIDCO, Aurangabad-431003, Maharashtra, India.

MAHATMA GANDHI MISSION
Mahatma Gandhi Mission's Medical College & Hospital
N-6 CIDCO, Aurangabad - 431003
DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)
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

Acknowledgment Of Receipt	
Received by :- (Authorized Person-Signature and stamp)	 Date :- 30 Nov 2020

Grapecity Research Solutions LLP

Address-D/2 Prakash Society, Thergaon, Pune-411033, Maharashtra, INDIA.
Phone- +91 84462 22284
Mobile No. +91 9665 041290
Email ID- info@grapecityresearch.com

Date - 09/11/2020.

To,
MGM Medical College.

Aurangabad, Maharashtra.

Subject- Professional Fees for PI Grant Covid Study.

Please find enclosed P.I Grant payment of Professional fees towards above mentioned study, details are mentioned below:

Total PI Grant: 9,44,400/-
Gross amount: 65% Your Share - 6,13,860/-
TDS deducted 7.5%: 46,040 /-
Net amount: 5,67,820/-
Cheque No: 000815 of ICICI Bank.(through NEFT)
Please provide us copy of acknowledgement once you receive the Payment through NEFT for our reference & record.

Yours Sincerely,

Dr.Sunil Chaudhary
Director-Grapecity Research Solutions LLP.

Acknowledgement Receipt	
Received By	
Signature with Date	

Customer Acknowledgement for NEFT transaction/ एनईएफटी लेनदेन के लिए ग्राहक रसीद

Customer name / ग्राहक का नाम: Grapecity research LLP. Date/ दिनांक: 09/11/2020
Beneficiary name / लाभार्थी का नाम: MGM College. Mode of payment / भुगतान का प्रकार: NEFT.
Beneficiary bank name / लाभार्थी के बैंक का नाम: IDBI Bank Beneficiary account number / लाभार्थी का खाता नंबर: 0376104000000107
Transaction Reference number / संदर्भ संख्या: Amount / रकम: 567820
Name and signature of Bank official / बैंक अधिकारी का नाम और हस्ताक्षर:

Received through NEFT-000097402703
Grapecity Re on 10/11/2020. 000575-067879

...of Pharmacology,
...ission's Medical College & Hospital,
...CO, Aurangabad-431003, Maharashtra, India

MAHATMA GANDHI MISSION
Mahatma Gandhi Mission's Medical College & Hospital
N-6 CIDCO, Aurangabad - 431003
DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)
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

Date: 30 Nov 2020

To,

The Dean,

MGM Medical College and Hospital

N-6 CIDCO, Aurangabad-431003.

Protocol No: - GPL/CT/2020/004/III

Protocol Title :- A randomized open-label study to evaluate the efficacy and safety of favipiravir and umifenovir as compared to favipiravir alone in moderate hospitalized adult Indian COVID-19 patients.

Subject: - Submission of Study Payments includes institutional overhead charges.

Respected Sir,

With reference to above subject, Here by I am submitting cheque details towards the study payment.

Payment Details:-

Sr. No	Payment	Cheque No.	Amount Rs
01	Study Payment	000926	2,62,521 /-

Kindly the receipt of the same by signing in the box below

Thanking You,

Dr.Deepak Bhosale
Professor & HOD
Clinical Research Unit &Department of Pharmacology,
Mahatma Gandhi Mission's Medical College & Hospital,
N-6, CIDCO, Aurangabad-431003, Maharashtra, India.

MAHATMA GANDHI MISSION
Mahatma Gandhi Mission's Medical College & Hospital
N-6 CIDCO, Aurangabad - 431003
DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)
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

Acknowledgment Of Receipt	
Received by :-	
(Authorized Person-Signature and stamp)	Date :- 30 Nov 2020

Grapecity Research Solutions LLP

Address-D/2 Prakash Society, Thergaon, Pune-411033, Maharashtra, INDIA.
Phone- +91 84462 22284
Mobile No. +91 9665 041290 Email ID- info@grapecityresearch.com

To, The Dean. Date - 19/11/2020.

MGM Medical College.

Aurangabad, Maharashtra.

Subject- for Hospital Payment & Lab Charges Covid Study .(Final Payment)

Please find enclosed Hospital payment & Lab Charges of towards above mentioned study, details are mentioned below:

Gross amount: 65% Your Share – 2,83,806/-
TDS deducted 7.5%: 21,285 /-
Net amount: 2,62,521/-
Cheque No: 000926 of ICICI Bank.(through NEFT)
Please provide us copy of acknowledgement once you receive the Payment through NEFT for our reference & record.

Yours Sincerely,

Dr.Sunil Chaudhary
Director-Grapecity Research Solutions LLP.

Acknowledgement Receipt	
Received By	
Signature with Date	

Customer Acknowledgement for NEFT transaction/ एनईएफटी लेनदेन के लिए ग्राहक रसीद

Customer name / ग्राहक का नाम Grapecity Research LLP. Date/ दिनांक 19/11/2020

Beneficiary name / लाभार्थी का नाम MGM College

Beneficiary bank name / लाभार्थी के बैंक का नाम ICICI B.

Transaction Reference number / लेन-देन संदर्भ

Name and signature of Bank official / बैंक अधिकारी का नाम और हस्ताक्षर

Mode of payment / भुगतान का तरीका NEFT

Beneficiary account number / लाभार्थी का खाता नंबर 037601400000010

Amount / राशि 2,62,521/-

Bank Seal / बैंक की मुहर

ICICI Bank Limited Branch Pune

Rs. 262521/- 000097766922
Received through NEFT. on 19/11/20
23/11

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital

N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS

(CLINICAL RESEARCH UNIT)

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: pharmacolgy@mgmmcha.org

Date: 08-DEC-2020

To,

The Dean,

MGM Medical College and Hospital.

N-6 Cidco Aurangabad- 431003

Study Title: Reference: :- A Randomized, Double-Blind, Placebo-controlled, Parallel-group, Multicentre Study To Demonstrate the effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes , Cardiovascular Risk Factors and Moderately Impaired Renal Function.

Study Code: - EFC14875

Subject: Submission of study payment

Respected Sir,

With Reference to above Subject, Here by I am submittimg study payment .

Payment Details

Sr. No	Payment	RTGS No	Amount Rs	Received On
1	Study Payment	DEUTR92020040300000768	2,78,823.60	3 rd Apr 2020

Kindly acknowledge the receipt of the same by signing in the below box.

With best regards,

Dr. Deepak Bhosle

HOD and Professor

Clinical Research Unit & Department of Pharmacology,

Mahatma Gandhi Mission's Medical College & Hospital,

N-6 Cidco, Aurangabad -431003 , Maharashtra , India.

CoCd	BusA	SG	Document Id	Vendor	Vendor Account Name	Type	DocumentNo	DD	PayT	Reference
0345	INAB		1232450	1155266	MGM Medical College	KR	190166790		D000	14875/040/04
0345	INAB		0	1155266	MGM Medical College	ZP	200155746			
Bar code	HO03452020001685									

Text	PM	PBk	Clrng doc.	User name	Assignment	Doc. Date	Pstng Date	Net due dt	Discount base amount	Amount in local cur.	Curr.
EFC14875_PI Fees (10-Sep-19 to 31-Jan-2020)_Dr. Pr	Z		200155746	I0154811		02/13/2020	03/26/2020	03/09/2020	-304,640.60	-278,823.60	INR
	Z		200155746	I0345288		04/03/2020	04/03/2020	04/03/2020	0.00	278,823.60	INR

Received through RTGS - DEUTR92020040300000768/Sanofi

Rs. 2,78,823=60 — on 3rd Apr-2020.

A/c 4/12/2020

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital

N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS

(CLINICAL RESEARCH UNIT)

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: pharmacolgy@mgmmcha.org

Date: 08 Aug 2019

To,
Dean,
MGM Medical College and Hospital.
N-6 Cidco, Aurangabad -431003.

Protocol Number: LUF-44-001

Protocol Title: Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study.

Subject: Submission of study procedural fees of sub no.012005 to sub no01210, Professional fees of sub no.012001 to sub no.012007 and Institutional overhead charges for protocol LUF-44-001

Respected Sir,

With Reference to above Subject Here by I am submitting 03 cheques towards procedural fees, professional fees and Institutional overhead charges.
Payment Details:

Sr.No	Payment	Cheque No	Amount Rs.	10%TDS deducted	Payable Amount
01	**Procedural fees** of sub no. 012005 to sub no.012010	035336	59,120	5, 912	53,208

Sr.No	Payment	Cheque No	Amount Rs.	10%TDS deducted	Payable Amount
02	**Professional fees** of sub no. 012001 to sub no.012007	035337	1,71,600	17,160	1,54,440

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital

N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS

(CLINICAL RESEARCH UNIT)

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: pharmacolgy@mgmmcha.org

Sr.No	Payment	Cheque No	Amount Rs.	10%TDS deducted	Payable Amount
03	**Institutional Overhead Charges**	035335	71,500	7,150	64,350

Kindly acknowledge the receipt of the same by signing the box below and attesting the stamp of the Ethics Committee.

With best regards,

Dr. Shivaji Pole
Principal Investigator
Mahtama Gandhi Mission's Medical College and Hospital.
N-6, Cidco .Aurangabad-431003.

यूनियन बैंक Union Bank of India

बी.टी. कवाडे रोड शाखा, पुणे - 411 001
B.T.Kawade Road Branch, Pun - 411 001
IFS Code : UBIN0560677

दिनांक DATE 02 08 2019

1RF42

PAY M.G.M Medical College या धारक को OR BEARER

रुपये RUPEES Sixty Four Thousand Three Hundred and fifty Only

अदा करें ₹ 64,350/-

खाता सं. A/c No. 438901010036758

चेक क्र. Cheque No. 12035335

For ARDENT CLINICAL RESEARCH SERVICES

Proprietor

PLEASE SIGN ABOVE THIS LINE

भारत की हमारी सभी शाखाओं में सममूल्य पर देय
PAYABLE AT PAR AT ALL OUR BRANCHES IN INDIA

⑈035335⑈ 411026040⑆ 606712⑈ 29

यूनियन बैंक Union Bank of India

बी.टी. कवाडे रोड शाखा, पुणे - 411 001
B.T.Kawade Road Branch, Pun - 411 001
IFS Code : UBIN0560677

VALID FOR 3 MONTHS FROM THE DATE OF ISSUE

दिनांक DATE 02 08 2019

1WX54

PAY M.G.M Medical College या धारक को OR BEARER

रुपये RUPEES Fifty three thousand two hundred and Eight.

अदा करें ₹ 53,208/-

खाता सं. A/c No. 438901010036758

चेक क्र. Cheque No. 12035336

For ARDENT CLINICAL RESEARCH SERVICES

Proprietor

PLEASE SIGN ABOVE THIS LINE

भारत की हमारी सभी शाखाओं में सममूल्य पर देय
PAYABLE AT PAR AT ALL OUR BRANCHES IN INDIA

⑈035336⑈ 411026040⑆ 606712⑈ 29

यूनियन बैंक Union Bank of India

बी.टी. कवाडे रोड शाखा, पुणे - 411 001
B.T.Kawade Road Branch, Pun - 411 001
IFS Code : UBIN0560677

VALID FOR 3 MONTHS FROM THE DATE OF ISSUE

दिनांक DATE 02 08 2019

1ZR60

PAY M.G.M. Medical College या धारक को OR BEARER

रुपये RUPEES One lakh Fifty four thousand four hundred and forty

अदा करें ₹ 1,54,440/-

खाता सं. A/c No. 438901010036758

चेक क्र. Cheque No. 12035337

For ARDENT CLINICAL RESEARCH SERVICES

Proprietor

PLEASE SIGN ABOVE THIS LINE

भारत की हमारी सभी शाखाओं में सममूल्य पर देय
PAYABLE AT PAR AT ALL OUR BRANCHES IN INDIA

⑈035337⑈ 411026040⑆ 606712⑈ 29

A/c

A/c 23/08/19

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital

N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS

(CLINICAL RESEARCH UNIT)

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: pharmacolgy@mgmmcha.org

Date: 04 Jul 2019

To,
Dean,
MGM Medical College and Hospital.
N-6 Cidco, Aurangabad -431003.

Protocol Number: EFC14875

Protocol Title: A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function

Subject: Submission of PI fees- Study Payment.

Respected Sir,

With Reference to above Subject Here by I am submitting cheque towards study payment including Institutional overhead charges.

Payment Details:

Sr.No	Payment	NEFT	Amount Rs.	TDS	Payable Amount
01	Study Payment	920190704000000 109X	2,51,704.80	23,307	275,011

Kindly acknowledge the receipt of the same by signing the box below and attesting the stamp of the Ethics Committee.

With best regards,

Dr. Prashant Udgire
Principal Investigator
Mahtama Gandhi Mission's Medical College and Hospital.
N-6, Cidco .Aurangabad-431003.

Gmail soni agale <soni.agale511@gmail.com>

EFC14875_3560040_Payments release details

AhmedAziz.Khan@sanofi.com <AhmedAziz.Khan@sanofi.com> Tue, Jul 9, 2019 at 3:58 PM
To: soni.agale511@gmail.com
Cc: cdevanpally@ardent-cro.com, prashant_udgire@rediffmail.com, umarazmed@gmail.com

Dear Soni,

Please see below the NEFT details of the payments made against the invoices received. Request you to check with accounts and confirm the receipt.

PI Payment:

356040	PI Fees	MGM Medical College	29/May/2019	INR 275.011	INR 275.011	NEFT done on 3rd Jul DEUTR 920190704000000109X

EC Payment:

3560040	EC Sub for Protocol Amendment	MGM Medical College	190604AHFGN00001XXXXXXX	INR 22,223	4-Jun-19

Best regards,

Ahmed Aziz

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital

N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS

(CLINICAL RESEARCH UNIT)

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: pharmacolgy@mgmmcha.org

Date: 04 Jul 2019

To,
Dean,
MGM Medical College and Hospital.
N-6 Cidco, Aurangabad -431003.

Protocol Number: EFC14875

Protocol Title: A Randomized, Double-blind, Placebo-controlled, Parallel-group, Multicenter Study to Demonstrate the Effects of Sotagliflozin on Cardiovascular and Renal Events in Patients with Type 2 Diabetes, Cardiovascular Risk Factors and Moderately Impaired Renal Function

Subject: Submission of PI fees- Study Payment.

Respected Sir,

With Reference to above Subject Here by I am submitting cheque towards study payment including Institutional overhead charges.

Payment Details:

Sr.No	Payment	NEFT	Amount Rs.	TDS	Payable Amount
01	Study Payment	920190704000000109X	2,51,704.80	23,307	275,011

Kindly acknowledge the receipt of the same by signing the box below and attesting the stamp of the Ethics Committee.

With best regards,

Dr. Prashant Udgire
Principal Investigator
Mahtama Gandhi Mission's Medical College and Hospital.
N-6, Cidco .Aurangabad-431003.

Ardent®
Clinical Research Services
The legacy of clinical excellence

098/ACRS/AUG/2020

To

Date: 17th Aug 2020

Dr. Shivaji Pole,
Mahatma Gandhi Mission Medical College & Hospital,
N-6 Cidco, Aurangabad- 431003, Maharashtra, India.

Reference Study: LUF-44-001

Study Title: Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues During Vascular Embolization, a phase IV study.

Sub: Professional fees and IOH of Protocol LUF-44-001.

Dear Sir,
Please find enclosed herewith 50% payment cheque for Professional fees and IOH of Protocol LUF-44-001.

Cheque details are as follows:

#	Payment Description	Cheque No.	Payee name	Amount	7.5% TDS	Total Amount	50% payment
1	Professional fees	037155	MGM Medical College	2,33,350	17,501	2,15,848	**1,07,924**
2	Institutional Overhead	037155	MGM Medical College	64,620	4,847	59,774	**29,887**

Kindly acknowledge the same and please do revert to us if you have any queries or concerns.

Thanks and Regards,

17-Aug-20

Mr. Gaurav Patil,
(Asst. Manager-CT Operation)
Ardent Clinical Research Services, Pune

ACKNOWLEDGEMENT		
Received By	**Designation**	**Sign & Date**

Investigator Grant

Payment details			
Study title Safety and Efficacy of Lipiodol® Ultra Fluid in Association with Surgical Glues During Vascular Embolization, a phase IV study.			
Site No.: 0120 **Pole**			**PI Name: Dr. Shivaji**
#	**Description**	**Unit**	**Amount**
1	**Professional fees of 012005, 012006, 012007 (Final Follow up visit), 012008, 012009, 012010, 012011, 012012, 012013, 012014, 012015 (Screening, First Study Procedure, Final Follow up visit)** ***As per CTA, 10% of the compensation earned by Site in accordance with the Budget will be reserved by CRO.**	1	2,33,350
	Total Amount		**2,33,350**
	7.5 % TDS deducted		**17,501**
	Total Amount		**2,15,848**
	50 % amount		**1,07,924**

#	Particulars	Quantity	Amount (in INR)
1	**Institutional Overhead (IOH) 20 % on Professional fees of 012005, 012006, 012007 (Final Follow up visit), 012008, 012009, 012010, 012011, 012012, 012013, 012014, 012015 (Screening, First Study Procedure, Final Follow up visit)** ***As per CTA, 10% of the compensation earned by Site in accordance with the Budget will be reserved by CRO.**	1	64,620
	Total		**64,620**
	7.5 % TDS deducted		**4,847**
	Grand Total		**59,774**
	50 % amount		**29,887**

यूनियन बैंक ऑफ इंडिया **Union Bank** of India

कोरेगांव पार्क पुणे – 411 001
Koregaon Park Pune - 411 001
IFS Code : UBIN0564460

VALID FOR 3 MONTHS FROM THE DATE OF ISSUE

दिनांक DATE 17082020 (D D M M Y Y Y Y)

1ZP58

PAY M. G. M. Medical college ... या धारक को OR BEARER

रुपये RUPEES One lakh Thirty Seven thousand Eighty hundred and leven.

अदा करें ₹ 1,37,811/-

खाता सं. A/c No.	438901010036758	चेक क्र. Cheque No.	12037155

For ARDENT CLINICAL RESEARCH SERVICES

AuthorisedSignatory

PLEASE SIGN ABOVE THIS LINE

भारत की हमारी सभी शाखाओं में सममूल्य पर देय
PAYABLE AT PAR AT ALL OUR BRANCHES IN INDIA

SESHAASAI | CTS-2010 01/02/20

06/03/20

CA 2096786M

⑈037155⑈ 411026051⑆ 644612⑈ 29

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital

N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)

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: pharmacolgy@mgmmcha.org

Date: 21 Aug 2020

To,
Dean,
MGM Medical College and Hospital.
N-6 Cidco, Aurangabad -431003,
Maharashtra, India.

Protocol Number: LUF-44-001

Protocol Title: Safety and Efficacy of Lipiodol ® Ultra Fluid in Association with Surgical Glues during Vascular Embolization, a phase IV study.

Subject: Submission of Professional fees & IOH

Respected **Sir,**
With Reference to above Subject Here by I am submitting cheque towards professional and IOH fees of protocol LUF-44-001.
Details:

Sr.No	Payment	Cheque No	Amount Rs.	Date
01	Professional Fees of Sub no 012005,012006,012007 (Final Follow up visit) 012008,012009,012010, 012011,012012,012013, 012014,012015(Screening, First study procedure, Final follow up visit)	037155	1,07,924	17/Aug/2020
02	IOH 20% on Professional Fees of Sub no 012005,012006,012007 (Final Follow up visit) 012008,012009,012010, 012011,012012,012013, 012014,012015(Screening, First study procedure, Final follow up visit)	037155	29,887	17/Aug/2020

Kindly acknowledge the receipt of the same by signing the box below.

Received
CRE
10/9/2020
O/C

यूनियन बैंक ऑफ इंडिया Union Bank of India

कोरेगांव पार्क पुणे – 411 001
Koregaon Park Pune - 411 001
IFS Code : UBIN0564460

VALID FOR 3 MONTHS FROM THE DATE OF ISSUE

दिनांक DATE 1 7 0 8 2 0 4 0

1ZP58

PAY M. G. M. Medical college या धारक को OR BEARER

रुपये RUPEES One lakh Thirty Seven thousand Eighty hundred and leven. अदा करें।

₹ 1,37,811/-

खाता सं A/c No. 438901010036758

चेक क्रं Cheque No. 12037155

For ARDENT CLINICAL RESEARCH SERVICES

AuthorisedSignatory

PLEASE SIGN ABOVE THIS LINE

भारत की हमारी सभी शाखाओं में सममूल्य पर देय
PAYABLE AT PAR AT ALL OUR BRANCHES IN INDIA

SESHAASAI : CTS-2010 01-02-30

CA 2098786M 08/03/20

⑈037155⑈ 411026051⑆ 644612⑈ 29

यूनियन बैंक ऑफ इंडिया Union Bank of India

कोरेगांव पार्क पुणे - 411 001
Koregaon Park Pune - 411 001
IFS Code : UBIN0564460

VALID FOR 3 MONTHS FROM THE DATE OF ISSUE

दिनांक DATE 17082020

D D M M Y Y Y Y

1ZP58

PAY M. G. M. Medical college — या धारक को OR BEARER

रुपये RUPEES One lakh Thirty Seven thousand Eight hundred and eleven. अदा करें। ₹ 1,37,811/-

खाता सं. A/c No.	438901010036758	चेक क्रं. Cheque No.	12037155

For ARDENT CLINICAL RESEARCH SERVICES

Authorised Signatory

PLEASE SIGN ABOVE THIS LINE

भारत की हमारी सभी शाखाओं में सममूल्य पर देय
PAYABLE AT PAR AT ALL OUR BRANCHES IN INDIA

SESHAASAI CTS-2010 01/02/20 06/03/20 CA 2096766M

⑈037155⑈ 411026051⑆ 644612⑈ 29

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital
N-6 CIDCO, Aurangabad - 431003
DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)

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: pharmacolgy@mgmmcha.org

Date: 25 Oct 2019

To,
The Dean,
MGM Medical College and Hospital.
N-6 Cidco, Aurangabad -431003.

Protocol No.: VoQuest01
Protocol Title: Survey to collect voice samples of patients and age matched healthy individuals.

Subject: Submission of Study Payment.

Respected Sir,

With Reference to above Subject, Here by I am submitting study payment.

Payment Details:

Sr.No	Payment	NEFT	Payable Amount Rs.	Payment Received Date
01	Study Payment	SBIN219296851160	31,555/-	23 Oct 2019

Kindly acknowledge the receipt of the same by signing in the below box.

With best regards,

Dr. Deepak Bhosle
Principal Investigator
Mahtama Gandhi Mission's Medical College and Hospital.
N-6, Cidco .Aurangabad-431003.

Acknowledgement of Receipt	
Received By:	
(Authorized Person- Signature & Stamp)	**Date:** 18 Dec 2019

IDBI BANK

Transactions Date from 01/10/2019 to 31/10/2019

A/c No. :0376104000000107

Srl	Txn Date	Value Date	Description	Cheque No	CR/DR	CCY	Trxn Amount	Balance
96	23/10/2019	23/10/2019	NEFT-SBIN219296851160-QUEST CL		CR	INR	31,555.00	3,04,70,863.17
97	24/10/2019	24/10/2019	BOMBAY INTELLIGENCE SECURITY	14091	DR	INR	15,00,000.00	2,89,70,863
98	24/10/2019	24/10/2019	140683--M G B		CR	INR	1,00,000.00	2,90,70,863

Mahatma Gandhi Mission's Medical College & Hospital
N-6 CIDCO, Aurangabad - 431003
DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)

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

Date: 11 Aug 2020

To,
The Dean,
MGM Medical College and Hospital,
N-6 Cidco, Aurangabad -431003.

Protocol Number: SII-rBCG/COVID-19/IN-01
Protocol 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.'

Subject: Submission of Study Payment
Respected Sir,
With Reference to above Subject, Here by I am submitting study payment towards institute find below is the details of payment
Payment Details:

Sr.No	Payment	NEFT No	Date	Payable Amount Rs.
1	STUDY PAYMENT	CMS150970758	07-Aug-2020	1496500

Kindly acknowledge the receipt of the same by signing below. TDS: deducted: 112500/-

With best regards,

Dr. Deepak Tayade
Principal Investigator
Mahtama Gandhi Mission's Medical College and Hospital,
N-6, CIDCO. Aurangabad-431003.

Dr.Deepak Bhosle
Prof & Head & I/C Clinical Research Unit
Department of Clinical Pharmacology

R
CHK
10/8/2020

Gmail

shaikh yahiya Ali <yahiya.mgmmcha@gmail.com>

SII-rBCG/COVID-19/IN-01: Site payment

1 message

Bhagyashree Shevade <bhagyashree.shevade@diagnosearch.com>
To: shaikh yahiya Ali <yahiya.mgmmcha@gmail.com>
Cc: Deepak Bhosle <drdeepakbhosle@gmail.com>, "drtayadepsm@gmail.com" <drtayadepsm@gmail.com>, "drshraddha.mgmmcha" <drshraddha.mgmmcha@gmail.com>, "mahesh.mgmmcha" <mahesh.mgmmcha@gmail.com>, Akash Autade <akash.autade@diagnosearch.com>

7 August 2020 at 14:34

Dear Shaikh,

Please find below payment confirmation, towards Sites as per attached tracker.

Debit A/c no	Beneficiary A/c No	Beneficiary Name	Amount	Date	IFSC Code	Payable Location Name	Remarks	Payment Ref No
2000000545	'0376104000000107	MGM MEDICAL COLLEGE	1496500	07-AUG-2020	IBKL0000376	MUMBAI	rBCG-20-2020	CMS15709[illegible]758

Regards,

Bhagyashree

NEFT Through Recieved Amt RS 14,96,500/- on 7/08/2020.
NEFT NO- CMS15709970758-Diagnosearch.

Bhagyashree Shevade | Project Manager | Mobile: +91 8888338567 | bhagyashree.shevade@diagnosearch.com

DiagnoSearch Life Sciences Pvt. Ltd. | 702, Dosti Pinnacle, E-7, Road 22, Wagle Estate, Thane- 400604 |

Board : +91 22-6777-6300 / 6116-6400 | Fax: +91 22-6777-6303 | Website: www.diagnosearch.com

MAHATMA GANDHI MISSION
Mahatma Gandhi Mission's Medical College & Hospital
N-6 CIDCO, Aurangabad - 431003
DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)

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

Date: 27 Jun 2020

To,
The Dean,
MGM Medical College and Hospital,
N-6 Cidco, Aurangabad -431003.

Protocol Number: SII-rBCG/COVID-19/IN-01
Protocol 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.'

Subject: Submission of Study Payment Including, Subject Reimbursement, RT-PCR Test Charges and Advance.

Respected Sir,

With Reference to above Subject, Here by I am submitting Study Payment Including, Subject Reimbursement, RT-PCR Test Charges and Advance.

Payment Details:

Sr. No	Payment	NEFT No	Amount Rs.	Payable Amount Rs.
2	RT-PCR+Subject Reimbursement	CMS1520258391	3,85,000/-	6,10,000/-
3	Advance		2,25,000/-	

Kindly acknowledge the receipt of the same by signing in the below box.

With best regards,

Dr. Deepak Tayade
Principal Investigator
Mahtama Gandhi Mission's Medical College and Hospital,
N-6, CIDCO. Aurangabad-431003.

Acknowledgement of Receipt	
Received By:	
(Authorized Person- Signature & Stamp)	**Date:** 27-06-20

email address for your queries ...
email address for your IDBI equity and Flexibond queries ...

IDBI BANK

Toll Free Numbers: 1800-209-4324 / 1800-200-1947 / 1800-22-1070,
For Query / Grievance resolution:
SMS "IDBICARE" to 9220800800

Primary Account Holder Name	: MGM MEDICAL COLLEGE
Address	:
	MAHARASHTRA
	INDIA
Account No	: 0376104000000107
	: 4658675
Account Branch:	: AURANGABAD - CORPORATE BANKING

YOUR SAVINGS A/C STATUS

Transaction Date From : 21/06/2020 to: 27/06/2020

A/C NO: 0376104000000107

Srl	Txn Date	Value Date	Description	Cheque No	CR/DR	CCY	Amount (INR)
1	26/06/2020 18:33:25	26/06/2020	NEFT-CMS1520258391-DIAGNOSEARC				

MAHATMA GANDHI MISSION
Mahatma Gandhi Mission's Medical College & Hospital
N-6 CIDCO, Aurangabad - 431003
DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)

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

Date: 10 Jun 2020

To,
The Dean,
MGM Medical College and Hospital,
N-6 Cidco, Aurangabad -431003.

Protocol Number: SII-rBCG/COVID-19/IN-01
Protocol 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.'

Subject: Submission of Study Payment Including Institutional Overhead, Subject Reimbursement, Subject Visit, RT-PCR Test Charges and Advance.

Respected Sir,

With Reference to above Subject, Here by I am submitting study payment including Institutional overhead, Subject Reimbursement, Subject Visit, RT-PCR Test Charges and Advance.

Payment Details:

Sr. No	Payment	NEFT No	Amount Rs.	Total	TDS Rs.	Payable Amount Rs.
1	SubVisit+Vaccinication+Institute overhead charges	CMS15004893 09	78,000	3,58,000	5850	3,52,150
2	RT-PCR+Subject Reimbursement		1,80,000			
3	Advance		100,000			

Kindly acknowledge the receipt of the same by signing in the below box.

With best regards,

Dr. Deepak Tayade
Principal Investigator
Mahtama Gandhi Mission's Medical College and Hospital,
N-6, CIDCO. Aurangabad-431003.

Acknowledgement of Receipt	
Received By:	
(Authorized Person- Signature & Stamp)	**Date:** 10/6/2020

30	06/06/2020 14 56 48	06/06/2020	JMEC EMP CREDIT COOP SCC LTD	15060	Dr	INR	31,500.00	6,96,39,092.55
31	06/06/2020 14 55:52	06/06/2020	JNEC EMP CREDIT COOP	15044	Dr	INR	31,500.00	6,96,70,592.55
32	06/06/2020 14 28:35	06/06/2020	RTGS/SVCBR52020060600000616/NAYAK REETA AJAY			INR	5,12,500.00	6,97,02,092.55
33	06/06/2020 13.35:34	06/06/2020	RTGS/SBINR12020060600055510/Mrs RATNA DEVI			INR	9,00,000.00	6,91,89,592.55
34	06/06/2020 13:17:42	06/06/2020	IPAY/INST/NEFT/006842734971/11162752750/SARDAR		Dr	INR	50,000.00	6,82,89,592.55
35	06/06/2020 13.02:42	06/06/2020	RTGS/ICICR52020060600739460/ANAY VASANT KAMAT			INR	25,00,000.00	6,83,39,592.55
36	05/06/2020 17 24 08	05/06/2020	IPAY/INST/NEFT/006842535291/082500100001437/RATNA		Dr	INR	27,787.00	6,58,39,592.55
37	05/06/2020 16 03 47	05/06/2020	NEFT-CMS1500489309-DIAGNOSEARC			INR	3,52,150.00	6,58,67,379.55
38	05/06/2020 15 31.25	05/06/2020	LAWRENCE AND MAYO IN	15074	Dr	INR	17,99,955.00	6,55,15,229.55
39	05/06/2020 15.31:25	05/06/2020	SARDAR SINGH AND SON	15077	Dr	INR	55,448.00	6,73,15,184.55
40	05/06/2020 15 31:24	05/06/2020	GENAXY SCIENTIFIC PR	15073	Dr	INR	41,207.00	6,73,70,632.55
41	05/06/2020 15:05:43	05/06/2020	NEFT-P20060502934458-MOHD.ASSA			INR	5,12,500.00	6,74,11,839.55
42	05/06/2020 14:34:56	05/06/2020	NEFT-SBIN220157639300-Mrs RAT			INR	9,00,000.00	6,68,99,339.55
43	05/06/2020 14 24 18	05/06/2020	JUILEE SHASHIKANT MORE			INR	5,12,500.00	6,59,99,339.55
44	05/06/2020 14 20 01	05/06/2020	RTGS/SBINR52020060500075504/PRAMOD LAHANE			INR	20,00,000.00	6,54,86,839.55
45	05/06/2020 13 58 38	05/06/2020	RTGS/HDFCR52020060582531299/DEEPAK BABURAO			INR	5,12,500.00	6,34,86,839.55
46	05/06/2020 12 33 44	05/06/2020	NEFT-000088066345-RANJIT SINGH			INR	8,50,000.00	6,29,74,339.55
47	05/06/2020 12 16 36	05/06/2020	349093-SBI-MEENA			INR	22,500.00	6,21,24,339.55
48	05/06/2020 12 16.36	05/06/2020	811193-SBI-RAJESH			INR	4,90,000.00	6,21,01,839.55
49	05/06/2020 11:08:27	05/06/2020	RTGS/ICICR52020060500607639/SARITA KUMAR			INR	20,00,000.00	6,16,11,839.55
50	04/06/2020 16.05:24	04/06/2020	NEFT-000088037071-RHEA VISHAL			IN	5,50,000.00	5,96,11,839.55
51	04/06/2020 15 45 50	04/06/2020	RTGS/SBINR52020060400094967/KAILAS BABURAO			IN	15,00,000.00	5,90,61,839.55
52	04/06/2020 15 14 12	04/06/2020	RTGS/CRUBR52020060400000064/ANIKET MEDICAL			IN	10,00,000.00	5,75,61,839.55
53	04/06/2020 14 24 05	04/06/2020	RTGS/SBINR12020060400067808/Mrs RATNA DEVI			IN	7,00,000.00	5,65,61,839.55
54	04/06/2020 14 21 48	04/06/2020	REMI SALES AND ENGIN	15075		IN	5,6[illegible]00.00	5,58,61,839.55
55	04/06/2020 14 03 38	04/06/2020	NEFT-000088013580-PALAK PREET			I	6,00,[illegible]00.00	5,64,22,339.55
56	04/06/2020 13 04 06	04/06/2020	NEFT-AXMB201568156150-KAMAL KA			I	5,1[illegible]0.00	5,58,22,339.55
57	04/06/2020 12 38 38	04/06/2020	811467-SBI-SBI BANK			I	[illegible].00	5,53,09,839.55
58	04/06/2020 12 38 38	04/06/2020	031813-SBI-SBI BANK			I	[illegible].00	5,52,74,839.55
59	04/06/2020 11 33 54	04/06/2020	RTGS/COSBR52020060400632892/AJAY P MALI			I	13,[illegible]0.00	5,52,58,839.55
60	04/06/2020 11 33 30	04/06/2020	NEFT-000087995306-ABHISHEK D K			I	25,[illegible]0.00	5,39,58,839.55
61	04/06/2020 11 33 26	04/06/2020	NEFT-CBINH20156724266-Miss. PR			I	5,[illegible]0.00	5,14,58,839.55
62	03/06/2020 13 46 00	03/06/2020	RTGS/COSBR52020060300627853/MALI SUCHITRA AJAY			I	7,[illegible]0.00	5,09,46,339.55
63	03/06/2020 13 30 20	03/06/2020	RTGS/SBINR52020060300057485/Mr SURYAKANT			I	5,[illegible].00	5,02,46,339.55
64	03/06/2020 06 51 20	03/06/2020	0076105000103695 : Closure Proceeds			I	1,9[illegible]5.60	4,97,33,839.55
65	03/06/2020 06 51 20	03/06/2020	0076105000103664 : Closure Proceeds			I	1,9[illegible].50	3,00,89,592.95

Statement Summary:-

Dr Count	Cr Count	Debits	Credits
15	50	28095583	87456547

This is an account statement generated through Net Banking and does not require signature.

Gmail

shaikh yahiya Ali <yahiya.mgmmcha@gmail.com>

SII-rBCG/COVID-19/IN-01- Invoices Payment confirmation

1 message

Bhagyashree Shevade <bhagyashree.shevade@diagnosearch.com> 9 June 2020 at 15:09
To: shaikh yahiya Ali <yahiya.mgmmcha@gmail.com>
Cc: "drtayadepsm@gmail.com" <drtayadepsm@gmail.com>, "drdeepakbhosle@gmail.com" <drdeepakbhosle@gmail.com>

Dear Yahiya,

Find below payment confirmation.

Site Number	Site Name	Invoice Number	Total	TDS ON Fee	Net Payment	Account No	IFSC	Payment Refrence
200	MGM	200-11/2020	358,000.00	5,850.00	**352,150.00**	0376104000000107	IBKL0000376	CMS1500489309

Regards

Bhagyashree

Debit A/c no	Beneficiary A/c No	Beneficiary Name	Amount	Payment Mode	Date	IFSC Code	Payment Ref No	Status
2005000545	037810400000137	MGM MEDICAL COLLEGE AURANGABAD	60000	AUTONEFT	04-MAY-2020	IBKL0000378	CMS1471733128	Paid

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS

(CLINICAL RESEARCH UNIT)

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: pharmacolgy@mgmmcha.org

Date:-12/Aug/2020

To,
Dean Sir,
MGM's Medical College and Hospital,
N-6 Cidco, Aurangabad

Protocol: CTQJ230A12001
Protocol Title: Multi-center, cross-sectional epidemiological study to characterize the prevalence and distribution of lipoprotein (a) levels among patients with established cardiovascular disease".

Principal Investigator: Dr. Prashant Udgire
Sponsor: Novartis Healthcare Private Limited
Subject: Regarding invoice sent to PI-Dr. Prashant Udgire

Respected Sir,
With reference to above mentioned study the sponsor has paid below payment to Dr. Prashant Udgire.

- Investigator/Co-Investigator Fees- Rs,56,000
- Institutional Overhead charges- Rs.19,600
- Central Lab (Metropolis)- Rs.48,050

1. From the above 60% of Investigator/Co-Investigator Fees (i.e.Rs.33,600) and full amount of Institutional Overhead charges (i.e.Rs.19,600) has to be credited (Total Rs 53,200) to the MGM Hospital.
2. Attached is the Account Details of Metropolis Lab to which Rs 48,050 has to be credited.

Kindly consider this for your Review & Record.

Thanking You

Dr Deepak S Bhosle
Professor & Head
Department of Pharmacology
Mahtama Gandhi Mission's Medical College and Hospital.
N-6, Cidco .Aurangabad-431003, Maharashtra, India.

Professor & H.O.D.
Department of Pharmacology
MGM's Medical College
Aurangabad.

MAHATMA GANDHI MISSION

Mahatma Gandhi Mission's Medical College & Hospital N-6 CIDCO, Aurangabad - 431003

DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS

(CLINICAL RESEARCH UNIT)

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: pharmacolgy@mgmmcha.org

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Kindly consider this for your Review & Record.

Thanking You

Dr Deepak S Bhosle
Professor & Head
Department of Pharmacology
Mahtama Gandhi Mission's Medical College and Hospital.
N-6, Cidco .Aurangabad-431003, Maharashtra, India.

Professor & H.O.D.
Department of Pharmacology
MGM's Medical College
Aurangabad.

MAHATMA GANDHI MISSION
Mahatma Gandhi Mission's Medical College & Hospital
N-6 CIDCO, Aurangabad - 431003
DEPARTMENT OF CLINICAL PHARMACOLOGY & THERAPEUTICS
(CLINICAL RESEARCH UNIT)

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

Date: 03 SEP 2020

To,
The Dean,
MGM Medical College and Hospital,
N-6 Cidco, Aurangabad -431003.

Protocol Number: CP/04/18

Protocol Title:: A Randomized, Open-label, Prospective, Comparative, Multi-centre, Parallel group, Active controlled, Phase III Study to Evaluate the Efficacy and Safety of the Ropivacaine Readyfusor 2mg/ml versus Ropivacaine Balloon Pump Infusor 2mg/ml as a continuous surgical site infusion for the Treatment of Post-Surgical Pain in lower abdominal laparotomy

Subject: Submission of Study Payment Including, Investigations.

Respected Sir,
With Reference to above Subject, Here by I am submitting Study Payment Including Investigations,
Payment Details:

Sr.No	Payment	Transaction Ref No	Amount Rs.	Date
1.	Study payment	N20244598347	153135/-	31 Aug 2020

Kindly acknowledge the receipt of the same by signing below.
With best regards,

Dr. Vasanti Kelkar
Principal Investigator
Mahtama Gandhi Mission's Medical College and Hospital,
N-6, CIDCO. Aurangabad-431003.

Dr.Deepak Bhosle
Prof & Head &-I/C Clinical Research Uni
Department of Clinical Pharmacology

Acknowledgement of Receipt	
Received By:	
Authorized Person- Signature	**Date:**

16/10/2020

Gmail

shaikh yahiya Ali <yahiya.mgmmcha@gmail.com>

CP/04/18_PI Invoice payment

1 message

Dipika Akre <dipika.akre@jssresearch.com>
To: shaikh yahiya Ali <yahiya.mgmmcha@gmail.com>
Cc: Khushbu Shah <Khushbu.shah@jssresearch.com>, "Dr. Chetan Metha" <chetan.metha@jssresearch.com>, SMB cipla <cipla@jssresearch.com>

3 September 2020 at 12:02

Dear Yahiya,

Ref Study: CP/04/18

Please find attached payment details done by JSS on 31 Aug 2020, request you to give payment confirmation on below details.

Transaction Ref No	Sender Account No	Sender Name	Amount	Beneficiary Account No	Beneficiary Name	Beneficiary IFSC
N20244598347	1041938	JSS Medical Research India Pvt Ltd	153135.00	0376104000000107	MGM Medical College, Aurangabad	IBKL0000376

Received Rs. 153,135/- on 31st Aug. 2020.
through NEFT-
N20244598347-

Thank You,

Dipika Akre

Dipika Akre
Clinical Trial Assistant

dipika.akre@jssresearch.com
T +(91)-22-25126782/83

JSS RESPONSIVE RELIABLE RESULTS

A/c.

Gmail

shaikh yahiya Ali <yahiya.mgmmcha@gmail.com>

CP/04/18_PI Invoice payment

Khushbu Shah <Khushbu.shah@jssresearch.com>
To: shaikh yahiya Ali <yahiya.mgmmcha@gmail.com>, Dipika Akre <dipika.akre@jssresearch.com>
Cc: "Dr. Chetan Metha" <chetan.metha@jssresearch.com>, SMB cipla <cipla@jssresearch.com>, Deepak Bhosle <drdeepakbhosle.mgmmcha@gmail.com>, "drshraddha.mgmmcha" <drshraddha.mgmmcha@gmail.com>

5 September 2020 at 14:30

Dear Yahiya,

As per to the trailing email , I have attached clarification email provided by our Finance Team.

Details

Invoice No	Site	Study Name	Base Amount (A)	IGST (B)	TDS (C)	Invoice Amount (A+B) D	Payable (D-C) E	Retention Amount (15% of E) F	Paid Amount (E-F)
7/2020	MGM Medical College	CIPLA CP/04/18	198,000	-	19,800	198,000	178,201	26,730	151,470
8/2020	MGM Medical College	CIPLA CP/04/18	1,800	-	135	1,800	1665	-	1,665
Total			**199,800**	-	**19,935**	**199,800**	**179,866**	**26,730**	**153,135**

Let us know if you have any further query.

Thank You

Best Regards

Khushbu

MGM INSTITUTE OF HEALTH SCIENCES
(Deemed University u/s 3 of UGC Act, 1956)
Grade 'A' Accredited by NAAC
Sector 1, Kamothe, Navi Mumbai – 410 209.
Tel: 022-27432471, 022-27432994, Fax No. 022-27431094
Email: registrar@mgmuhs.com ; Website: www.mgmuhs.com

Ref.No.MGMIHS:RES.:2019-20: 352

18th December , 2019

To,
Dr. Sadhana S Kularni
Professor & Head
Department of Emergency Medicine
MGM Medical College & Hospital
Aurangabad.

Ref.: Letter no.MGM/MCA/2019/5124 dated 24.10.2019
Sub.: Sanction of Seed Money for Research Project entitled "Major neurological complications following central neural blockade – A pilot study in Aurangabad City (MGMA CNB Study) "

Dear Sir,

This is in reference to your research project entitled **"Major neurologica complications following central neural blockade – A pilot study in Aurangabad Cit (MGMA CNB Study)"**. You have asked for funding of the above mentioned project.

As per the guidelines for the project to be funded by MGMIHS, you have presented t study proposal in front of the Scientific Advisory Committee (RRC/SAC) of t MGMIHS on 20.11.2019. As stated by Scientific Advisory Committee of the MGMIH the Research Project is a multi-centric study, which will help to formulate guidelines Central Neural Blocks and increase patient's safety, this is first of its kind in India a may benefit for formulating India National Guidelines. The Committee recommended this research project looking into its validity.

It was forwarded to the Vice Chancellor for granting permission to fund the project. Vice Chancellor has sanctioned the seed money of Rs. 25,000.00 for the project.
He has further suggested that, you should explore the possibility of extra-m funding for the same.

Please note that, progress of the research work to be submitted to the University eve six month, which will be reviewed by SAC Committee.

Thanking you,

Dr. Rajesh B G
Registrar

Dr. Rajesh B
Registr
MGM Institute of H
(Deemed University u/s 3
Navi Mumbai

Copy to : The Dean, MGM Medical College & Hospital, Aurangabad.

2019

2019-02305	Mr. Divas garg	Approved
2019-02307	Ms. priya vashistha	Approved
2019-02308	Ms. Aumina Akhtar	Approved
2019-02340	Mr. Sanay Nayesh Patani	Approved
2019-02342	Ms. Sivasakthi G	Approved
2019-02359	Mr. Meet Chintan Shah	Approved
2019-02360	Mr. Subham Poddar	Approved
2019-02365	Ms. ritika ranjan	Approved
2019-02367	Mr. saurodeep bhattacharjee	Approved
2019-02370	Ms. Trisha Pratihar	Approved
2019-02379	Ms. Anjali Rajagopal	Approved
2019-02382	Mr. BHARAT JOSHI	Approved
2019-02399	Ms. Sunaina Aghanashini Harish	Approved
2019-02401	Mr. AJAY VASUDEV	Approved
2019-02402	Ms. Aarya Ajay Naik	Approved
2019-02413	Ms. NagaNimisha Naga Sateesh Indugu	Approved
2019-02417	Mr. Arjun Tripathy	Approved
2019-02420	Ms. Yogita Ghanshyam Bajaj	Approved
2019-02424	Ms. Reshmi E	Approved
2019-02435	Ms. Priyanka Ramkumar	Approved
2019-02439	Mr. harsh jain	Approved
2019-02462	Ms. Swathi P	Approved
2019-02471	Ms. SHREYA VIKAS VENURKAR	Approved
2019-02483	Ms. mohini chauhan	Approved
2019-02488	Ms. Akshatha Shenoy U	Approved
2019-02492	Mr. Sourav Kumar Haldkar	Approved
2019-02493	Ms. anushka agarwal	Approved
2019-02504	Ms. Gargie Sharma	Approved
2019-02507	Mr. Neel Nathmal Kavediya	Approved
2019-02509	Ms. ANANYA N KRISHNASWAMY	Approved
2019-02539	Ms. Ruhi Chahal	Approved
2019-02543	Ms. Rashiqa Sharvany	Approved
2019-02545	Mr. Sagar Ramesh Patel	Approved
2019-02548	*Ms. Lubna Tyagdal	Withheld
2019-02567	Ms. Sara Samreen	Approved
2019-02572	Mr. Syed Abdul Raheem	Approved
2019-02573	Mr. Rohit kumar M	Approved
2019-02580	Ms. Trishna A Rao	Approved
2019-02589	Ms. Japleen Kaur	Approved
2019-02593	Ms. NAMRATHA KONJETI	Approved
2019-02595	Mr. Raghav Grover	Approved
2019-02597	*Mr. Nilesh Ramrao Ade	Withheld
2019-02600	Ms. Saumya Raj	Approved

(*AAF-Submit your attestation form as per timeline otherwise application will be rejected)

2019-01799	Mr. Jay Vipul Shah	Approved
2019-01800	Ms. Greeshma Joy	Approved
2019-01819	Ms. Elizabeth Thomas	Approved
2019-01850	Ms. Sana Siddiqui	Approved
2019-01862	Ms. Shravani D Patil	Approved
2019-01864	Ms. KARISHMA V	Approved
2019-01865	*Ms. SHIVANGI SHARMA	Withheld
2019-01869	Ms. Garvita Singhal	Approved
2019-01873	Ms. Vidhina Bhojraj Khade	Approved
2019-01874	Ms. Arulkavi A	Approved
2019-01875	Ms. Rithya Kuppam	Approved
2019-01876	Ms. Sneha Chandrabhan Vaidya	Approved
2019-01879	Ms. Shreya Gajanan Namjoshi	Approved
2019-01889	Ms. Deeksha Rana	Approved
2019-01901	Mr. Anand Raj	Approved
2019-01908	Mr. Niraj Anilkumar Bennur	Approved
2019-01913	Mr. Darsh Aggarwal	Approved
2019-01922	Ms. TejaSri Gattu	Approved
2019-01924	*Ms. Madhumitha Muruganandam	Withheld
2019-01925	Mr. Harsh Upadhyay	Approved
2019-01935	Ms. Anupama V S	Approved
2019-01939	Ms. Bhagyajyoti Priyadarshini	Approved
2019-01944	Ms. SHRUTI GUPTA	Approved
2019-01947	Mr. Karthik Ajith	Approved
2019-01957	Ms. KAMAL DIGVIJAY SINGH	Approved
2019-01959	Ms. Swadha Shivam	Approved
2019-01961	Ms. Ashwathy A	Approved
2019-01968	*Ms. Nidhi Devi Beniwal	Withheld
2019-01969	Mr. HITESH BHATIA	Approved
2019-01981	Ms. Monika Nannapaneni	Approved
2019-01994	Mr. Kunal Singal	Approved
2019-02014	Mr. Ananya Tapadar	Approved
2019-02019	Mr. Ashwin Ayyappan Velauthan	Approved
2019-02024	Ms. Priyadharshini K M	Approved
2019-02027	Ms. Shreya Pandey	Approved
2019-02028	Ms. Karishma Wasnik	Approved
2019-02033	Ms. Praggya Yaadav	Approved
2019-02034	Ms. Amulya R Rao	Approved
2019-02035	Ms. Krishanga Srivastava	Approved
2019-02040	Ms. Ragavi Elango	Approved
2019-02044	Ms. Komal	Approved
2019-02055	Ms. Navkiran	Approved
2019-02056	Mr. Alan Siby	Approved

(*AAF-Submit your attestation form as per timeline otherwise application will be rejected)

2019-06841	Ms. Kavyasri Suresh Kumar	Approved
2019-06843	Ms. V.S.Darshine	Approved
2019-06845	Ms. Indhuja Vetriselvan	Approved
2019-06853	Mr. Harshit Garg	Approved
2019-06855	Ms. Praveenya Pulagam	Approved
2019-06859	Ms. Arshiya Khaiser Husain Shaikh	Approved
2019-06864	Ms. Arunaakshara Thirunavukkarasu	Approved
2019-06867	Ms. Mitthrashree Vs	Approved
2019-06877	Mr. M Kamaleshwarran	Approved
2019-06891	Mr. Mithesh Nivas B	Approved
2019-06892	Ms. Aparna Swaminathan	Approved
2019-06894	Mr. Swarnava Sarkar	Approved
2019-06897	Ms. Monika Murugaiyan	Approved
2019-06909	Ms. Avanthika Krishnakumar Vineetha	Approved
2019-06910	Ms. Kolli Pooja Chowdary	Approved
2019-06912	Mr. Mohammed Riyaz A	Approved
2019-06915	Ms. Sonal Nawani	Approved
2019-06919	Mr. Arham Khan	Approved
2019-06925	Mr. Nakkeeran V.R.	Approved
2019-06928	Ms. Chandrika	Approved
2019-06944	Ms. Rajvee Biren Shah	Approved
2019-06946	Mr. Shri Yuvan A	Approved
2019-06958	Ms. Disha Yadav	Approved
2019-06959	Mr. Pravesh Lallu Gupta	Approved
2019-06963	Mr. Srinivasa Nambi	Approved
2019-06965	Ms. Vasundhara	Approved
2019-06971	Ms. Pilli Swetha Sai Sree	Approved
2019-06975	Ms. Kairavi Singh	Approved
2019-06977	Ms. Gloria Varghese	Approved
2019-07011	Ms. Utsavi Devang Desai	Approved
2019-07012	Mr. Pradhuman Upadhyay	Approved
2019-07013	Ms. Reeva Shivram Nadkarni	Approved
2019-07020	Mr. Navin Mallya	Approved
2019-07032	Ms. Akansha Priya	Approved
2019-07038	Mr. Aditya Sharma	Approved
2019-07042	Mr. Mayank Dungarwal	Approved
2019-07045	Ms. Archana Saravanan	Approved
2019-07046	Ms. Hema Manvi Badi	Approved

(*AAF-Submit your attestation form as per timeline otherwise application will be rejected)

2019-05387	Ms. Saba Ali	Approved
2019-05390	Ms. Bankapalli Saloni	Approved
2019-05391	Ms. Naushin Ramzanali Moledina	Approved
2019-05392	Ms. Akankshya Arunima	Approved
2019-05395	Mr. Navya Chetankumar Raval	Approved
2019-05399	Mr. Viju V	Approved
2019-05422	Ms. Anjali Changulani	Approved
2019-05425	Ms. S. Nisha Jaisree	Approved
2019-05435	Mr. Piyush Pradip Kharche	Approved
2019-05464	Ms. Sweta Shashikant Bhagat	Approved
2019-05474	Ms. Taanya Mahesh	Approved
2019-05492	Mr. Siddhant Passey	Approved
2019-05497	Ms. Abhigna Ailla	Approved
2019-05498	Mr. Hanumantha S	Approved
2019-05499	Ms. Susmita De	Approved
2019-05516	Ms. Navya Pidamarthi	Approved
2019-05519	Ms. Ishita Upadhyay	Approved
2019-05522	Mr. Harsh Jain	Approved
2019-05524	Mr. Raushan Kumar	Approved
2019-05525	Ms. Khushali Vimalbhai Shah	Approved
2019-05545	Mr. Ayush Kumar	Approved
2019-05558	Mr. Jangala Sai Vihar	Approved
2019-05562	Ms. Kushalini Kogalur Ananth Raj Urs	Approved
2019-05583	Mr. Thati Sai Vighnesh	Approved
2019-05588	*Mr. Akshansh Garg	Withheld
2019-05590	Ms. Clovey Ashok Gupta Singhal	Approved
2019-05612	Mr. Aditya Raj	Approved
2019-05613	Ms. Menali Uthpala Dissanayake	Approved
2019-05620	Ms. Niharika Barak	Approved
2019-05621	*Ms. Tiwai Yukta Ajay	Withheld
2019-05632	Ms. Helly Parag Shah	Approved
2019-05654	Mr. Rakesh O S	Approved
2019-05658	Ms. Rohini Kunta	Approved
2019-05664	Ms. Renita Jacob	Approved
2019-05667	Mr. Lokesh Kumar Dudani	Approved
2019-05685	Mr. Ieshitva Jain	Approved
2019-05695	Ms. Maithili Ghosh	Approved
2019-05702	Ms. Priya Singh	Approved

(*AAF-Submit your attestation form as per timeline otherwise application will be rejected)

2019-04713	Mr. Saumya Amin Shah	Approved
2019-04714	Mr. Rajasudhakar	Approved
2019-04716	Ms. Nayantara Nair	Approved
2019-04723	Mr. Sahil Dhull	Approved
2019-04746	Ms. Sri Vishnupriya Ravipati	Approved
2019-04748	Mr. D. Srinivasan	Approved
2019-04766	Ms. Megana D	Approved
2019-04768	Mr. Sathish Chandra	Approved
2019-04769	Ms. Shreya Sharma	Approved
2019-04777	Mr. Shardul Vijay Kamale	Approved
2019-04778	Ms. Shambhavi Shukla	Approved
2019-04787	Ms. Hanny Japhina C.	Approved
2019-04798	Ms. Subhasri Subhadarsini	Approved
2019-04809	Ms. Priya Mehar	Approved
2019-04811	Ms. Moumita Das	Approved
2019-04813	Mr. Mayank Garg	Approved
2019-04823	Ms. Saumya Arun Verma	Approved
2019-04834	Ms. Smriti Singh	Approved
2019-04846	Mr. Shreyak Garg	Approved
2019-04860	Ms. Rutuja Laxmikant Challawar	Approved
2019-04866	Ms. Raina Garg	Approved
2019-04896	Ms. Vrinda Mariam Lukose	Approved
2019-04901	Ms. Sonali Pathak	Approved
2019-04918	Ms. Aastha Sharma	Approved
2019-04936	Mr. Ayushman Ujjawal	Approved
2019-04945	Mr. Gururaj Balachandra Pattar	Approved
2019-04948	Ms. Divyani Jena	Approved
2019-04954	Ms. Sharwari Mahesh Panse	Approved
2019-04959	Mr. Kiran R	Approved
2019-04963	Ms. Gayathri Sankar	Approved
2019-04984	Mr. Sinan P H	Approved
2019-04990	Ms. Shreshtha Paul Chowdhury	Approved
2019-04991	Mr. Mojit Deswal	Approved
2019-05002	Ms. Chitwan Kaur Ghuman	Approved
2019-05024	Ms. Rithee Ramesh	Approved
2019-05036	Ms. Niharika Tibrewal	Approved
2019-05047	Mr. Shubham Mandiya	Approved
2019-05054	Mr. Priyank Modi	Approved

(*AAF-Submit your attestation form as per timeline otherwise application will be rejected)

List of Students Selected for STS – 2019

Ref_Id	Name	Result
2019-00013	Ms. Eshana Kaur	Approved
2019-00025	Ms. Vaishnavi R	Approved
2019-00027	Mr. Pulkit Kalra	Approved
2019-00030	Mr. Anand Kumar Kizhakkayil Padikkal	Approved
2019-00034	Ms. Megha Thampy	Approved
2019-00039	Mr. Bhuvaneshan Ramaswamy	Approved
2019-00040	Mr. Pallav Das	Approved
2019-00047	Mr. Mudit Agarwal	Approved
2019-00049	Ms. M Hari Priya	Approved
2019-00075	Ms. Ria Sharma	Approved
2019-00079	Mr. Sakthi Surya P	Approved
2019-00081	Ms. Gahana S	Approved
2019-00085	Ms. Miruthulah Ramkumar	Approved
2019-00086	Mr. Andrew Thomas	Approved
2019-00087	Mr. Rahul Paul Justin	Approved
2019-00090	Mr. Manraj Singh Sra	Approved
2019-00093	Mr. Dinesh Raja A	Approved
2019-00097	Mr. Aneesh Chacko	Approved
2019-00099	Ms. Poorani S	Approved
2019-00102	Mr. Naman Somani	Approved
2019-00104	Ms. Shwetha R S	Approved
2019-00106	Ms. S. Ajitha	Approved
2019-00108	Mr. Siddesh Tribhuvan Gupta	Approved
2019-00115	Mr. Sumanth M	Approved
2019-00119	Mr. Paritosh Gupta	Approved
2019-00124	Mr. Sai Surya Dinesh Pydi	Approved
2019-00131	Ms. Aishwariya Balaji	Approved
2019-00135	Ms. Achsa Alex	Approved
2019-00146	Mr. Vishwas Mahajan	Approved
2019-00156	Ms. Twinkle Kerwani	Approved
2019-00168	Ms. Namrata Gajjala	Approved
2019-00170	Ms. Krutika P Naik	Approved
2019-00178	Ms. Kanupriya Vats	Approved

(*AAF-Submit your attestation form as per timeline otherwise application will be rejected)3

2020 -

879	2020-06321	Mr. Jarajapu Vidya Sagar	Approved
880	2020-06341	Ms. M S Samyuktha	Approved
881	2020-06344	Ms. Minal Marlecha	Approved
882	2020-06345	Mr. Pradeep Kumar	Approved
883	2020-06361	Mr. Sourav Musib	Approved
884	2020-06364	Mr. Vaishak Basavaraj Wodeyar	Approved
885	2020-06378	Ms. S.Rajalakshmy	Approved
886	2020-06382	Mr. Mohamed Khalidh	Approved
887	2020-06394	Ms. Afrah Saleef Abdul Salam	Approved
888	2020-06395	Ms. Sukriti Honnavalli	Approved
889	2020-06397	Ms. Madem Devi	Approved
890	2020-06404	Ms. Asha Bonam	Approved
891	2020-06412	Mr. Ankireddy Ritish Reddy	Approved
892	2020-06414	Mr. Maulik Sanjay Kumar Mehta	Approved
893	2020-06417	Mr. Karan Vijay Sharma	Approved
894	2020-06426	Ms. Shreya Singh	Approved
895	2020-06427	Ms. Dharini V	Approved
896	2020-06437	Ms. Purva Dinkar Lanjekar	Approved
897	2020-06444	Ms. Keerti Shravani K	Approved
898	2020-06450	Ms. Karuna Sethi	Approved
899	2020-06452	Ms. Komsani Tejaswini	Approved
900	2020-06467	Mr. Prashanth . V	Approved
901	2020-06473	Ms. Arushi Chaturvedi	Approved
902	2020-06489	Mr. Prasanna Kumar S	Approved
903	2020-06494	Mr. Prashanth Chandrasekaran	Approved
904	2020-06504	Ms. Sudhanya Sinha	Approved
905	2020-06512	Ms. Amruta Varshini V R	Approved
906	2020-06515	Ms. Khushi B S	Approved
907	2020-06523	Mr. Sangram Sikdar	Approved
908	2020-06529	Ms. Bhanu Thejaswi Pallempati	Approved
909	2020-06544	Mr. Abhinav Goyal	Approved
910	2020-06551	Ms. V.Divyashree	Approved
911	2020-06565	Ms. Harshitha H	Approved
912	2020-06569	Mr. Soumyadeep Sinha	Approved
913	2020-06576	Ms. Suha Tarannum	Approved
914	2020-06587	Ms. Sure Charishma	Approved
915	2020-06589	Mr. Nishanth R Subash	Approved
916	2020-06595	Mr. Saqib Qamar Riyaz Ahmed	Approved
917	2020-06597	Mr. Arpan Roy	Approved
918	2020-06603	Mr. Rahul Prakash Tahilramani	Approved
919	2020-06610	Ms. Venkata Anantha Shreya Bharat	Approved
920	2020-06631	Ms. Nandhitha V	Approved
921	2020-06633	Mr. Aman Jawwad	Approved
922	2020-06640	Mr. Deepak Mahapatra	Approved

615	2020-04525	Ms. Likhitha S	Approved
616	2020-04526	Ms. Reshma Rajeev	Approved
617	2020-04527	Ms. Shallin Reema S.	Approved
618	2020-04528	Ms. Ananya Kabi	Approved
619	2020-04577	Ms. Anshu Tarun Agrawal	Approved
620	2020-04578	Mr. Anil R Rathod	Approved
621	2020-04582	Ms. Alenta Merin Babu	Approved
622	2020-04585	Mr. Thomas J Mannath	Approved
623	2020-04586	Ms. Sheryl Ann Antony	Approved
624	2020-04587	Mr. Parth Kalpesh Patel	Approved
625	2020-04593	Ms. Jaiversni Rajendran	Approved
626	2020-04598	Ms. Abhilasha Singh	Approved
627	2020-04599	Ms. Shreeya Vaibhav Pradhan	Approved
628	2020-04600	Ms. Sana Shabbir Khan	Approved
629	2020-04601	Ms. V Pooja	Approved
630	2020-04605	Mr. Rahul Rai	Approved
631	2020-04612	Ms. Medhavini Shivanand Angadi	Approved
632	2020-04617	Ms. Sri Vasavi Yarram	Approved
633	2020-04638	Mr. Abhishek Kumar	Approved
634	2020-04642	Ms. Bushra Sulmaz	Approved
635	2020-04644	Ms. Chavali Sai Chandralekha	Approved
636	2020-04659	Mr. Krishna Vishwanatha Kini	Approved
637	2020-04665	Ms. Pragya Gupta	Approved
638	2020-04666	Mr. Abhijeet Raju Chaudhary	Approved
639	2020-04668	Mr. Sunag Padukudru	Approved
640	2020-04670	Ms. Krishna Priya T	Approved
641	2020-04672	Mr. Shyam Chaitanya	Approved
642	2020-04675	Ms. Saurvee Bedarker	Approved
643	2020-04681	Ms. Shriya Ravichandran	Approved
644	2020-04682	Ms. Smriti Venkatesh	Approved
645	2020-04688	Ms. Lakshika Sharma	Approved
646	2020-04705	Ms. Tanisha Thomas	Approved
647	2020-04715	Ms. Roshini	Approved
648	2020-04732	Ms. Sree Laya Kalluru	Approved
649	2020-04741	Ms. Mantha Mani Kruthika	Approved
650	2020-04749	Ms. Deepshidha Velpandian	Approved
651	2020-04754	Ms. Christina Treville Pereira	Approved
652	2020-04755	Mr. Shayon Mukherji	Approved
653	2020-04761	Ms. Deepanshi	Approved
654	2020-04763	Ms. Tuba Fathima	Approved
655	2020-04767	Mr. Girik Rajesh Rohira	Approved
656	2020-04769	Mr. Raghav Prasad	Approved
657	2020-04770	Mr. Shreyas Mukeshkumar Virvani	Approved
658	2020-04774	Ms. Bhagyashree Atul Tayade	Approved