भारतीय गैर न्यायिक

भारत INDIA

रु. 500 FIVE HUNDRED RUPEES

पाँच सौ रुपये Rs. 500

सत्यमेव जयते

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA ◑ 2020 ◑ AY 043234

21 AUG 2020 500/-

नं. 11629 दि. ..... मु.शु.रक्कम .....

दस्ताचा प्रकार ..... Agreement .....

दस्त नोंदणी करणार आहेत का ? होय/नाही.

मिळकतीचे वर्णन .....

मुद्रांक विकत घेणाऱ्याचे नांव ..... For Serum Institute of India Pvt. Ltd.

पत्ता .....

दुसऱ्या पक्षकाराचे नांव .....

हस्ते व्यक्तीचे नांव व पत्ता .....

किरण देवराम लडकत

परवाना क्र. २२०११२५

मुद्रांक विकत घेणाऱ्याची सही जि.प. अंडर ग्राऊंड, मंगळवार पेठ, पुणे-११

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

14 AUG 2020

This stamp paper forms an integral part vide sectio
24-H of the Clinical Trial Agreement by and amongs
Serum Institute of India Private Limited, Diagno
Search Life sciences Pvt. Ltd., Dr. Tayade Deepa
Narayan and MGM Medical College and Hospit
dated 2nd May, 2020.

X SIIPL

X CRO

X PI

X Institution

CLINICAL TRIAL AGREEMENT

THIS CLINICAL TRIAL AGREEMENT ("Agreement") is made and entered into as of 2nd day of May 2020 (hereinafter "Effective Date") by and between:

Serum Institute of India Pvt. Ltd. a company incorporated under Companies Act, 1956 having its registered office at 212/2, Off Soli Poonawalla Road, Hadapsar, Pune 411028, India. (hereinafter **"Sponsor"**);

DiagnoSearch Life Sciences Pvt. Ltd. a company incorporated under Companies Act, 1956 having its registered office at 702, Dosti Pinnacle, Plot No. E-7, Road No. 22, Wagle Industrial Estate, Thane- 400604, Maharashtra, India (hereinafter **"CRO"**), acting on behalf of **Serum Institute of India Pvt. Ltd. / the Sponsor;**

Dr. Tayade Deepak Narayan, MGM Medical College and Hospital,N-6, CIDCO, Aurangabad 431 003,Maharashtra, India :hereinafter referred to as **Investigator;**

MGM Medical College and Hospital, a deemed university having its office at N-6, CIDCO, Aurangabad 431 003, Maharashtra, India an unit of Mahatma Gandhi Mission (a Charitable Trust registered Societies Registration Act and Bombay Public Trust Act) hereinafter referred to as **Institution.**

WHEREAS CRO is engaged in the business of managing and providing clinical research services and related activities and has been appointed by Sponsor to arrange and administer a clinical Study entitled:

A Multicenter, Phase III, Double-Blind, Randomized, Placebo Controlled Study to Evaluate the Efficacy of Recombinant BCG VPM1002 in Reducing Infection Incidence and Disease Severity of SARS-COV-2/COVID-19 Among High-Risk Subject under Protocol no. – SII-rBCG/COVID-19/IN-01, Version 3.0 Dated: 11 April 2020 ("the Protocol") and has entered into an agreement with Sponsor or one of its affiliates concerning the management, funding and administration of the Study;

AND WHEREAS Sponsor intends to appoint Investigator relating to the said **SII-rBCG/COVID-19/IN-01,** Clinical Study and requires CRO to supervise the services / activities to be undertaken by Investigator along with the services provided by CRO to Sponsor.

AND WHEREAS Institution and Investigator have each reviewed sufficient information regarding Sponsor's vaccine viz. SII-rBCG VPM1002 (the "Study Vaccine"), the Protocol for the Study and the Investigator Brochure to evaluate their interest in participating in the Study and each desires to participate in the Study as more particularly described in this Agreement.

NOW, THEREFORE, subject to the terms, conditions and covenants hereinafter set forth CRO, Investigator and Institution agree as follows.

The Sponsor, CRO, Investigator and Institution are sometimes hereinafter individually referred to as a Party and collectively as Parties.

Article 1 – The Study

1.1 The Institution and the Investigator undertake to conduct the Study in strict accordance with various guidelines and applicable regulatory requirements including but not limited to (a) the current World Medical Association Declaration of Helsinki titled, "Ethical Principles for Medical Research Involving Human Subjects;" (b) the current ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95); (c) the current Indian Ministry of Health and Family Welfare guideline for good clinical practice titled, "Good Clinical Practices for Clinical Research in India;" (d) the current Indian Council of Medical Research ethical guideline for clinical research titled, "Ethical Guidelines for Biomedical Research on Human Subjects;" (e) the written requirements of all reviewing Institutional Ethics Committees and institutional review boards (collectively, the Institutional Ethics Committees) (f) Sponsor's Standard Operating Procedure (SOP)s, if required; Institution's own SOP, the Protocol which is approved by Sponsor, Investigator and the IRB and a copy of which is attached hereto as Schedule A (g) such other guidelines as may be issued by Indian Council of Medical Research and Ministry of Health and Family Welfare and (h) data privacy laws as may be applicable and subsequent amendments if any, to the above guidelines and such other regulations that may be pronounced by a competent authority from time to time (hereinafter "Regulatory Requirements"). It is understood and agreed that, in the event of a conflict among any of the Standards, the most stringent Standard shall apply.

1.2 The Investigator hereby certifies and undertakes that s/he is not and has not been debarred under the Drugs and Cosmetics Acts 1940, Drugs and Cosmetics Rules, 1945, and any legislation in connection with any of the services or work provided hereunder as amended, or any other similar legislation, or excluded by a regulatory authority from participating in the development or approval of a drug or biological or disqualified by a regulatory authority as a clinical investigator, and that this certification may be relied upon in any applications to the Federal Food and Drug Administration for drug approval. Furthermore, the Institution and Investigator hereby certify and undertake that they will not use the services of a person so debarred, and that such certification can be similarly relied upon. It is understood and agreed that this certification imposes a continuing obligation upon the Institution and Investigator to notify the CRO/Sponsor of any change in the truth of this certification.

1.3 The Investigator acknowledges and agrees that its obligations set forth herein are of a personal nature and that the character, competence and reputation of the Investigator were instrumental in the Sponsor's / CRO's selection of the Investigator for the conduct of the Study. Consequently, it is agreed that the Investigator may not in any way transfer, cede or assign, directly or indirectly, the rights granted herein to any third party. If Investigator should become unwilling or unable to conduct the Study, the Institution shall consult with the CRO regarding the appointment of a new principal investigator. In such an event, CRO shall supervise the services / activities undertaken by new principal investigator relating to the Study along with the services provided by CRO to Sponsor. If both Parties cannot agree on a substitute, all further enrolment of subjects into the Study shall immediately cease and decision on the continuation of subjects already recruited in the Study will be taken jointly by CRO & Sponsor on a case to case basis. However, it is agreed between the Parties that,

the outgoing Investigator shall be liable and responsible for all his acts, deeds, actions, omissions, and liabilities arising there from, during the period he / she acts as a Principle Investigator.

1.4 The Institution and the Investigator undertake to conduct the Study in an efficient and professional manner under the provisions of this Agreement and will use their best efforts to complete the Study within the time period agreed between the Parties.

1.5 Parties agree to coordinate the day-to-day management of the Study with each other and to comply with and perform their respective responsibilities and activities as set forth in this agreement.

1.6 CRO will act as a contact point for the Investigator, Institution and Sponsor, regarding any issue which may arise in the implementation of the Study.

1.7 Before commencing the Study, within seven (7) business days the Investigator will seek approval to conduct the Study from the IRB and shall obtain consent as per applicable local regulations of all Study Subjects (or, if permitted their legal representative) who participate in the Study, including consent to allow Sponsor and its Affiliates (hereinafter defined) to access personal and medical information as necessary to monitor the Study or to receive and use Study data. Investigator must deliver to the Sponsor/CRO the written approval for the conduct of the Study, the approved informed consent form and the terms of the Protocol from the IRB. Sponsor may terminate this Agreement under Article 9 (**Term and Termination; Effect of Termination**) upon the failure of the Investigator to seek the aforementioned approval from IRB. In this Agreement "Affiliate" means any entity that controls, is controlled by, or is under common control with the party being referred to. In this context, "control" shall mean (1) ownership by one entity, directly or indirectly, of at least fifty percent (50%) of the voting stock of another entity; or (2) power of one entity to direct the management or policies of another entity, by contract or otherwise;

1.8 The Sponsor/CRO is under no obligation to release Study Vaccine or any other related supplies as defined in Protocol to the Investigator unless and until satisfactory proof of IRB approval is submitted to the CRO.

1.9 The Investigator and Institution hereby warrants that they:

(a) shall use Study Vaccine only to conduct the Study in accordance with the Protocol; shall not chemically, physically or otherwise modify Study Vaccine, unless specifically required to do so by the Protocol; and shall handle, store, ship and dispose of Study Vaccine with appropriate care and in compliance with manufacturer's instructions in writing or over an email and all applicable local, state and federal laws, rules and regulations, including, but not limited to, those governing hazardous substances.

(b) shall not charge any Study subject or third-party payer for Study procedures required by the Protocol that are paid for by CRO/Sponsor under this Agreement or for any Study Vaccine that is provided or paid for by CRO/Sponsor.

(c) received a copy of the Investigator Brochure and has read and understood its contents.

(d) shall prepare, document and maintain records and case histories on the case report form supplied by the CRO, retain such data and records after completion of the Study, and obtain advance informed consent from each of the subjects, or their duly authorized representatives, as defined in the Protocol participating in the Study (hereinafter "Subjects").

(e) shall administer the preparation of laboratory tests for shipment (e.g., centrifuge, freezing, packing, labeling) and arrange for courier services with respect to the shipment of biological samples (e.g., completion of shipment forms, ensure the relevant shipment procedure and safe delivery of the shipment);

(f) shall report adverse events and serious adverse events as required by the regulation in force and amended from time to time. The definition of 'Adverse Events' and 'Serious Adverse Events' and the reporting procedure are included in the Protocol, which shall be followed for such reporting.

(g) agree to inform Sponsor / CRO promptly if they become aware of material non-compliance with the Protocol, ICH Good Clinical Practices, or any applicable laws, rules or regulations; incomplete or inaccurate recording of data; or any significant misconduct or other matters of concern relating to the performance of the Study at Institution.

1.10 Any change, amendment or modification to this Agreement or any Schedule hereto must be authorized in witting by all Parties. Provided however those changes to the Protocol may be made (i) in accordance with procedures outlined in the Protocol, or (ii) with the agreement of the Investigator, Institution and Sponsor. Any changes to the Protocol shall be accompanied by such notification, review and/or approval of the IRB as may be required by applicable law and/or the Protocol. The Institution and the Investigator shall not consent to any change in the Protocol requested by the relevant IRB without the prior written consent of CRO or SPONSOR.

1.11 The Investigator may appoint such other individuals as she/he, in accordance with applicable law and/or the Protocol, may deem appropriate as sub-investigators to assist in the conduct of the Study (such other individuals are collectively referred to hereinafter as "Sub-investigators"). All such Sub-investigators must be approved by CRO / Sponsor and copies of their curriculum vitae and other regulatory documentation as required (such as financial disclosure forms) forwarded to CRO/ Sponsor. The Investigator shall be responsible for leading any such team of Sub-investigators, and shall ensure that such Sub-investigators are properly qualified and licensed.

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

1.13 Institution and Investigator agree that Sponsor / CRO may make public the names of the Investigator and the Institution as part of a list of Investigators and Institutions conducting the Study when making either protocol or results summary register postings. Institution and Investigator agree that Sponsor may make public the amount of funding provided to

Institution by Sponsor for the conduct of the Study and may identify Institution and Investigator as part of this disclosure. Investigator agrees that, if Investigator, consistent with the terms of this Agreement, speaks publicly or publishes any article or letter about a matter related to the Study or Study Vaccine or that otherwise relates to Sponsor, Investigator will disclose that he/she was an investigator for the Study.

1.14 The CRO/ Sponsor shall provide, without cost, sufficient amounts of the Study Vaccine to conduct the Study. The Institution and Investigator may not use or dispose of the Study Vaccine in any way other than as specified in the Protocol.

1.15 Institution agrees that any nationally-licensed medicinal products that are not the subject of the Study but are required for the routine care of a Study subject during and after the Study for the disease or condition to which the Study relates are expected to be available to the Study subject and funded through the usual operations of the local healthcare system independently from the Study and without expectation of support from CRO and/or Sponsor.

1.16 Institution/Investigator agree to record all side effects including laboratory abnormalities, whether serious or not, of which they may become aware in the appropriate Case Report Forms (CRFs) and in medical files of the subjects in accordance with the requirement set out in the Protocol.

1.17 Upon reasonable notice and at reasonable times, Institution and the Investigator shall permit representatives of the CRO and/or the Sponsor to examine their representative facilities, to validate case reports against original data in their files, to make copies of relevant records and monitor the work performed hereunder, and to determine the adequacy of the facilities and whether the Study is being conducted in compliance with this Agreement, and Regulatory Requirements. CRO/Sponsor representative should also be permitted to review the relevant financial documents related to the Study including but not limited to quotations, invoices, employee agreement, salary slips, attendance records, subject compensation logs, annual maintenance contract (applicable for instruments, equipments being used in the Study) agreements, physical verification of assets.

Article 2 – Compensation

2.1 All payments will be made by CRO/Sponsor as per payment schedule provided in schedule B hereto and assumptions provided thereunder.

2.2 The Parties hereby agree and covenant that Investigator / Institution will directly issue invoices to Sponsor which will be certified by CRO. The Parties agree that CRO shall act as a pure agent of Sponsor and facilitate payments to be made to the Investigator / Institution. Invoices shall be addressed to CRO and be sent at the following addresses:

DiagnoSearch Life Sciences Pvt. Ltd.
702, Dosti Pinnacle, Wagle Estate
Thane – 400 604, India

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

2.4 It is understood that Sponsor enjoys exemption from GST by claiming status of Special Economic Zone (SEZ) unit and accordingly invoices will be raised without levying GST. Further, as per Rule 96A of Central Goods and Service Tax Act, 2017 Parties agree that:

(i) If invoices issued by CRO, Investigator and Institution are without levying GST, then such invoices shall specifically mention - "**Supply to SEZ Unit or SEZ Developer for Authorised Operations under Bond or Legal Undertaking without payment of Integrated Tax (LUT)"** Every such invoice must also mention the GSTIN No. 27AABCS4225M2Z6 of our SEZ unit and ARN no for LUT.

(ii) However, if CRO, Investigator and Institution opt to levy GST, then such invoices shall specifically mention - "**Supply to SEZ Unit or SEZ Developer for Authorised Operations on payment of Integrated Tax. The Integrated Tax paid will have to be claimed as refund and Sponsor will not reimburse GST paid."** Further these invoices should also mention GSTIN No 27AABCS4225M2Z6 of our SEZ unit.

(iii) However, the Sponsor shall reimburse the amount including but not limited to tax liability, interest and penalty thereon imposed on CRO/Investigator/Institution by any competent authorities arising out of breach, action, inaction or failure to comply with provisions of Central Goods and Service Tax Act by Sponsor.

2.5 The payment shall be made in either by electronic transfer to the beneficiary account details given below or cheques should drawn by the CRO and be made payable to **MGM Medical college, Aurangabad** and delivered to the following address

Clinical research unit, Department of pharmacology 4th floor MGM medical college and Hospital N-6 Cidco Aurangabad-431003, MH, India

Beneficiary Name	MGM Medical college ,Aurangabad
Bank Name:	IDBI bank
Bank Address	Adalat Road Branch,Survey No.20292,Ratnaprabha Building Kesarsinghpura Opp.LIC Bld.Aurangabad
Branch	Adalat Road Branch
Beneficiary Account No.	0376104000000107
TAX ID NUMBER (PAN)	AAATM4256E
IFSC Code	IBKL0000376

Article 3 – Institution Staff and Facilities

3.1 The Institution acknowledges that all payments for all necessary laboratory and other facilities, equipment, supplies (other than the Study Vaccine), and physicians and clinical support staff required to discharge its obligations under this Agreement are provided for in the compensation schedule as provided in Schedule B. Institution shall ensure that all such facilities and staff are arranged to support the Study.

3.2 All matters, terms and payment of compensation, benefits and other conditions of engagement of any nature for the Investigator, any Sub-investigators and any support staff used in the Study shall be solely a matter between the Institution and such individuals, regardless of whether such individuals are considered employees, agents or independent contractors of the Institution and no amounts payable by CRO under this Agreement shall be considered to be a salary payment by CRO or Sponsor to Investigator, sub-investigator or support staff. All Institution/Investigator staff performing Services under this Agreement shall at all times be employed or engaged by Institution/Investigator and shall not be employees or subcontractors of CRO or Sponsor. Accordingly Institution/Investigator shall deal with all issues relating to the employment or engagement of the Institution/Investigator staff including without limitation: payment of salary and any employment-related benefits; deduction of all Pay As You Earn, National Insurance and any other employee-related taxes and contributions; disciplinary and performance issues; grievances; issues relating to a member of staff's ill health; and issues relating to a member of staff's terms and conditions of employment or engagement

3.3 The Investigator and the Institution will take appropriate steps to inform each physician, Study staff of the terms of this Agreement, obtain their agreement to abide by the terms and conditions of this Agreement and ensure that those persons comply with the terms and conditions of this Agreement. "**Study Staff**" mean the individuals providing services under the supervision of the Investigator with respect to the conduct of the clinical study, including without limitation sub-investigators, study coordinators, and other trial Site employees, agents, any support staff etc.

Article 4 – Reports

4.1 The Investigator will maintain accurate and complete records in accordance with Regulatory Requirements and the Investigator will comply with all reporting requirements contained in the Protocol/SOPs/any other Sponsor's specification. The Investigator will provide the CRO/Sponsor with copies of all reports provided to the Investigator's IRB/IEC.

4.2 The Investigator shall keep the CRO advised of the status of the Study via periodic reports, which are to be transmitted via electronic means or other mutually agreeable method. The frequency of reports shall be mutually agreed to by both Parties. If required by the Sponsor, there shall also be a final report of the Study presented to the CRO/Sponsor.

4.3 All case report forms and other reports submitted to the CRO and all data including Study Data generated under this Agreement shall be the property and Confidential Information of the Sponsor and may be used by the Sponsor for any purpose without further obligation or liability to the Institution and/or the Investigator.

4.4 The Institution and the Investigator shall provide such expense statements/reports to Sponsor as CRO/Sponsor may request, on such forms as Sponsor may supply or as Sponsor may approve. During the time the Study is being conducted and for one year thereafter, Investigator and each sub-investigator shall update such forms promptly and provide the same to the Sponsor/CRO as may be requested by Sponsor and whenever any material changes occur in the information disclosed by the previous forms.

4.5 A Subject's individual medical records shall remain the property of the Investigator / Institution. The Investigator will, where duly authorized or where allowed by law, provide or make such medical records and individual Subject data available to the CRO / Sponsor and governmental agencies.

4.6 Institution shall make and retain records regarding the Study as required by the Protocol, applicable law or regulation, or ICH/GCP Guidelines, and in accordance with Institution's standard archiving procedures. Institution will retain such records for a minimum of fifteen (15) years from conclusion of the Study. Thereafter, Institution will contact Sponsor prior to any destroying such records and will retain the records if requested by Sponsor.

4.7 The Investigator agrees not to provide the Study data to any third party or to use the Study data in any way without the Sponsor's prior written consent. The Investigator also agrees to not identify, Subjects in order to benefit research conducted or sponsored by any third party, without the Sponsor's prior written consent.

4.8 All Study Data and reports and any other information that generated, provided to and created by Investigator or Institution, in the performance of their duties hereunder remain the property and confidential information of Sponsor at all times. The Parties hereby agree that, subject to the applicable laws and requirements and each Party's rights and obligations under this Agreement, Sponsor shall be the sole owner of all the information mentioned above and shall have the unrestricted right during and after the term of this Agreement, to use the same for any purpose; "Study Data" shall mean all records and reports, (other than Study Subject's medical records), generated, collected or created pursuant to or prepared in connection with the Study including, without limitation, reports (e.g. CRFs, data summaries, interim reports and the final report) etc.

Article 5 – Inventions

5.1 The Institution and Investigator hereby acknowledge and agree that Sponsor shall own all right, title and interest in and to the Protocol, all intellectual property rights arising from the Study including but not limited to reports, discoveries, data, inventions, developments, structures, designs, protocols, biochemical strategies, biological materials, formulations, compositions, analytic methodology, chemical and quality control procedures, devices, know-how, technologies, techniques, systems methods, products, processes, algorithms, concepts, formulas, processes, ideas, writings, trade names, business names, logos, design marks or other proprietary marks, technical research, development and manufacturing data, trade secrets or utility models in any stage of development, whether or not patentable and whether or not reduced to practice, and all improvements, modifications, derivative works from, other rights in and claims related to, any of the foregoing and whether or not made, discovered, conceived, invented, originated, devised or improved by the Institution, Investigator , Sub investigator and Study Staff in the performance of the Study or relating to the Study Vaccine or which incorporate Sponsor's confidential Information (collectively, the "Inventions"), and the Institution and Investigator hereby expressly and irrevocably assign, and will cause Sub-investigators and Study Staff to assign, to the Sponsor, all right, title and interests that they may have in any such Inventions without payment of additional consideration.

5.2 The Investigator shall promptly disclose to the CRO/Sponsor in writing any and all Inventions generated pursuant to this Agreement and undertake not to use such Inventions than for the purposes of this Agreement without the prior written consent of the Sponsor.

5.3 If CRO/Sponsor requests, Institution and Investigator shall execute, and will cause the Sub investigators and Study Staff to execute, any instruments or testify as Sponsor deems necessary for Sponsor and/or Sponsor's Affiliates to draft, file, and prosecute patent applications, defend patents, or to otherwise protect Sponsor 's interest in the Inventions . CRO/Sponsor will reasonably compensate Institution and/or Investigator (as applicable) for the time devoted to such activities and will reimburse Institution and or Investigator (as applicable) for reasonable and necessary expenses incurred. The Institution and the Investigator hereby grant to Sponsor an exclusive, worldwide, irrevocable, non-restrictive and full royalty free license under such Inventions to exploit the same for any purpose whatsoever.

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

Article 6 – Publication; Publicity

Except as otherwise expressly agreed between the Parties, Institution and Investigator agree that they will not issue nor allow their employees, sub-investigators or representatives to issue or disseminate any press release or statement, nor any communication of information regarding the Study, written or oral, to the communications media or any third party without the prior written consent of Sponsor. Additionally, all announcements or publicity concerning the Study, or this Agreement by Institution or Investigator may be approved by the Sponsor, at its sole discretion.

The Institution and the Investigator agree not to publish any Study related material, including the Results, other than in accordance with this Section 6.

Article 7 - Confidential Information

7.1 In connection with the performance of Study services, CRO and/or Sponsor may provide, or have provided, certain Confidential Information (hereinafter defined) to Institution and Investigator solely for the purpose of enabling the Institution and Investigator to conduct the Study. Institution and Investigator agree not to use, or permit the use of Confidential Information except for the performance of this Agreement and not to disclose Confidential Information to third parties except as necessary to conduct the Study and under an agreement by the third party to be bound by the obligations of this Section. Institution shall safeguard Sponsor / CRO Confidential Information with the same standard of care that is used with Institution's confidential information, but in no event less than reasonable care.

7.2 In this Agreement "Confidential Information" means all information (including, without limitation, study protocols, case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans, processes, procedures) of Sponsor / CRO or their Affiliates that are: (1) provided to Institution and Investigator in connection with this Agreement or the Study; (2) Study data, results, or reports created by Institution, Investigators, Sub-investigators or Study Staff in connection with the Study (except for a Study subject's medical records); and (3) cumulative Study data, results, and reports from all sites conducting the Study.

7.3 The obligations of confidentiality and limited use under this Section shall not extend to:

(i) any information that is or becomes publicly available, except through breach of this Agreement;

(ii) any information that Institution/ Investigator can demonstrate that it possessed prior to, or developed independently from, disclosure or development under this Agreement;

(iii) any information that Institution/ Investigator receives from a third party (other than Sponsor or its Affiliates) which is not legally prohibited from disclosing such information;

(iv) a Study subject's specific medical information, as necessary for the appropriate medical care of the subject.

7.4 Notwithstanding any termination of this Agreement the provisions of confidentiality will apply for a period of ten (10) years from the date hereof.

7.5 If Institution or Investigator is required by law to disclose certain confidential information to statutory authorities then it shall do so based on legal advice from its legal advisors and only to the extent required. It shall also intimate the CRO and Sponsor immediately on receipt of such disclosure request / notice / order so that CRO / Sponsor can take necessary steps if they wish to in order to limit the dissemination of the Confidential information.

Article 8 – Independent Contractor

The relationship of Sponsor, CRO, Institution and Investigator under the Agreement is that of independent contractors. The Parties do not intend to create a partnership or joint venture employer-employee relationship between themselves. Institution and/or Investigator are not an agent of CRO / Sponsor and have no right or authority to bind CRO and/or Sponsor in any manner to any agreement or obligation whatsoever.

Each Party shall act solely as an independent contractor and shall have no right to act for or to sign the name of or bind the other Party in any way or to make quotations or to write letters under the name of the other Party or to represent that such other Party is in any way responsible for any acts or omissions of such Party. This Agreement does not in any way create a master and servant relationship between Parties. Under no circumstances, the Employees of the Institution and Investigator shall be considered as employees of Sponsor /CRO nor shall such relationship be considered to exist.

Article 9 – Term and Termination; Effect of Termination

9.1 This Agreement shall commence on the Effective Date and shall, unless sooner terminated as herein expressly provided, continue until completion of the Study.

9.2 This Agreement may be terminated by the Sponsor or by the CRO acting solely on the instructions received from the Sponsor in this behalf, at any time, with or without cause, immediately upon notice to Investigator to this effect; a notice by CRO and/or Sponsor that the Study is terminated shall also constitute effective notice of termination of this Agreement.

9.3 Upon termination or expiry of this Agreement:

(a) Institution and Investigator will not enroll additional Study Subjects, and will cooperate with CRO and Sponsor in the orderly discontinuation of the Study;

(b) the Parties will meet and confer promptly to determine an appropriate phase-out for Subjects already enrolled in the Study;

(c) Institution and Investigator shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study;

(d) Investigator and Institution shall be entitled to receive payment by CRO of any amounts accrued as of the date of termination for Study- related work actually performed and expenses actually and reasonably incurred; in the event CRO has pre-paid Investigator and/or Institution for Study services not yet performed as of the date of termination, Investigator shall promptly refund to CRO all such pre-payments;

(e) Investigator and Institution shall deliver to CRO/Sponsor all case report forms and any other reports or documentation prepared during the course of the Study, whether completed or not, in their possession or under their control; and

(f) Investigator and Institution shall either return to CRO / Sponsor or destroy, in accordance with CRO / Sponsor's instructions and / or the terms of the Protocol, all unused or partially used Study Vaccine in their possession or under their control.

(g) All Confidential Information of Sponsor (except for such records that the Institution and Investigator are required by law or regulation to retain) which in the Institution's and/or Investigator's possession shall be promptly delivered to Sponsor, or at Sponsor's discretion destroyed with destruction certified in writing.

(h) Institution represents that medical care for the disease or condition to which the Study relates is available to Study subjects following the Study in accordance with local standard of care through the usual operations of the local healthcare system, and that upon completion of the Study, Institution will appropriate transition Study subjects from the Study to such medical care or refer Study subjects to a health care provider for such medical care.

(i) No termination hereunder shall constitute a waiver of any rights or causes of action that either Party may have based upon events occurring prior to the termination date. Articles 4, 5, 6, 7, 10, and 11 shall survive any termination or expiration of this Agreement, as well as any other terms which by their intent or meaning are intended to so survive.

Article 10 – Indemnification

10.1 Sponsor shall defend, indemnify, save and hold harmless the Institution, its directors, officers, employees, agents, assigns and the Investigator (each, an "Institution Indemnitee") from any and all liabilities, claims, actions or suits by third parties for bodily injury or death, that arise out of Institution's administration of the Study Vaccine or procedures provided for by the Protocol ("Institution Claim"), provided that Sponsor shall not indemnify any Institution Indemnitee for any Institution Claim to the extent the Institution Claim arose out of:

(a) failure by Institution Indemnitees to conduct the Study in accordance with (i) this Agreement and the Protocol, (ii) all written instructions delivered by CRO/Sponsor concerning conduct and administration of the Study, (iii) all applicable government laws, rules and regulations and (iv) the manner required of a reasonable and prudent clinical investigator or physician; and

(b) the negligence or willful malfeasance of any Institution Indemnitee, or any other person on the Institution's property or under its control, exclusive of CRO / Sponsor employees.

10.2 Sponsor's obligations under this Section with respect to an Institution Claim are conditioned on:

(a) Prompt written notification to Sponsor of the Institution Claim so that Sponsor's ability to defend or settle the Institution Claim is not prejudiced; and

(b) Institution Indemnitees' agree that CRO/Sponsor has full control over the defense or settlement of the Institution Claim and to fully cooperate with CRO/Sponsor in the defense or settlement of the Institution Claim; provided, that CRO/Sponsor will not settle any such Institution Claim under terms that include an admission of fault or wrongdoing by any Indemnitee or which requires an Indemnitee to undertake a future course of action without that Indemnitee's written consent to such components.

10.3 Additionally, Sponsor also agrees to compensate as required by the current compensation guidelines under the new Drugs and Clinical Trials Rules, 2019), and any amendment or new pronouncement notified by the Competent Authority

Notwithstanding clause 10.3, Sponsor shall not stand to pay any medical expenses of any human subject in the Study in the event of any adverse reaction arising out of or resulting from:

(i) A failure to adhere to the terms of this Agreement, Sponsor's written instructions relating to the Study (including the Study Protocol) and/or ICH-GCP guidelines and / or all applicable Standards. All the deviation from the Protocol need to be notified to Sponsor and CRO.

(ii) Institute shall be responsible for all the medical management expenses for the injury caused by negligent acts or omissions or intentional, reckless or willful malfeasance by Investigator, the Institution, or the Study Staff .

10.4 The Investigator, jointly and severally with Institution, will indemnify and hold the CRO, the Sponsor and their affiliated corporations, successors, directors, trustees, officers, employees

and agents harmless from any and all Liabilities suffered by same as a result of a claim asserted against same, arising, or are alleged to arise, from;

(a) negligence or intentional or gross fault on the part of the Institution, Investigator, or any other Study staff, personnel involved in the performance of the Study;

(b) activities contrary to the provisions of this Agreement, including a failure to use the Study Vaccine in compliance with the Protocol or to adhere to the terms of the Protocol;

(c) the Investigator's failure to obtain IRB review and approval;

(d) the Investigator's failure to obtain proper written informed consent from the Subjects; or

(e) a breach of any applicable laws by the Institution, Investigator, or any other Study personnel involved in the performance of the Study.

In the event a claim or action is or may be asserted, an Institution Indemnitee shall have the right to select and to obtain representation by separate legal counsel. If an Institution Indemnitee exercises such right, all costs and expenses incurred by such Institution Indemnitee for such separate counsel shall be fully borne by the Institution Indemnitee; provided, that without CRO/Sponsor prior written consent, the Institution Indemnitee shall make no admission to, or any settlement or agreement with, any person or party who is in any manner related to the Liabilities for which indemnification may be sought.

The obligations of this section shall survive termination of this Agreement.

Article 11 – Limitation of Liability

Except for as provided in 10.1 and 10.3, whether attributable to contract, tort, warranty, negligence, strict liability or otherwise, Sponsor/CRO's liability for any claims, damages, losses or liabilities arising out of or related to this Agreement or the Services performed hereunder shall not exceed the amounts paid by CRO to Investigator and/or Institution for Services under this Agreement.

IN NO EVENT SHALL EITHER PARTY BE LIABLE HEREUNDER FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, PUNITIVE OR SPECIAL DAMAGES (INCLUDING BUT NOT LIMITED TO LOST PROFITS AND LOSS OF USE OF FACILITIES) SUSTAINED BY THE OTHER PARTY OR ANY OTHER INDIVIDUAL, THIRD PARTY OR OTHER ENTITY FOR ANY MATTER ARISING OUT OF OR PERTAINING TO THE SUBJECT MATTER OF THIS AGREEMENT. THE PARTIES EXPRESSLY ACKNOWLEDGE THAT THE FOREGOING LIMITATIONS HAVE BEEN NEGOTIATED BY THE PARTIES AND REFLECT A FAIR ALLOCATION OF RISK.

Article 12- Insurance

12.1 Sponsor Insurance: Sponsor shall at all times during the term of this Agreement obtain and maintain at its own cost and expense, clinical trial insurance policy, with respect to its activities

hereunder as required by the laws of India or laws as per the country where the clinical trial shall be conducted. Such insurance shall be placed at commercially appropriate levels of insurance.

12.2 Institution Insurance: Institution shall maintain medical professional liability insurance with limits in accordance with the laws of India or laws of the country where the clinical trial shall be conducted, for each medical professional involved in the Study or require that each medical professional maintain such insurance.

12.3 Evidence of Insurance: Upon request, Sponsor and Institution respectively, will provide to each other a certificate of insurance evidencing such coverage.

Article 13 - Human Rights

Institution represents that, with respect to employment and conducting the Study under this Agreement, Institution will comply with all applicable human rights/employment laws /labour laws, including but not limited to compliance with rules and regulations governing child labor, forced labor, safe and healthy work place, minimum wages, employee non-discrimination etc.

Article 14 - Anti-Bribery and Anti-Corruption

The Institution and Investigator represent and warrant that they shall not, directly or indirectly, take any action which would cause them, or their employees and sub-investigators to be in violation of any anticorruption or anti-bribery law or regulations applicable to the Investigator ("Anticorruption Laws").

Article 15 – Equipment

With respect to any equipment ("Loaned Equipment") provided to Institution by CRO or Sponsor exclusively to perform the Services pursuant to this Agreement Institution agrees that no title to nor any proprietary rights related to the Loaned Equipment is transferred to Institution, that the Loaned Equipment will be used only for the Study and only as described in the Protocol and any other written directions provided by CRO/Sponsor, that the Loaned Equipment will not be transferred by Institution to the possession of any third party without the written consent of CRO/Sponsor, and that, at the completion of the Study or at CRO's/Sponsor's request, Institution will return the Loaned Equipment and all related training materials and documentation to CRO /Sponsor.

(a) Investigator and Study Staff will attend scheduled training to use the Loaned Equipment following reasonable advance notice of scheduling. The Loaned Equipment will be kept in a safe and secure location and Institution will be responsible for any theft, damage, or loss to the Loaned Equipment other than normal wear and tear. Institution will be responsible for arranging and paying for any required electricity supply, backup power supply, internet connection, telephone line, and/or facsimile line as necessary to use the Loaned Equipment. Institution shall also be responsible for maintenance cost and annual calibration cost which is required to keep the loaned equipment in a working condition. If the Institution fails to return the Loaned Equipment within the timeframe specified by CRO/Sponsor, the Institution will be responsible for reimbursing CRO/Sponsor for any penalties, late fees, and/or replacement costs.

(b) Institution acknowledges that the Loaned Equipment may involve valuable patent, trademark, trade name, trade secret, and other proprietary rights of the Loaned Equipment manufacturer. Institution will not violate and will take appropriate steps and precautions to ensure that those with access to the Loaned Equipment do not violate these proprietary rights, including, without limitation:

(i) not removing any label or notice of Loaned Equipment ownership or other rights,
(ii) not making any copy, reproduction, changes, modification, or alteration of any software or firmware included with the Loaned Equipment or
(iii) not disassembling or decompiling any such software or firmware or otherwise attempting to discover any source code or trade secret related to such software or firmware.

Article 16 – Force Majeure and Delays

In the event either Party shall be delayed or hindered or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, failure of power, restrictive government or judicial orders, or decrees, riots, insurrection, war, Acts of God, inclement weather or other similar reason or cause beyond that Party's control, then performance of such act (except for the payment of money owed) shall be excused for the period of such delay; provided the Party provides notice of the existence of and reason for such nonperformance or delay in specific detail. In the event of a delay for a consecutive of 90 days, the non-affected Party will have right to terminate this Agreement by serving written notice to the other Party.

Article 17 – Applicable Law

This Agreement shall be construed, governed, interpreted, and applied in accordance with the laws of India and dispute under this Agreement and shall be subjected to the exclusive jurisdiction of courts of the City of Pune without regard to its conflict of laws provisions.

Article 18 - Recordkeeping and Regulatory Inspection:

18.1 Throughout the term of this Agreement, Institution/Investigator shall maintain and Investigator shall require Study Staff to maintain the complete and accurate books and records (including scientific, clinical and financial records) pertaining to all work performed and expenses incurred hereunder in connection with the Study and preserve them as per the directions of Sponsor/CRO for a minimum of fifteen (15) years from the date of completion of the Study or termination of this Agreement, whichever is earlier, or such longer period as required by the Protocol and the applicable laws and requirements. Archival of these records will be with Institution. Sponsor and its representatives shall have access to these records during the period of 15 years stated above. If required, Institution shall provide the copies of these records to Sponsor.

18.1.1 Sponsor or its designee shall have the right upon prior written notice to have their representatives review and copy all books and records of Investigator, the trial Site and the Study Staff relating to the Study, including without limitation books and records relating to any funds expended hereunder in connection with the Study. In each case access to such books and records

shall occur during regular business hours (or such other agreed time) following reasonable notice to Institution whose records are sought for review.

18.1.2 Sponsor or its designee upon reasonable advance notice, and during regular business hours (or such other agreed time), shall have the right to access the trial site to carry out Sponsor's rights and obligations hereunder and to inspect such trial site's facilities used in the conduct of the Study. The Parties agree to maintain the confidentiality of any subject-identifiable medical records should such information be made accessible under this Article 18.1.2.

18.2 The Investigator/Institution shall notify the Sponsor/CRO immediately by telephone or facsimile in case they receive any communication from Food and drug Administration or any other governmental or regulatory body with regard to Inspection/Audit of the Institution's facility relating to the Study during the term of this Agreement and shall allow CRO/Sponsor to be present at the inspection or participate in any response to the action, and provide to Sponsor/CRO copies of all materials correspondence, statements forms and records which the site receives, obtains or generate pursuant to any such Inspection. Investigator and Institution agrees to promptly take any reasonable actions requested by CRO/Sponsor to cure deficiencies noted during an inspection or audit.

Article 19 – Electronic Record and Electronic Signature

Investigator/ Institution acknowledges that Electronic Records (defined hereinafter), Electronic Signatures (defined hereinafter), and handwritten signatures executed to Electronic Records, utilized for capturing study related data and for performing services under this Agreement, will be trustworthy, reliable, and are equivalent to paper records and handwritten signatures executed on paper.

As defined in 21 CFR Part 11 "Electronic record" shall mean any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system. "Electronic signature" shall mean a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

Investigator/ Institution shall remain accountable and responsible for actions initiated under its Electronic Signature.

Article 20 – Representations and warranties

The Parties each represent and warrant that the execution, delivery and performance of this Agreement does not conflict with, violate or breach any agreement to which it is a party and no Party will enter into any, agreements, assignments or encumbrances binding on it or its respective Affiliates inconsistent with the provisions of this Agreement.

Article 21 - Assignment:

No Party may assign this Agreement or any interest hereunder without the prior written consent of other Party; provided, however, that Sponsor may assign this Agreement to any corporation with which it may merge or consolidate or to which it may sell all or substantially all of its assets, without obtaining the prior written consent of Institution. In the event of any assignment by any Party permitted under this Agreement, such assignment will be effective only if (i) the assignee has the requisite power, authority and capability to fulfill all obligations of the assignor Party under this Agreement and (ii) such assignee agrees in writing to other Party, in a form reasonably acceptable to the other Party, to fulfill all obligations and liabilities of the assignor Party under this Agreement. Each Party will promptly notify other Party of any such assignment. To the extent permitted above, this Agreement shall be binding upon and inure to the benefit of the Parties and their permitted successors and assigns.

Article 22 – Severability

If any provision(s) of this Agreement should be illegal or unenforceable in any respect, the legality and enforceability of the remaining provisions of this Agreement shall not be affected. In the event that the terms and conditions of this Agreement are materially altered as a result of this Article 20, the Parties will renegotiate the terms and conditions of this Agreement to resolve any inequities, adhering as closely as possible to the original intent of the Parties.

Article 23 – Waiver / Modification of Agreement

No waiver, amendment, or modification of any of the terms of this Agreement shall be valid unless in writing and signed by authorized representatives of all Parties. Failure by a Party to enforce any rights under this Agreement shall not be construed as a waiver of such rights, nor shall a waiver by a Party in one or more instances be construed as constituting a continuing waiver or as a waiver in other instances.

Article 24 – Miscellaneous

24.1 Institution will obtain written consent from staff involved in the Study that allows Sponsor, Sponsor affiliates, and third party suppliers working for Sponsor or its affiliates to hold and process personal data provided with respect to Study Staff anywhere in the world, both manually and electronically, for all purposes relating to the performance of this Agreement, for the purposes of administering and managing the business activities of any company in the SPONSOR group of companies, and for compliance with applicable procedures, laws, and regulations. Investigator consents to the use, storage and processing of his/her personal data as set out above.

24.2 This Agreement, including the annexed Schedules and Appendices , sets forth the entire understanding between the Parties herein, and there are no other understandings or promises, written or verbal, not set forth herein, relating to the subject matter hereof and supersedes all other prior agreements, discussions whether oral or in writing. This Agreement may not be changed or supplemented, except by a writing executed by all Parties.

24.3 All legal notices to be given by either Party to the other shall be made in writing by hand delivery or by registered or certified mail, return receipt requested or by other method reasonably capable of proof of receipt thereof and addressed to the Parties at their respective addresses first set forth above to the attention of:

If to the Institution, to:

MGM Medical college and hospital N-6 Cidco Aurangabad-431003,MH,India
Name: Dr. Rajendra Bohra
Designation: Dean
Address: MGM Medical College and hospital N-6 Cidco Aurangabad-431003, MH, India
Phone No.: 9225304660
Email: rajbohra@msn.com

If to the Investigator, to:

Dr. Tayade Deepak Narayan

MGM Medical College and Hospital N-6 Cidco Aurangabad431003, MH, India
Name: Dr. Tayade Deepak Narayan
Designation: Assistant Professor of Community Medicine
Address: MGM Medical College and Hospital N-6 Cidco Aurangabad431003, MH, India
Phone No.: 7776900089 / 8788416747
Email: drtayadepsm@gmail.com

If to the CRO, to:

Name: Mr. Mandar Vaidya, Director - Operations
DiagnoSearch Life Sciences Pvt. Ltd
702, Dosti Pinnacle, Plot No. E-7, Road No. 22,
Wagle Industrial Estate, Thane- 400604,
Maharashtra, India
Name: Mr. Mandar Vaidya
Phone No.: 022 6777 6314
Email: mandar.vaidya@diagnosearch.com

If to the Sponsor, to:

Dr. Hitt Sharma
Additional Medical Director
Serum Institute of India Private Limited 212/2 Hadapsar, Pune 411 028, India
Phone: 91-20-26602451
Facsimile: 91-20-26993921
Email: drhjs@seruminstitute.com

With a copy to:
Name: Makarand Karkare, General Counsel
Serum Institute of India Private Limited,
Sarosh Bhavan, 16/B-1, Dr. Ambedkar Road
Pune 411001
Phone: 91-20-26100341
Email: mac@seruminstitute.com

Or to such other address and any Party may designate in writing from time to time to the other. Any notice shall be effective as of its date of receipt.

24.4 The Parties hereby agree that, considering the current scenario of Novel COIVD 19 pandemic and non availability of stamp papers, the Agreement shall be executed on the plain paper and subsequently upon availability the stamp paper signed / initialed by all the Parties shall be appended to the Agreement which shall form an integral part of the Agreement.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed in multiple counterparts by their duly authorized representatives.

FOR Principal Investigator:

By: Tayade Date 11 May 2020
Name: Dr. Tayade Deepak Narayan
Title: Principal Investigator

FOR AND ON BEHALF OF:
MGM Medical College and Hospital
N-6 Cidco Aurangabad-431003, MH, India

By: Date 11 May 2020
Name: Dr. Rajendra Bohra
Title: Dean

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

By: Date May 08, 2020
Name: Gajendra Sharma
Title: Controller Finance & Accounts

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

By: Date 8th May, 2020
Name: Dr. Hitt Sharma
Title: Additional Medical Director

SCHEDULE A
PROTOCOL NUMBER: SII-rBCG/COVID-19/IN-01
CLINICAL TRIAL PROTOCOL SYNOPSIS

STUDY TITLE	A Multicenter, Phase III, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy of Recombinant BCG VPM1002 in Reducing Infection Incidence and Disease Severity of SARS-COV-2/COVID-19 Among High-Risk Subjects
SPONSOR	Serum Institute of India Pvt. Ltd.
CLINICAL RESEARCH ORGANIZATION (CRO)	DiagnoSearch Life Sciences Pvt. Ltd.
PROTOCOL ID	SII-rBCG/COVID-19/IN-01
CLINICAL DEVELOPMENT PHASE	Phase III
INDICATION	Protection of high-risk population from SARS-CoV-2/COVID-19 through immune boost/activation by rBCG (VPM1002) vaccination
NUMBER OF SITES	Approximately 40 sites will be initiated to enroll the required population
STUDY POPULATION	A total of 5946 male and female adults ≥18 years of age who are at a high risk of SARS-CoV-2/COVID-19 infection
DURATION OF PARTICIPATION	The maximum duration of study participation for a subject will be 194 days

STUDY RATIONALE

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection is accelerating globally leading to an increase in morbidity and mortality. Although individuals of any age can acquire SARS-CoV-2/COVID-19, certain individuals are at a higher risk of infection with SARS-CoV-2/ COVID-19. The high-risk group includes the health care workers (HCW) (physicians and paramedical staff) working amid SARS-CoV-2/COVID-19 infected patients and all other people including household contacts of SARS-CoV-2/ COVID-19 confirmed patients or people currently residing or working in SARS-CoV-2/ COVID-19 hotspots/outbreak areas where there is a high risk of transmission of COVID-19 infection. Though SARS-CoV-2/ COVID-19 infection may cause mild symptoms in many, nearly 14% develop severe disease that requires hospitalization and oxygen support, and 5% require admission to an intensive care unit (ICU). In severe cases, COVID-19 can be complicated by the acute respiratory distress syndrome, sepsis, septic shock and multiorgan failure with an estimated case fatality of 3.5% in China.

The COVID-19 pandemic is rapidly worsening in all parts of the world, overwhelming health systems. There is a serious threat to HCW capacity in a thickly populated country like India. Also, reports from all

over the world demonstrate that the disease takes a severe course in the elderly people and people with co-morbid conditions leading to higher mortality rates. Thus, there is an urgent need to ensure the safety and health of existing HCWs and all other people living in SARS-CoV-2/COVID-19 infected areas where there is a high risk of disease transmission and find strategies to reduce the incidence, duration and intensity of SARS-CoV-2/COVID-19 infection among such population. Evidence from experimental studies suggest that Bacille Calmette Guérin (BCG) vaccine has beneficial heterologous effects and proven antiviral and immune modulatory properties that protect against infectious diseases other than tuberculosis. BCG vaccine can potentiate immune responses to other vaccines through induction of trained innate immunity and heterologous adaptive immunity. Based on this evidence it is hypothesized that BCG vaccination may induce protection against susceptibility to SARS-CoV-2/COVID-19 infection. VPM1002, a genetically modified BCG vaccine, is being developed with an aim to replace BCG by a vaccine that has a better safety profile and superior efficacy. Evidence from pre-clinical and clinical studies demonstrate that VPM1002 is safer and more immunogenic. It is therefore anticipated that VPM1002 will perform well and may improve the clinical course of SARS CoV-2/COVID-19 infection. Even though vaccine manufacturers across the globe have embarked on rapid development, SARS-CoV-2 vaccines are many months away from widespread availability to the masses. VPM1002 rBCG may act to ameliorate disease severity and mitigate transmission. Even moderate individual efficacy can have dramatic impact at population level directly by reducing severe disease burden on health systems and possibly indirectly by reducing the disease transmission and spread thereby sustaining health systems through this crisis, using a safe, affordable and available vaccine. The manufacture of VPM1002 using state-of-the-art production methods will help hasten the production of millions of doses in a very short time and thus would be beneficial in the current situation. Investment in large scale manufacturing will depend on strong evidence of efficacy from randomized evaluation. Thus, the current study will evaluate the efficacy of VPM1002 in reducing infection incidence and disease severity of SARS-CoV-2/COVID-19 infection including hospital admissions and clinical consequences of SARS-CoV-2 infection in the high-risk subjects.	
INVESTIGATIONAL VACCINE	**VPM1002** The active ingredient of the recombinant BCG vaccine, VPM1002 is Mycobacterium bovis rBCG ΔureC::hly, freeze-dried and standardized to number of viable colony forming units (CFU) of mycobacteria per application available as lyophilized cake. After reconstitution with water for injection, 1 dose (0.1 ml) contains VPM1002, live, 2-8 x 10e5 CFU. A single dose of 0.1 ml of the reconstituted vaccine is to be administered as an intradermal injection in the arm, over the distal insertion of the deltoid muscle onto the humerus (approximately one

	third down the upper arm) OR lateral to posterior aspect of forearm.
COMPARATOR	**Placebo,** 0.1ml 0.9% sodium chloride, will be used as the comparator
PRIMARY OBJECTIVE	1. To reduce the incidence or severity of SARS CoV-2/COVID-19 infection up to 6 months (180 days) following vaccine administration among health care workers (HCW) 2. To reduce the incidence or severity of SARS CoV-2/COVID-19 infection up to 6 months (180 days) following vaccine administration among other high-risk subjects
PRIMARY ENDPOINT	1. Number of subjects with laboratory confirmed SARS-CoV-2/COVID-19 infection among HCWs 2. Number of subjects with laboratory confirmed SARS-CoV-2/COVID-19 infection among other high-risk subjects 3. Number of laboratory confirmed SARS-CoV-2/COVID-19 infection with severe, critical or life-threatening disease severity as assessed by the Investigator among HCWs 4. Number of laboratory confirmed SARS-CoV-2/COVID-19 infection with severe, critical or life-threatening disease severity as assessed by the Investigator among other high-risk subjects
SECONDARY OBJECTIVE	1. To reduce the duration of SARS-CoV-2/COVID-19 symptoms in HCWs 2. To reduce the duration of SARS-CoV-2/COVID-19 symptoms in other high-risk subjects 3. To reduce severe SARS-CoV-2/COVID-19 disease outcomes in HCWs 4. To reduce severe SARS-CoV-2/COVID-19 disease outcomes in other high-risk subjects 5. To reduce severe SARS-CoV-2/COVID-19 disease outcomes in elderly subjects (≥ 60 years of age) 6. To reduce severe SARS-CoV-2/COVID-19 disease outcomes in subjects with co-morbidities 7. To assess the safety of VPM1002 when administered as a single dose in subjects at a high-risk of disease exposure during the SARS-CoV-2 outbreak
SECONDARY ENDPOINT	1. Duration of SARS-CoV-2/COVID-19 symptoms in HCWs 2. Duration of SARS-CoV-2/COVID-19 symptoms in other high-

	risk subjects 3. Severe Disease Outcomes in HCWs: ● Cumulative incidence of hospital admission among HCWs due to documented SARS-CoV-2 infection ● Cumulative incidence of ICU admission among HCWs due to documented SARS-CoV-2 infection ● Cumulative incidence of requirement of mechanical ventilation among HCWs due to documented SARS-CoV-2 infection ● Cumulative incidence of deaths among HCWs due to documented SARS-CoV-2 infection 4. Severe Disease Outcomes in other high-risk subjects ● Cumulative incidence of hospital admission among other high-risk subjects due to documented SARS-CoV-2 infection ● Cumulative incidence of ICU admission among other high-risk subjects due to documented SARS-CoV-2 infection ● Cumulative incidence of requirement of mechanical ventilation among other high-risk subjects due to documented SARS-CoV-2 infection ● Cumulative incidence of deaths among other high-risk subjects due to documented SARS-CoV-2 infection 5. Severe Disease Outcomes among in elderly subjects (≥ 60 years) ● Cumulative incidence of hospital admission among elderly subjects due to documented SARS-CoV-2 infection ● Cumulative ICU admission among elderly subjects due to documented SARS-CoV-2 infection ● Cumulative incidence of requirement of mechanical ventilation among elderly subjects due to documented SARS-CoV-2 infection ● Cumulative incidence of deaths among elderly subjects due to documented SARS-CoV-2 infection 6. Severe Disease Outcomes among subjects with Co-morbidities (including hypertension, diabetes mellitus, COPD, asthma, any other cardiac conditions) ● Cumulative incidence of hospital admission among subjects with co-morbidities due to documented SARS-CoV-2 infection ● Cumulative incidence of ICU admission among subjects with

	co-morbidities due to documented SARS-CoV-2 infection ● Cumulative incidence of requirement of mechanical ventilation among subjects with co-morbidities due to documented SARS-CoV-2 infection ● Cumulative incidence of deaths among subjects with co-morbidities due to documented SARS-CoV-2 infection 7. Incidence of Adverse Events (AE) and Serious Adverse Events (SAE)
EXPLORATORY OBJECTIVE	Immunogenicity analysis will be performed in a subset of approximately 500 subjects who provide consent for the same. Blood samples will be collected at baseline prior to vaccine administration and at 3 months post vaccine administration

STUDY DESIGN

This is a placebo controlled, randomized, double blind, adaptive study to evaluate the reduction in infection incidence and severity of SARS-CoV-2/ COVID-19 infection among high-risk subjects by enhanced trained immune response through VPM1002 vaccine.

A total of 5946 subjects who fulfil the criteria for high-risk will be enrolled across various hospitals treating COVID-19 patients in India. The Investigator/site staff at each site will inform the Health care workers (HCWs) about the clinical trial while other high-risk subjects (household contacts or people living or working in SARS-CoV-2/ COVID-19 infected areas) will be recruited through contact tracing of confirmed SARS-CoV-2/ COVID-19 cases and through posters/advertisements.

All interested subjects will be requested to download a mobile application/portal designed for the study on their smart phone/tablet/laptops and to register themselves. The study has a screening period of up to 14 days during which subjects who provide informed consent will be assessed for eligibility criteria which includes RT-PCR testing to rule out SARS-CoV-2/ COVID-19 infection. Among the household contacts, the laboratory sampling to rule out SARS-CoV-2/ COVID-19 infection will be done 14 days after the last contact with the confirmed SARS-CoV-2/ COVID-19 patient while in other high risk subjects, the laboratory sampling will be performed on the day of screening. The subjects who fulfill all the eligibility criteria will be randomized in a 2:1 ratio to receive a single dose (0.1 ml) of either VPM1002 or placebo, administered as an intradermal injection. The preparation and administration of the study vaccine will be done by designated unblinded personnel who will not participate in any of the clinical study evaluations. Considering that India is currently in a lockdown situation, the vaccine administration may happen at the study clinic or at the place of isolation of the subject. All the study personnel working with the subjects will wear personal protective equipment with adequate gloves as recommended by Indian Council of Medical Research (ICMR) and Ministry of Health and Family Welfare (MoHFW). The study vaccine should be administered within 48 hours of randomization.

Post vaccination the subjects will be observed for 20 minutes for any hypersensitivity/anaphylactic

reactions.

While the monthly follow-up visits are telephonic for all subjects, in case of HCWs, these may be clinic visits depending on the circumstances (e.g., if they are reporting for their routine duty at the study site). Subjects can consult/visit the study site or request for home visit anytime during the study for emergencies or any safety concerns.

Follow-up information must be entered by the subjects regularly. In case the follow-up information is not completed within 7 days, subjects will receive reminders via the mobile application/portal and further telephonic reminders, if required. In case the subjects do not answer the telephone, information on subject's well-being and symptoms may be obtained from alternate contacts. Additionally, follow-up information regarding hospital admission, ICU admission or death will also be retrieved from the hospital.

The duration of follow-up will be based on the results of interim analysis however the maximum follow-up period will be up to 180 days.

Immunogenicity analysis is planned in a subset of approximately 500 subjects. Immunogenicity samples will be collected, from approximately 500 subjects who provide consent for the same, at two time-points, at baseline prior to vaccine administration and at the end of at 3 months (± 14 days) post vaccination. Based on the circumstances, if necessary, the immunogenicity sampling may be done at subject's place of isolation.

During the follow-up, if any subject experiences fever AND cough and/or shortness of breath, all attempts should be made to obtain a throat (nasopharyngeal and/or oropharyngeal) swab or any appropriate sample as directed by the treating physician. Subjects can consult/visit the study site anytime during the study for emergencies or any safety concerns. The sample will be collected by trained health care professionals who shall wear appropriate PPE with adequate gloves (as recommended by ICMR) while collecting the sample from the subject and maintain proper infection control when collecting specimens.

All treatment protocols for HCW and household contacts as recommended by ICMR and MoHFW will be permitted throughout the duration of the study.

Subjects will receive a notification on the mobile application/portal whenever the study ends and will be requested to fill in an end-of- study questionnaire. A subject is considered to have completed the study if he/she completes the end-of-study questionnaire. The end of the study is defined as the last subject's completion of end of study questionnaire in the mobile application/portal.

Interim analyses are planned at 2-monthly intervals during the study to assess the efficacy and futility based on which the study will be stopped.

An independent Data and Safety Monitoring Board (DSMB) will be appointed to review the safety and primary endpoint data for efficacy/futility. Safety data pertaining to incidences of SARS-CoV-2/COVID-19 infections, hospitalizations, ICU admissions and deaths and interim analysis data will be provided to the DSMB, at 2-monthly intervals. The DSMB will provide their observations to the sponsor with recommendations as to whether there are safety concerns and whether the study should continue without change, be modified, or terminated. The DSMB recommendations will be carefully considered by the

sponsor. The final decision rests with the sponsor.	
STUDY ELIGIBILITY CRITERIA	
INCLUSION CRITERIA	Subjects are eligible to be included in the study only if all of the following criteria apply 1. Male or Female subjects ≥ 18 years of age at high-risk of SARS-CoV-2/COVID-19 infection Subjects with high-risk of infection to COVID-19 cases defined as: ● Health care workers (physicians, nurses, ward boys, paramedical staff) working in direct contact with COVID-19 patients ● Other high-risk subjects: o House-hold contacts* defined as a resident in the same dwelling as a confirmed case of COVID-19 o People currently residing or working in COVID-19 hotspots/outbreak areas with a history of contact* with suspected or confirmed case of SARS-CoV-2/COVID-19 infection * Definition of contact ● Face-to-face contact with a suspected/confirmed case (as applicable) within 1 meter and for more than 15 minutes ● Direct physical contact with a suspected/confirmed case (as applicable) ● Direct care for a patient with a confirmed COVID-19 disease without using proper personal protective equipment, OR, ● Other situations as indicated by local risk assessments Adapted from WHO Definition [**Error! Reference source not found.**] 2. Test negative for SARS-CoV-2 infection (RT-PCR test) at screening ● For House-hold contacts, the sampling should be performed 14 days after the last contact with the confirmed SARS-CoV-2 patient and the result should be negative. ● For HCWs and other high- risk subjects, the sampling can be done on the day of screening 3. Capable of giving informed consent
EXCLUSION CRITERIA	Subjects are excluded from the study if any of the following criteria apply 1. Previous history of Tuberculosis or known active Mycobacterium tuberculosis infection 2. Received BCG vaccine within one year prior to screening

	3. Fever (≥ 38 ºC/100.4°F) or any other respiratory symptoms/illnesses within the past 14 days 4. Pregnant or lactating women 5. Women of child-bearing potential not agreeing to use adequate contraception 6. Current active viral or bacterial infection 7. Expected vaccination during the study period, independently of the type of vaccination 8. Severely immunocompromised subjects. This exclusion category comprises a) subjects with known infection by the HIV; b) subjects with solid organ transplantation; c) subjects with bone marrow transplantation; d) subjects under chemotherapy/radiotherapy; e) subjects with primary immunodeficiency; g) treatment with any anticytokine therapies. h) treatment with oral or intravenous steroids defined as daily doses of 10mg prednisolone or equivalent for longer than 3 months from the time of screening, or probable use of oral or intravenous steroids in the following four weeks 9. Active solid or non-solid malignancy or lymphoma within the prior two years 10. Individuals known to be hypersensitive to any component of the vaccine 11. Eczema or other significant skin lesion or infection at the site/s of injection. 12. Any other medical condition which in the opinion of the investigator may affect the subject's safety or study participation and conduct
SAFETY ASSESSMENTS	Subjects will be observed for 20-minutes post vaccination for any hypersensitivity/ anaphylactic reactions. After this, data regarding documented SARS-CoV-2/COVID-19 infections, hospitalizations, any other AEs will be obtained via various short questionnaires configured in the mobile application/portal. The investigators will review the safety data and if required, may call the subject to obtain more details or may ask the subject to visit the site for further evaluation. All AEs and SAEs will be collected from the time of informed consent

	until the end of study. The investigator/designee will report all SAEs, irrespective of causality or expectedness to the sponsor, DCG(I) and ethics committee (IEC) within 24 hours of occurrence of the SAE.
SAMPLE SIZE	This is adaptive design based on Bayesian approach. Since sufficient data is not available for COVID-19 disease if assumptions change then sample size re-estimation can be done. For initial sample size calculation, we used Fisher's exact test for testing two independent proportion in terms of Relative Risk (RR) [Hazard ratio (HR) for cox proportional hazard model], considering following assumptions: RR under H_1 = 0.7 (30% reduction in incidence of laboratory confirmed SARS-CoV-2/COVID-19 infection observed in Other High-Risk Subjects / HCWs. Same assumption is used for two primary endpoints defined for each strata), Power = ~ 90% α = 0.0125 (one-sided, adjusted for two primary endpoints analyzed for strata: Other High-Risk Subjects) Allocation Ratio: VPM1002 group: Placebo group = 2:1 The study is separately powered in "Other High-Risk Subjects" and "HCWs" treating them as strata. ● Other High-Risk Subjects: Assumption - Percentage of "Other High Risk" Subjects in Placebo group showing laboratory confirmed SARS-CoV-2/COVID-19 infection = 20% (same assumption is used for two primary endpoints) Thus, for stratum "Other High-Risk Subjects", the total sample size calculated is 2228 evaluable subjects, 1485 in VPM1002 group and 743 in Placebo group. Considering approximately 10% drop out rate we need to randomize 2478 subjects, 1652 in VPM1002 group and 826 in Placebo group. ● HCWs Assumption - Percentage of HCWs in Placebo group showing laboratory confirmed SARS-CoV-2/COVID-19 infection = 15% (same assumption is used for two primary endpoints) Similarly, for stratum "HCWs" for the total sample size calculated is 3119 evaluable subjects, 2079 in VPM1002 group and 1040 in Placebo group. Considering approximately 10% drop out rate we need to randomize 3468 subjects, 2312 in VPM1002 group and 1156 in

	Placebo group. Thus, we require 5946 randomized subjects in two strata distributed in 2:1 ratio in two groups VPM1002 and Placebo.
STATISTICAL ANALYSIS	Data will be reported quantitatively. Efficacy analyses will be performed on FAS population using the intention-to-treat principle. Two primary endpoints for each strata are "Number of HCWs / Other High-Risk Subjects with laboratory confirmed SARS-CoV-2/COVID-19 infection" and "Number of HCWs / Other High-Risk Subjects with laboratory confirmed SARS-CoV-2/COVID-19 infection with severe, critical or life-threatening disease severity as assessed by the Investigator". These endpoints are treated as Time-to-event data. The endpoints represent incidence of first laboratory confirmed SARS-CoV-2/COVID-19 infection with severe, critical or life-threatening disease severity as assessed by the Investigator. The events will be considered till time point when study is stopped due to decision rule of interim analysis or patient is discontinued due to any reason or followed up to maximum follow-up of 180 days (6 months follow-up). To analyze this endpoint hazard ratio (HR) is calculated and compared between VPM1002 vaccine group and Placebo group. Cox proportional hazards model will be used treating treatment groups as fixed effects and hospital, age, comorbidities, severity, time to recovery will be evaluated as covariates for including them in the model. Secondary endpoints related to severe disease outcomes in HCWs, Other high risk subjects, Elderly subjects (≥ 60 years) and subjects with co-morbidities measured in terms of incidence such as cumulative incidence of hospital admission due to documented SARS-CoV-2 infection, Cumulative incidence of ICU Admission due to documented SARS-CoV-2 infection, Cumulative incidence of death due to documented SARS-CoV-2 infection, Cumulative incidence of requirement of mechanical ventilation due to documented SARS-CoV-2 infection will be analyzed using cox proportional Hazard model. Secondary endpoints related to duration such as Duration of SARS-CoV-2/COVID-19 symptoms in HCWs and Other high-risk subjects will be analyzed by analysis of covariance using mixed model analysis. Continuous baseline characteristics will be reported as mean and

	standard deviation or median and inter-quartile range, as appropriate. Categorical baseline characteristics will be reported as count and percentage. No statistical testing for baseline characteristics will be performed. Safety data related to AE, SAE will be analyzed as frequency and % by System organ Class (SOC) and Preferred term (PT) Coded using MedDRA. The frequency and % will be provided for overall AEs, AEs by severity and relatedness.
INTERIM ANALYSIS	An interim analysis will be performed by the study statistician of the trial, once every 2 months. The results if available for futility or efficacy (with group level unblinding) will also be provided to the DSMB, once every 2 months along with safety data. In case of suggested futility or efficacy, the DSMB statistician may independently replicate the full data analysis before drawing conclusions. The Bayesian model used for primary endpoint yields a posterior distribution of the relative risk RR (hazard ratio (HR) of incidence rates). The posterior probability of the superiority hypothesis (RR < 1) will be calculated as well as the posterior probability of futility hypothesis (RR > 0.7). If during any of the interim analyses, the posterior probability of superiority is > 0.995 or the posterior probability of futility is > 0.99, a conclusion is reached, and the trial will be stopped. These posterior probability breakpoints have been chosen such that the type-1 error rate is <0.025 (similar to a two-sided alpha of 0.05) and the power of detecting superiority is > 90% if the true RR is 0.7.

SCHEDULE B
STUDY BUDGET AND PAYMENT SCHEDULE

No.	Budget Head	Unit	No. of Subjects	Unit Fees / Cost	Total
1	Investigator & Site Team Fees (Screening visit + vaccination)	Screening visit + vaccination	175	INR 6,500.00	INR 11,37,500.00
2	Investigator & Site Team Fees (Post screening visit data completion)	Post screening visit data completion	175	INR 4,700.00	INR 8,22,500.00
3	Investigator & Site Team Fees (End of study visit data completion)	End of study visit data completion	175	INR 2,000.00	INR 3,50,000.00
4	Transportation expenses for home visits (assumed average one per subject for High Risk Subject) *	Subject	100	INR 1,000.00	INR 1,00,000.00
5	Subject compensation (transportation expenses for site visits, if required) **	Subject			
	For Health care workers	04 visits (Per visit Rs. 500)	75	INR 2,000.00	INR 1,50,000.00
	For High Risk subjects	02 visits (per visit Rs. 500)	100	INR 1,000.00	INR 1,00,000.00
6	Advertisements, recruitment Related, Referrals expenses CRC marketing strategies, miscellaneous charges	Site	1	INR 10,000.00	INR 10000.00
7	Payment for screen failures ***	Screen failed subject**	18	INR 4,000.00	INR 72,000.00
8	Institutional overheads (applicable on Investigator & Site Team Fees and Payment for screen failures)	Percentage	25% on Sr. No.1,2,3		INR 5,77,500.00
9	Archival expenses	Site	1	INR 50,000.00	INR 50,000.00
	Total				**INR 33,69,500.00**

*	Transportation cost will be applicable for visits outside site i.e. for home visit of high risk subjects or in rare case Health Care workers as well
**	Average number of subjects estimated per site. Since recruitment will be competitive, the actual number per site may vary and even the proportion of Health Care worker and other High risk subjects may also vary accordingly subject compensation visits will also vary
***	Payment for screen failures refers to payment for the Investigator's and site team members' time towards activities conducted for screen-failed subjects. For each 10 eligible subjects, payment will be made for one screen failed-subject.
****	Cost of RT-PCR COVID test will be reimbursed.
*****	Expenses for medical care for related AEs and expenses related to treatment or compensation in case of related SAEs has not been included herein. These will be paid at actuals.
******	Personal Protective Equipment cost will be provided to the site.

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

1. Recruitment for this Study will be through competitive enrolment, and Institution and Investigator may enroll more or less depending on the enrolment at other sites. Investigator agrees that enrolment in the Study will be restricted pursuant to the Protocol based on the Inclusion / Exclusion criteria. CRO/Sponsor retain the right, to be exercised at CRO's/Sponsor's sole discretion, to terminate this Agreement for any reason, including poor enrolment.

2. The Investigator /Institution shall complete and deliver the work to CRO/Sponsor (including any technical report and financial statement that may be required) by the date fixed in this Agreement or any additional period that may be granted by CRO/Sponsor. If the payment schedule on the face of this Agreement provides for a final payment upon completion of the work, this final payment shall be made only after satisfactory receipt of all deliverables called for under this Agreement, including any technical report and financial statement.

3. In full and complete consideration of Investigator's and Institution's participation in the Study and of their covenants and obligations hereunder, within the date agreed in the Agreement or any alternative that may be granted by the CRO/Sponsor (including submissions of technical report and financial statements that may be required under the Agreement), and to cover their respective costs connected with the conduct of the Study, CRO shall pay amount as set forth in Schedule B. Said amount is based on Subjects completing the Study in full compliance with the Protocol for whom completed case report forms have been delivered by Investigator to CRO/Sponsor or CRO's/Sponsor's designee and all queries have been resolved. The Parties agree that these payment terms are consistent with the principles of fair market value payments for the performance of Study-related activities. If the payment schedule on the face of this Agreement provides for a final payment upon completion of the work, this final payment shall be made only after satisfactory receipt of all deliverables called for under this Agreement, including any technical report and financial statement.

4. Institution agrees to apply all funds received from CRO, including all interest accrued on such funds, if any, toward the performance of the Study. Within the Study Budget as provided in Schedule B, Institution may adjust budget line item amounts as reasonably necessary for performance of this Agreement; provided, however, that such adjustments shall not exceed ten percent (10%) of any line item without the prior written approval of Sponsor. Without the prior written approval of Sponsor/CRO, the total payments to Institution shall not exceed the amounts set forth in the Study Budget.

5. If a subject does not complete the Study, the amount payable will be pro-rated according to the number of visits attended by said Subject; provided that, prior to any payment by CRO completed case report forms for such Subjects have been accepted by CRO/Sponsor.

6. There is no payment for Subjects who are chart screened, but who do not have a informed consent as required by the regulation for the research project and do not complete any of the Screening Visit procedures.

7. All payment obligations are conditioned upon Institution's and Investigator's compliance with the standards identified in this Agreement. CRO will not make payments for or, if payment has been made, Institution/Investigator will repay to CRO any payments for Study visits, procedures, or other work associated with a Study subject if CRO/Sponsor determine that the Study visits, procedures or other work associated with the subject was not conducted by Investigator, sub investigator or Study Staff in compliance with the Protocol, applicable law or regulation, or ICH/ GCP Guidelines.

8. Investigator and Institution are responsible for all applicable direct taxes including but not limited to State, Central and municipal taxes presently or hereafter imposed upon any and all such amounts, including but not limited to professional and incomes taxes, Wealth Tax, Transaction tax. However CRO agrees to pay any indirect tax that may be introduced by any local, state, Central Government / authority including but not limited to service tax, excise, Goods and service tax (GST) based on the revenue and /or out of pocket expenses that are paid/payable by CRO to the Investigator/Institution under this agreement.

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

10. Payments (Investigator Grant, Institutional overheads and Patient Compensation) will be made on monthly basis for the amount proportional to the no. of subject visits completed in the preceding month. Site should submit the invoice for the completed subject visit at the end of each month. Sponsor/ designee will arrange to remit the funds to site within 45 days of receipt of correct invoice from the site. If for any reason, site is unable to randomize even one patient in the study, the advance payment(if applicable) will be returned to the Sponsor/ designee within a reasonable period (not exceeding 30 calendar days) on receipt of written communication from Sponsor/ designee to refund this amount.

11. Monthly invoices will be cleared by the Sponsor/ designee within 45 days of submission irrespective of the data being source verified by the monitors. However, site needs to ensure that source data is updated real time and electronic Case Report Form is filled within 05 working days of subject visit. While clearing the invoices at Sponsor/ designee end, in-house monitors will remotely review the compliance to the data entered vs. actual patient visit in the period of invoicing

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

13. Screen failures would be paid at 4000 INR per subject. Notwithstanding the foregoing, the maximum number of screen failures for which Investigator shall be compensated shall not exceed 10% of randomized subjects at site.

14. Reimbursement for any investigation performed for safety evaluation will be on actuals on submission of bills.

<u>Other Terms and conditions:</u>

1. Investigator acknowledges that the Study is a multicenter study and the recruitment for this Study will be through competitive enrolment, and investigator may enroll more or less depending on the enrolment at other sites. Investigator agrees that enrolment in the Study

will be restricted pursuant to the Protocol based on the inclusion / exclusion criteria. CRO / Sponsor retain the right, to be exercised at Sponsor's sole discretion, to terminate this Agreement for any reason, including poor enrolment.

2. Payment for drop outs or early terminated subjects would be pro-rated depending on the number of completed study visits. Invoice for completed visit will be raised at the end of each month.

3. If the payment towards the Institutional grant and subject compensation is paid to the investigator/institute directly by DiagnoSearch then it will be sole responsibility of the investigator/institute to pay the same to the concerned parties / individual (as applicable)

PAYMENT INSTRUCTIONS

1. All payments except subject compensation will be released after deduction of applicable taxes.

2. Payments will be made through cheque / bank transfer as per the payee details provided below.

Beneficiary Name	MGM Medical college ,Aurangabad
Bank Name:	IDBI bank
Bank Address	Adalat Road Branch, Survey No.20292,Ratnaprabha Building Kesarsinghpura Opp.LIC Bld.Aurangabad
Branch	Adalat Road Branch
Beneficiary Account No.	0376104000000107
TAX ID NUMBER (PAN)	AAATM4256E
IFSC Code	IBKL0000376