

Authorised Signatory

THE DECCAN MERCHANT CO-OP BANK LTD.
DADAR BR. BISMILLA BUILDING, FIRST FLOOR
RAMADE ROAD, DADAR(WEST)
MUMBAI - 400 028

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CLINICAL STUDY AGREEMENT

This Clinical Agreement ("Agreement") is entered into as of 12 JULY 2019 ("Effective Date") between **Novartis Healthcare Private Limited**, a company registered under the Companies Act, 1956 and having its registered office at 6th & 7th floor, Inspire BKC, G Block, Bandra Kurla Complex, Bandra (East), Mumbai - 400051 ("Novartis") which expression shall mean and include its successors and assigns of the ONE PART; AND

MGM MEDICAL COLLEGE AND HOSPITAL, N-6 CIDCO, Aurangabad, Maharashtra-431003, INDIA ("Institution") registered under Mahatma Gandhi Mission is a charitable trust, registered under the society's Registration Act.(1960) on 20th Dec. 1982, with its prime objective of Social welfare, Human Resource Development, Medical Care, Education, Forestry and Environment, Mass Communication, Sports & Fine Art. and having its address at **N-6 CIDCO, Aurangabad, Maharashtra-431003, INDIA** which expression shall mean and include its successors and assigns of the SECOND PART;

AND **Dr. Prashant Prabhakar Udgire** as clinical practitioner in the field of *Cardiology* acting in the role of principal investigator ("**Principal Investigator**") which expression shall mean and include his/her heirs, executors, administrators and assigns of the THIRD PART;

Novartis and Institution and Principal Investigator are hereinafter individually referred to as the "**Party**" and jointly as the "**Parties**".

RECITALS:

WHEREAS, Novartis is to perform a clinical trial (hereinafter the "Study") to evaluate the prevalence of Lipoprotein (a) (hereafter the "Study") in accordance with a protocol entitled *TQJ230A12001- Multi-center cross-sectional epidemiological study to characterize the prevalence and distribution of lipoprotein(a) levels among patients with established cardiovascular disease* and its amendments (hereinafter collectively the "Protocol") and,

WHEREAS, the Institution and the Principal Investigator having each reviewed the Protocol for the Study and sufficient information regarding the Study to evaluate their interest in participating in the Study, wish to conduct 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 Parties wish to set forth certain terms and conditions under which the Study shall be conducted;

NOW THEREFORE, the Parties, in consideration of the above and the mutual promises set forth below, agree as follows:



1. CONFORMANCE WITH LAW AND ACCEPTED PRACTICE

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) any applicable direction received from a regulatory authority (DCGI) or ethics committee with jurisdiction over the Study;
- (e) any “**Applicable Law(s)**” being hereinafter defined as : all regional, federal, state, and local directives, laws, including but not limited to Schedule Y of Drugs and Cosmetics Act 1940, those related to anti-bribery and promotion, rules, regulations, orders, published guidelines, operating procedures applicable to the Study and/or the Parties including but not limited to, legislation applicable to clinical Studies, the Parties, medical treatment and the processing of personal and medical data.
- (f) comply with all guidelines provided to it by Novartis from time to time individually but not limited to Code of Conduct, Novartis global Anti-bribery Policy and Professional Practices Policy

The Institution warrants that the Principal Investigator and the Institution’s employees and collaborators involved in the Study will comply with all Applicable Laws.

2. PROTOCOL

- 2.1 The Parties agree that the Protocol, including any subsequent amendments thereto and the Annexes herein form an integral part of this Agreement.
- 2.2 Institution and Principal Investigator agree to use their best efforts and professional expertise to perform the Study in accordance with the Protocol, all Applicable Laws, the identified timelines and the terms and conditions of this Agreement. Institution and Principal Investigator shall not start the clinical trial without prior approval of the appropriate Ethics Committee and Regulatory Authority.

3. APPROVALS

The Study shall not commence until:

- (a) all the necessary approvals of the relevant regulatory authority has been obtained by Novartis (*wherever applicable as per Indian regulations*) and the competent ethics committee have been obtained in writing by the Principal Investigator. Such approvals shall be forwarded to Novartis no sooner they are obtained;
- (b) the written approval of relevant authority or organisation that owns or is responsible for the administration of the facility in which the Study is to be performed has been obtained, if such authority or organisation is not the Institution.
- (c) the Informed Consent Form as defined in Section 6.3 provided by Novartis, has been approved by the Principal Investigator and/or the ethics committee.

4. DURATION OF THE STUDY

The Study shall commence on **29 Jul 2019**, subject to the compliance of Section 3 prior to this date **28 Jul 2022**. The Institution shall use its best efforts to complete the Study and to perform its obligations under this Agreement by *[date]* or as may be extended by a formal writing between the parties in that behalf. Provided that such extended study shall under no circumstances extend beyond the term of this Agreement.

5. TERM OF THIS AGREEMENT

- 5.1 This Agreement shall be effective upon 26 June 2019 and shall expire upon unless extended or terminated in terms of this Agreement.
- 5.2 The following provisions shall survive the termination or expiry of this Agreement: Section 11 (Intellectual Property), Section 13 (Publication) and Section 14 (Confidentiality), as well as any other provisions which by their terms are understood to survive the termination or expiry of this Agreement, including compliance with Applicable Laws.
- 5.3 In the event that the Principal Investigator decides to no longer conduct the Study both Principal Investigator and the Institution shall provide written notice to Novartis 30 (thirty) days prior to such termination. It is clarified that neither the Principal Investigator nor the Investigator shall be discharged of his/her or their obligations under this Agreement unless Novartis has been provided notice in terms of this clause.

6. PERFORMANCE OF THE STUDY

Principal Investigator and the Institution shall jointly and severally be responsible for the performance of the Study, in particular for the following:

- 6.1 Principal Investigator may appoint individuals and investigational staff as they may deem appropriate as sub-investigator (the "Sub-Investigators") to assist in the conduct of the Study at his/her sole discretion, costs, risks and consequences including but not limited to such Sub-Investigators qualification, remuneration, work record, compliance with statutory obligations etc without recourse to Novartis. The Principal Investigator alone shall be responsible for the conduct of the clinical investigation in its entirety and the well-being of the study subjects ("Study Subjects") and undertake in particular to have it executed by competent resources.

6.2 Study Site

The Study shall be conducted at the premises of Institution at the *MGM MEDICAL COLLEGE AND HOSPITAL*: (hereinafter the "Study Site").

- 6.3 **Study Subject consent and entry into Study:** Before enrolling a Study Subject into the Study, the Principal Investigator shall:

- (a) Exercise independent medical judgement as to the compatibility of each prospective Study Subject with the requirements of the Protocol;
- (b) advise Novartis of all instances in which, in the Principal Investigator's judgement, there is any question as to any prospective Study Subject's suitability for participation in the Study, and abide by Novartis's decision as to whether or not to enroll that Study Subject;
- (c) ensure that, before their participation in the Study, the Study Subject, and/or as the case may be, his/her legal representative, are duly informed in language understandable to them, about all aspects of the Study that are relevant to them, including: (i) the purpose, duration, nature, significance, implications, potential benefits and/or risks of the Study; and (ii) the processing, auditing, and monitoring of data (including personal data) under this Agreement;
- (d) ensure that, before his /her participation in the Study, each Study Subject and/or as the case may be his/her legal representative has given his or her Informed Consent on the basis of the information described in Clause 6.3 (c) by signing a consent form ("Informed Consent Form" or "ICF") in accordance with the Protocol and without the undue influence or coercion of any person directly involved in the Study, and in accordance with Applicable Laws;
- (e) ensure that a copy of the signed Informed Consent Form be provided to the Study Subject, and/or as the case may be, his/her legal representative;

- (f) acknowledge that the use of the Informed Consent Form does not release the Principal Investigator from his or her legal, regulatory and contractual obligations relating to Informed Consent, and that it remains the Principal Investigator's responsibility to ensure that those obligations are complied with;
- (g) comply with the procedures described in the Protocol in relation to that Study Subject; and,
- (h) provide details of the proposed Study Subject to Novartis.

6.4 Study Subject Recruitment

Principal Investigator has estimated that he/she can recruit the number of Study Subjects as specified in Annex 1. This target of recruitment can be increased only upon written agreement of Novartis. The Principal Investigator undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by Novartis.

Novartis will review the Study Subjects recruitment on an on-going basis to ensure that the enrollment continues at an acceptable rate. Novartis is empowered to discontinue the Study at Institution medical facilities in case of no or poor enrollment.

In a multicentre study, Novartis reserves the right, at its sole discretion, to require Institution and Principal Investigator to cease enrollment of Study Subjects prior to enrollment of the targeted number of Study Subjects. Institution and Principal Investigator undertake to cease such enrollment upon request of Novartis and further undertake not to seek any compensation therefor.

6.5 Recordkeeping, Reporting, Access and Inspections

(a) Recordkeeping, Reporting

The Institution and the Principal Investigator shall perform the following recordkeeping and reporting obligations in a timely manner:

- (i) Preparation and maintenance of complete, accurately written and electronic records, including accounts, notes, reports, Case Reports Forms, records of Study Subject identifications, medical notes, clinical observations, laboratory tests and all supportive documentation and data for each Study Subject of this Study (hereinafter "Records").
- (ii) Maintain a copy of all documents related to this Study for a period of a) fifteen (15) years following the Study completion or discontinuation by Novartis or b) as required by applicable laws and regulations.
- (iii) Meet with a representative of Novartis to discuss the progress of the Study; and notify Novartis immediately upon discovering any significant violations of the Protocol.
- (iv) In accordance with the procedure set out in the Protocol : Complete a Case Report Form for each Study Subject; review and sign each of the Case Report Forms to ensure and confirm their accuracy and completeness; promptly submit the Case Report Forms to Novartis following their completion,
- (v) Cooperate with Novartis in all their efforts to monitor the Study and to support Novartis in all matters of data collection, verification and discrepancy resolution
- (vi) Maintain all documents and other Records generated in the Study in safe keeping for such period as is required by any applicable regulations, and in any event for 15 years following termination of the Study; and obtain Novartis approval prior to disposing of any Record, provided that 'safe disposal' of any Record shall at all times be in compliance with 'Data Privacy and Protection' provisions set out in this Agreement. In the event of the insolvency or bankruptcy of Institution, Institution agrees to promptly transmit all copies of such records to Novartis in accordance with Novartis'



written instructions and in line with the transfer and disclosure terms set out in the ICF signed by concerned trial participants, at Novartis' expense.

- (vii) Ensure the hospital records of Study Subjects are kept safely in a known and accessible location during the period defined here-above.
- (viii) Make all Records available to Novartis or its nominee promptly upon request for monitoring and/or auditing purposes;
- (ix) Be responsible for making any necessary applications for registration under the data protection legislation in connection with data obtained under this Agreement, as provided in Article 27.

(b) **Access and Inspection**

It is agreed that the authorized representatives of Novartis, and regulatory authorities to the extent required by law, shall be entitled to:

- (i) Examine and inspect the Institution's facilities required for performance of the Study; and
- (ii) Inspect and copy all data and work products relating to the Study (including, without limitation, access to records as necessary for study monitoring or to audit the conduct of the Study in accordance with Novartis standards). Novartis will maintain the confidentiality of any subject-identifiable medical records.
- (iii) If any governmental or regulatory authorities notifies Institution or the Principal Investigator that it will inspect Institution's records, facilities, equipment, or procedures, or otherwise take action related to the Study, Institution shall promptly notify Novartis or any of Novartis designated person within 24 hours, allow Novartis to be present at the inspection/action and/or participate in any response to the inspection/action, and provide Novartis with copies of any reports or information issued by the authority and Institution's proposed and final response.
- (iv) Grant access to Novartis or its representative to visit the Study Site periodically, as frequently as required for the proper performance and oversight of the Study, in order to proceed with any and all monitoring activities required for the Study.
- (v) The Institution and the Principal Investigator will use their best efforts to facilitate the performance of any audit and inspection and shall give Novartis and any person designated by them access to all necessary facilities, data and documents.
- (vi) The Institution and the Principal Investigator shall take appropriate measures required by Novartis to correct without delay all observations found during the audits or inspections.
- (vii) It is expressly agreed between the Parties that Novartis will not compensate the Institution or the Principal Investigator for the audits and inspection.

The rights and obligations under this Article shall remain in effect for fifteen (15) years after the end of the Study.

6.6 **Reporting:** The Principal Investigator shall, either by himself/herself or his/her duly authorized representative, on reasonable notice

- (a) Meet with a representative of Novartis to discuss the progress of the Study; and
- (b) Make the hospital notes and Case Report Forms for each Study Subject available for source data verification or auditing purposes by representatives of Novartis representatives and the officers of any competent authority.

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- (c) On discovering any significant violations of the Protocol, the Principal Investigator shall notify Novartis immediately.

6.7 Reporting of Safety Information:

The Principal Investigator shall notify Novartis of each Serious Adverse Event encountered in the Clinical Trial within twenty-four (24) hours of becoming aware of it in accordance with the instructions set forth in the Protocol as well as local regulatory requirements. Each such notice shall be given by telefax or e-mail on a Novartis Serious Adverse Event Report form, whether or not notification was initially given by telephone. Section 6.6 shall apply to both the original copy of each Serious Adverse Event Report form and the telefax confirmation sheet or e-mail reflecting its transmission to Novartis.

The Principal Investigator shall also ensure that any person involved in the conduct of the study shall:

- (a) Immediately report to Novartis according to the procedure set out in the Protocol, any new safety findings, including Serious Adverse Event or Serious Adverse Reaction affecting or which could have an impact on the safety of the Study Subject. The Principal Investigator shall follow up such immediate reports and provide the additional information in a detailed, written manner to Novartis in accordance with the Protocol and local regulatory requirements;
- (b) Report to Novartis all Adverse Events (refer definition of adverse event as per ICH E6 guidelines for Good Clinical Practice and/or as mentioned in the protocol) in accordance with the study Protocol, applicable study procedures for safety data reporting;
- (c) Cooperate with and supply any further information required by Novartis and/or any relevant ethics committee or Regulatory Authority with jurisdiction over the Study.-

These reporting obligations shall survive expiration or earlier termination of the Agreement.

Novartis shall further report the adverse events to the competent Regulatory Authorities, in accordance with the current Applicable Laws. Novartis will furthermore provide the Principal Investigator with analysed report of the Serious Adverse Event or Serious Adverse Reaction reported to Novartis and SUSARs LL in order to inform the ethics committees IRB/IEC, Head of Institution in accordance with the current Applicable Laws.

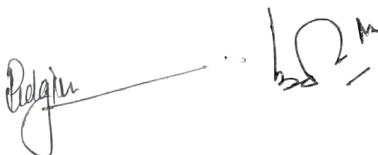

After completion of the Study and evaluation of the results, Novartis will inform the Principal Investigator about relevant safety-related findings in accordance with the guidelines and Study procedures.

6.8 Items supplied by Novartis

Novartis shall provide directly or indirectly the Principal Investigator and/or the Institution with all necessary information, documents and materials, including but not limited to:

- (a) Package insert
- (b) the Protocol,
- (c) the CRF/e-CRF

- 6.9 The Principal Investigator, or sub-investigator for multicentre studies, shall sign the clinical Study reports.



7. LIABILITY-INDEMNIFICATION

- 7.1 In the case of any injury occurring to a clinical trial subject or in the event of clinical trial related death of the subject, Novartis assumes responsibility to the extent and in the manner provided under the Drugs and Cosmetics Act, 1940 and rules thereunder as may be applicable from time to time.
- 7.2 The Institution and Principal Investigator (“**Indemnifying Party**”) jointly and severally shall indemnify and hold harmless Novartis from and against any and all liabilities, claims, damages, losses, settlements, penalties, fines, costs and expenses, including attorneys’ fees, (collectively, “**Damages**”) of whatever kind or nature arising from any third party demand, investigation, claim, action or suit based on (i) the gross negligence, bad faith or willful or intentional misconduct of the Indemnifying Party (ii) a material breach by the Indemnifying Party of any term of this Agreement, or (iii) a violation of any relevant law, rule or regulation by the Indemnifying Party in the performance of its duties under this Agreement.

8. INSURANCE


The Institution warrants that it has appropriate and adequate professional indemnity insurance to cover claims or damages including those arising out of negligence of the Principal Investigator for which it shall be liable under this Agreement. The Institution shall provide evidence of its insurance upon request by Novartis.

Novartis warrants that it has insurance for the Study Subjects included in the Study in place at the commencement of the Study.

9. COMPENSATION

- 9.1 In consideration for the satisfactory performance of the Study according to this Agreement and the Protocol, The Principal Investigator agrees and the Institution confirms the Payment Schedule attached hereto as Annex 1.
- 9.2 Novartis reserves the right to terminate the Agreement immediately with notice if no subjects have been recruited at the Study Site by *[insert date]*.
- 9.3 Subjects not completing the Study will be paid for on a prorated basis according to the number of completed visits. All payment will be made for subject visits according to the above Payment Schedule attached as Annex 1. No payment will be made for any Study Subject excluded from analysis because of Protocol violations that were within the Institution or Principal Investigator’s control. Reimbursement for expenses related to patient travel will be made according to the Payment Schedule in Annex 1.
- 9.4 The Principal Investigator shall send the invoices to:
- Novartis Healthcare Private Limited**
GDO Trial Monitoring, India
Saumya Mathew/Shumaila Qureshi
6 & 7 floor, Inspire BKC
G Block, BKC Main Road
Bandra Kurla Complex
Bandra (East), Mumbai - 400051
Maharashtra, India
- 9.5 Each invoice shall specify the Study Code. Novartis shall make payments into the account indicated by the Institution and Principal Investigator within 60 (sixty) days of receipt of an invoice from the Institution.

10. TERMINATION

-  10.1 Either party may terminate this Agreement for any safety and/or efficacy concerns or other ethical grounds by giving written notice to the other party with immediate effect. In case of early termination the *Institution/Principal Investigator* shall notify the relevant

ethics committee of the early termination, and Novartis shall notify the regulatory authorities and any other competent authorities as relevant and appropriate within specified timelines

- 10.2 Novartis may terminate this Agreement for convenience by giving written notice to the Institution with immediate effect.
- 10.3 If Novartis terminates this Agreement, Novartis shall have no obligations under this Agreement save and except to reimburse the Institution for such reasonable costs and non-cancellable obligations which has been approved by Novartis incurred in the performance of the Study prior to receiving notice of termination.
- 10.4 The termination or expiry of this Agreement shall not affect the rights and obligations of the parties which accrue prior to the date of termination. In particular, the Institution/Principal Investigator shall provide all outstanding Case Report Forms to Novartis and return to Novartis all documents and Equipment provided by Novartis under this Agreement.

11. INTELLECTUAL PROPERTY

- 11.1 All data, information and documents provided to the Institution by or on behalf of Novartis, whether in paper, oral, electronic or other form, shall remain the sole property of Novartis.
- 11.2 All data, information, documents, inventions and discoveries, resulting from or developed in the performance of the Study or this Agreement shall be the sole property of Novartis and may be used and/or transferred by Novartis in its sole discretion with no further payment or other obligation to the Institution. The Institution shall have no rights whatsoever therein.
- 11.3 The Institution agrees to, and to cause its employees and collaborators and the Principal Investigator to, execute promptly all documents and take all such other action as may reasonably be requested by Novartis to enable Novartis to obtain the benefit of its rights under this Agreement. This includes without limitation taking all necessary steps for the transfer of ownership of all data, information, documents, inventions and discoveries to Novartis in accordance with this Agreement, and assisting Novartis in the preparation and prosecution of patent applications. Furthermore, Institution and Investigator shall execute, or procure the execution of, and enforce all documents and deeds and do, or procure the doing of, all things as Novartis including but not limited to assignment of any and all rights, title and interest in resulting intellectual property in Novartis.
- 11.4 The Institution shall ensure that the Principal Investigator and the Institution's employees and collaborators involved in the Study will comply with its obligations under this Agreement.

12. TAXES AND SOCIAL SECURITY CONTRIBUTIONS

It shall be the Institution's responsibility to comply with all obligations in respect of taxes and social security contributions, if applicable, which relate to the subject matter of this Agreement, including without limitation those which relate to the Principal Investigator, the Institution and its employees and/or collaborators.

13. PUBLICATION

- 13.1 Novartis recognizes the Institution's interest in making publications and presentations relating to the Study in journals, at meetings or otherwise, and may therefore permit such publications and presentations, provided however that the Institution shall provide to Novartis any proposed presentation at least 15 (fifteen) working days prior to being disclosed and any other proposed publication at least 45 (forty-five) working days prior to being disclosed, and provided that Novartis shall have the right to request amendments to any such proposed presentation or publication on reasonable grounds including without limitation:

- (a) to ensure the accuracy of the presentation or publication;
- (b) to ensure that proprietary information is not inadvertently divulged;

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- (c) to enable intellectual property rights to be secured;
- (d) to enable relevant supplementary information to be provided.

13.2 Authorship of any publications relating to the Study shall be determined by mutual agreement.

13.3 Novartis may require any proposed publication or presentation to be delayed for up to 4 (four) months to enable a patent application to be prepared and filed. The 4 (four) month period shall commence on the date of receipt of the proposed publication or presentation, or from the date when all relevant data from the Study are made available to Novartis, whichever is later.

13.4 If the Study is a multi-centre study, the first publication of data shall be based on consolidated data from all centres analysed according to the Protocol, unless otherwise agreed in writing by all the Principal Investigators involved in the Study and Novartis.

13.5 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 officers, agents or employees without the prior written consent by an authorised representative of the non-releasing Party.

14. CONFIDENTIALITY

14.1 All information and data, trade secrets, privileged records and other confidential or proprietary information (including but not limited to the Protocol, CRFs and information on password-protected Novartis websites) disclosed to or collected or developed by the Institution, the Principal Investigator and/or the Institution's employees and/or collaborators in connection with this Agreement or the Study (collectively "Information") shall be treated as confidential. The Institution and/or the Principal Investigator agree not to disclose to any third parties or to use any Information for any purpose other than the performance of the Study. The Institution and/or the Principal Investigator shall ensure that the Institution's employees and collaborators are bound by confidentiality obligations not less strict than those set out herein prior to receiving any Information.

14.2 Upon termination or expiry of this Agreement, the Institution and / or Principal Investigator shall safely destroy (as set in the Data Privacy and Protection annexure to this Agreement) or return to Novartis, as per Novartis' request, all documents, samples and material containing or relating to Information, except for one copy of Information which is to be retained in the confidential files of the Institution for record purposes only. If requested by Novartis, such safe destruction shall be promptly confirmed in writing by the Institution to Novartis.

14.3 The confidentiality obligations set out above shall not apply to:

- (a) Information which is, at the time of disclosure, in the public domain or thereafter becomes part of the public domain otherwise than by the act or omission of the Institution, the Principal Investigator, or the Institution's employees and/or collaborators;
- (b) Information that the Institution can demonstrate by written evidence was in its possession prior to its disclosure by Novartis or that said information, its collection or creation did not occur during or in connection with the Study;
- (c) Information which the Institution received from any third party not engaged in the activities which are the subject of this Agreement, where such information is not subject to an obligation of confidentiality in favour of Novartis or any of its affiliates.

15. NOTICES

Any notice given in connection with this Agreement shall, unless otherwise provided herein, be in writing and shall be delivered personally, or sent by registered mail or facsimile to the address given in this Agreement

GDO Trial Monitoring, India

Handwritten signature and initials in black ink, appearing to be 'D. J. M.' and 'b. S. M.' respectively.

Novartis Healthcare Private Limited

Mr. Murugananthan K

6 & 7 floor, Inspire BKC

G Block, BKC Main Road

Bandra Kurla Complex

Bandra (East), Mumbai - 400051

Maharashtra, India

Telephone: 022 – 50243544

Fax: 022 - 50243005

or to such other address as may have notified to the other party in writing.

16. ASSIGNMENT

Neither Party may assign its rights and obligations under this Agreement without the other Party's prior written consent, except that Novartis may (a) assign its rights and obligations under this Agreement or any part hereof to one or more of its Affiliates; or (b) assign this Agreement in its entirety to a successor to all or substantially all of its business or assets to which this Agreement relates. Any permitted assignee will assume all obligations of its assignor under this Agreement (or related to the assigned portion in case of a partial assignment). Any attempted assignment in contravention of the foregoing will be void. Subject to the terms of this Agreement, this Agreement will be binding upon and inure to the benefit of the Parties and their respective successors and permitted assigns.

17. SUBCONTRACTING

The Institution and /or Principal Investigator shall not retain any subcontractor to perform any of its obligations under this Agreement without the prior written consent of Novartis. Any such consent shall not relieve the Institution and/or Principal Investigator of its obligations hereunder.

18. 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 hereof.

19. 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 any such term, provision or condition, or of any other term, provision or condition of this Agreement.

20. ENTIRE AGREEMENT

This Agreement (including the Protocol) represents the entire understanding between the parties with respect to the subject matter hereof. No amendment to this Agreement will be effective or binding unless it is in writing signed by both parties and refers to this Agreement.

21. DEBARMENT

Neither the Principal Investigator nor the Institution, nor any person employed thereby nor any collaborator who is involved in the performance of the Study has been debarred under the law including but not limited to provisions of the Indian Medical Council Act, 1956 as amended, Drug and Cosmetics Act, 1940 as amended or under Applicable Law and no debarred person will in the future be employed or engaged by the Institution in connection with any work to be performed for or on behalf of Novartis. If at any time after the execution of this Agreement, the Institution becomes aware that the Principal Investigator or the Institution or any person employed or engaged thereby is debarred, or is in the process of being debarred, the Institution hereby certifies that the Institution will so notify Novartis at once.



22. CONFLICT OF INTEREST, FINANCIAL DISCLOSURE

The Institution and the Principal Investigator confirm that there is no conflict of interests between the Parties that would inhibit or affect their performance of the work specified in this Agreement. The Institution and the Principal Investigator further certify that they will promptly inform Novartis in the event any conflict of interests arises during the performance of this Agreement and certify that their performance hereunder does not violate any other agreement they may have with any other third party.

23. TRANSPARENCY/DISCLOSURE

23.1 In all materials relating to Services intended for an external audience, Principal Investigator shall disclose:

- (a) that Novartis has retained Principal Investigator for professional services in relation to the conduct of the Study; and
- (b) any other relationships that Novartis has with Principal Investigator which a reasonable and ethical person would expect to be disclosed.

23.2 Both parties agree to make all other disclosures and/or notifications as may be required in connection with entering into, performing, or receiving compensation under this Agreement, and Principal Investigator shall follow all Applicable Laws in this respect, including those relating to Principal Investigator's professional relationships with decision-making authorities or bodies (if any), such as, for instance, recusal from any votes, discussions or recommendations regarding investigational or marketed products of Novartis, regardless of whether such are subject to the Services.

23.3 The Institution and Principal Investigator understand and agree that Novartis may be required to disclose certain information to governmental agencies in different jurisdictions in order to comply with local laws regulating clinical trials. The Institution and Principal Investigator consent to the disclosure of certain information that otherwise may constitute personal data in order to comply with laws regulating clinical trials, including but not limited to the Institution's and/or Principal Investigator's name, clinical trial Study Site contact information, name of the clinical trial, sponsor, copy of the Agreement, and costs and fees relating to Study Site's activities performed under the Agreement. Novartis will provide upon written request a list of any such disclosure made regarding the Institution and/or the Principal Investigator.

24. JURISDICTION AND APPLICABLE LAW

This Agreement shall be governed by and construed in accordance with the laws of India. The parties hereby submit to the exclusive jurisdiction of the competent courts of Mumbai, India for any disputes concerning or arising out of this Agreement.

25. DATA PROTECTION

A form regarding the disclosure of the Principal Investigator's personal data together with the general provisions regarding any personal information processed by the Institution under this Agreement is attached as Annex 2.

26. COUNTERPARTS

This Agreement may be executed in two or more counterparts each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

27. PRECEDENCE

To the extent that there may be any inconsistency between this Agreement and the Protocol, the Protocol shall take precedence in ONLY AND SPECIFICALLY in relation with trial procedures while in all other instances the Agreement shall prevail.



IN WITNESS WHEREOF, the Parties intending to be bound have caused this Agreement to be executed by their duly authorised representatives.

NOVARTIS HEALTHCARE PRIVATE LIMITED

MGM Medical College , Aurangabad

By: *S Mathew*

By: *hsm*

Name: SAUMYA MATHEW

Name: DR. RAJENDRA BOHRA

Title: CLINICAL STUDY MANAGER

Title: DEAN

Date: 12 JUL 2019

Date: 18 JUL 2019
*Dean
MGM Medical College,
Aurangabad.*

Dr. Prashanth Udgire

By: *Prashanth*

Name: DR. PRASHANT UDGIRE

Title: PRINCIPAL INVESTIGATOR

Date: 18 JUL 2019

DR. PRASHANT P. UDGIRE
M.D.(Medicine),D.M.Cardiology)Mumbai
Asst. Prof. & Interventional Cardiologist,
MGM Medical College & MCRI,A'bad,
Reg. No.2002/03/

ANNEX 1: PAYMENT SCHEDULE

STUDY NUMBER: CTQJ230A12001

STUDY NAME: MULTI-CENTER CROSS-SECTIONAL EPIDEMIOLOGICAL STUDY TO CHARACTERIZE THE PREVALENCE AND DISTRIBUTION OF LIPOPROTEIN(A) LEVELS AMONG PATIENTS WITH ESTABLISHED CARDIOVASCULAR DISEASE

Investigator's Name: Dr. Prashant Prabhakar Udgire

Institute Name: **MGM MEDICAL COLLEGE AND HOSPITAL.**

Payee Name: Dr. Prashant Prabhakar Udgire

Pan Card Number: ABNPU2403M

GSTIN: NA

Committed Number of Study Subjects:80

List of Equipment's provided to Institution / Principal Investigator: NA

Epoch	Screening / Randomization
Visit	1
Investigator Grant	4000
CRC Grant	3000
Institutional Overhead (20 %)	1400
Total Per Patient Visit	8400 INR

Payment Schedule:

Payment Terms:

- The amount of payment due to the Institution/Investigator will be calculated in respect of each patient visit according to the attached budget schedule.
- Any other third parties designated by the Institution/Investigator that would receive remuneration, will be managed by & paid by the Institution/Investigator.
- Sponsor shall reimburse patient's travel cost per protocol visit as per actuals for which institution/PI shall provide original invoice along with the supporting bills.
- The Ethics committee charge will also be paid via Novartis, and this cost is not included in the budget schedule.
- Prior to site closeout, sponsor shall provide INR 75,000 for archival of study documents for 15 years.
- All payments are based on actual patient visits.
- All values are in INR. All budget schedule payments are subject to TDS (subject to Government of India, Tax regulations) and GST as applicable. GST will be paid on providing valid tax invoice with relevant details mentioning GST registration number on it.

ANNEX 2: PRINCIPAL INVESTIGATOR – PERSONAL DATA DISCLOSURE FORM

Novartis wants to ask your permission to include certain elements of your personal data in a database maintained by a third party. The Grant Plan database, which is maintained and provided to pharmaceutical research sponsors by a company called TTC in the United States, is intended to assist research sponsors with transparency relating to clinical trial expenses. The database is used to support country specific forecasts for clinical trial costs and to provide benchmarking information in order to achieve transparency and fairness in setting costs for performing clinical trials.

The information is entered into the database in such a way that it is not possible for anybody except the personnel of TTC to view your name or link your site to a particular clinical trial or sponsor company.

In that regard, Novartis is asking for your permission to submit your name, clinical trial site contact information, name of the clinical trial, sponsor, copy of the clinical trial agreement, and costs and fees relating to your site's retention, to a third party administrator of this database. This information will be maintained in that database for five years. If you are conducting research for Novartis in countries other than the United States, such as those in Europe, you should note that the United States does not offer the same standards of privacy protection as those offered in Europe. You are not required to give consent to this disclosure in order to proceed with this clinical study. However, by doing so, you are helping to collect information on fair costs in clinical trials.

- Yes, I hereby agree that Novartis may disclose my personal data in connection with the Grant Plan database.
- No, I do not give my permission to disclose my personal data in connection with the Grant Plan database.

Place and Date:

AURANGHABAD
18 JUL 2019



Name: Dr. Prashant Prabhakar Udgire
Principal Investigator

DR. PRASHANT P. UDGIRE
M.D.(Medicine),D.M.Cardiology/Mumbai
Asst. Prof. & Interventional Cardiologist
MGM Medical College & MCRI,A'bad.
Reg. No.2002/031



Data Privacy and Protection

Provisions regarding any Personal Information Processed by Institution under this Agreement:

Defined Terms. For the purposes of this Section, the following terms shall have the meanings given below:

“Personal Information or Data” means any information that relates to an identified or identifiable person including without limitation electronic data and paper based files that include such information such as: (a) name or initials; (b) home or other physical address; (c) work, cell or home telephone number; (d) work or home email address or online identifier associated with the individual; (e) identification code; (f) credit card number; and (e) employment information, that is Processed directly or indirectly, by Institution on behalf of Novartis in connection with this Agreement.

“Sensitive Personal Information or Data” – constitutes a subset of Personal Information and relates to of an individual’s (a) physical, physiological or mental characteristics, (b) economic status, (c) racial or ethnic origin, (d) political, ideological, religious opinions or philosophical beliefs, (e) trade union membership, (f) health or medical information including information related to payment for health services, (g) sex life or sexual preference, (h) genetic material or information, (i) human biological samples or cells, (j) unique biometric data, (k) Personality Profiles or (ii) an individual’s name in combination with the individual’s (a) Social Security number, (b) alien registration number, (c) driver’s license number, (d) passport number, visa number or other government identifier, (e) credit card, debit card, or other financial account numbers, with or without any associated code or password that would permit access to such account, or (f) mother’s maiden name; and as applicable under local laws.

“Data Subject” – and identified or identifiable person who’s Agreement Personal Data are processed, accessed, received, transmitted, or maintained by the Supplier. An identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity.

“Processing” means any operation or set of operations which is performed upon personal information, whether or not by automatic means, such as collection, recording, organisation, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction or any other operation or set of operations otherwise defined in applicable Data Privacy Laws. This also includes the processing of personal information in structured manual files.

“Institution Third Parties” – any third party that assists Institution in performing its obligations under the Agreement, including an affiliate or direct or indirect subcontractor of Supplier.

General Obligations of Institution:

a. **Compliance with Applicable Laws and Permitting Processing.** Institution will, and will cause all Institution Third Parties to, hold Personal Information in confidence, use Process such data only for the benefit of Novartis and its Affiliates and Process such information in compliance with (i) all Applicable Data Protection Laws, (ii) the Agreement, (iii) any consent, authorization of a Data Subject or other authorized participant, such as subject’s legal representative, (iv) industry standards, and (v) this Data Privacy and Protection Exhibit; provided, however, that Institution (or Institution’s Third Party) may Process Personal Information only under the written instructions of an authorized signatory of Novartis.

To the extent that the Agreement involves the processing of personal information owned by or licensed to Institution prior to or separately from the Services, Institution represents and warrants that such data has been obtained in compliance with applicable laws and regulations, including Applicable Data Protection Laws and all necessary consents and authorizations, including those of any patient, if applicable. Institution further represents and warrants that Institution and/or Novartis is authorized to use such data as contemplated by this Agreement.

b. Obligations with respect to the Data Subjects participating in trials:

Institution shall take reasonable steps to ensure that each individual whose Personal Information were, or are, in its possession is able to assert his or her rights under local law, including but not limited to right of access to view and correct his or her Personal Data, right to withdraw consent and file complaint or grievance if any, with the Institution.

c. Obligations with Respect to Institution's Third Parties.

Within seven (7) business days of Novartis' written request, Institution will produce clear and accurate information stating who is holding and processing Agreement Personal Data, and in what country they are located. In all such arrangements, Supplier will enter into agreements with Supplier Third Party(ies) that are substantially similar to this Data Privacy Exhibit. Supplier shall provide copies of such agreements to Novartis within seven (7) business days following a written request from Novartis therefor.

Data Safeguards. The parties agree to comply with the following:

- (a) Without limitation of any provision of this Agreement, the parties agree to comply with all applicable Laws governing the privacy and security of Personal Information that Institution shall create, acquire, access or receive as a result of this Agreement, to the extent that such Laws apply to either party.
- (b) Institution agrees to implement administrative, technical and physical security measures to protect Personal Information, from (i) unauthorised or accidental destruction, (ii) theft, forgery or loss, (iii) technical faults, (iv) forgery, theft or unlawful use (v) unauthorised alteration, copying access; or (vi) any other unauthorised processing.
- (c) Security measures implemented by Institution must take into account (i) the purpose of the data processing, (ii) nature and extent of the processing, (iii) assessment of possible risks to the data subject; and (iv) current industry best practices and state of the art technologies, including but not limited to encryption of information at rest and in transit. Security measures shall be reviewed on a periodic basis and updated as required.
- (d) All email communication with Novartis, especially those involving trial related information should happen via secure 'Institutional email Ids'. Exceptions (i.e. use of non-institutional email Ids), if any must be discussed with Novartis and a secure communication solution, as mutually agreed and in line with Novartis' security standards, is implemented.
- (e) Institution shall not sub-contract any of its rights or obligations without the prior written notification to Novartis. In the event that any Institution Subcontractor shall have access to Personal Information, such access shall be permitted under a need-to-know basis and only to the extent required for the due performance of Institution's obligations. Institution shall enter into Agreements with its' subcontractors that contain privacy and security provisions that are equivalent to the provisions under this Agreement.
- (f) Institution shall ensure that personnel who will be undertaking the Processing of Novartis Personal Information, including that by Institution's Third Party (if any) have appropriate skills and privacy and security training to handle Sensitive Personal Information.
- (g) If Institution disposes of any paper, electronic or other record containing Agreement Personal Data, Supplier shall do so by taking all reasonable steps to destroy the information by (a) shredding; (b) permanently erasing and deleting; (c) degaussing; or (d) otherwise modifying the Agreement Personal Data in such records to make it unreadable, un-reconstructable and indecipherable.
- (h) Institution shall maintain procedures to detect and respond to a Data Security Breach. Institution shall notify Novartis of any Data Security Breach within 24 hours of discovery of a data security breach. Institution shall promptly make available to Novartis details of the Data Security Breach and shall use commercially

reasonable efforts to investigate and prevent the recurrence of such Data Security Breach. The parties shall reasonably cooperate to remediate a Data Security Breach and prevent any recurrence. Novartis, at its sole discretion, after consultation with Institution, shall determine whether and when to notify any individuals or persons (including Governmental Authorities) regarding any Data Security Breach affecting Novartis Personal Information. Institution, as determined in its sole discretion, shall comply with all applicable Laws to which it is subject with regard to the Data Security Breach.

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ANNEX 3: NOVARTIS POLICIES

I / We, the undersigned Institution and Principal Investigator for study number CTQJ230A12001 declare that I have received a copy of;

- (a) Novartis global Anti-bribery Policy
- (b) Professional Practices Policy

I / We, have read the policy (ies) understood its meaning and shall comply with the same.

<p>MGM MEDICAL COLLEGE AND HOSPITAL</p> <p>By: <u><i>Dr. Rajendra B. Bohra</i></u></p> <p>Name: Dr. Rajendra B. Bohra</p> <p>Title: <u>DEAN</u></p> <p>Date: <u>18 JUL 2019</u></p>	<p>Dr. Prashant Prabhakar Udgire</p> <p>By: <u><i>Prashant</i></u></p> <p>Name: Dr. Prashant Prabhakar Udgire</p> <p>Title: <u>PRINCIPAL INVESTIGATOR</u></p> <p>Date: <u>18 JUL 2019</u></p>
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MGM Medical College,
Aurangabad.

DR. PRASHANT P. UDGIRE
M.D.(Medicine), D.M. Cardiology Mumbai
Asst. Prof. & Interventional Cardiologist
MGM Medical College & MCRI, A'bad.
Reg. No. 2002/03/

Dr. Bohra