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Unique Doc. Reference	:	SUBIN-KAKAKSFCL0891473954750545R
Purchased by	:	IQVIA RDS INDIA PRIVATE LIMITED
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	IQVIA RDS INDIA PRIVATE LIMITED
Second Party	:	MGM MEDICAL COLLEGE AND HOSPITAL
Stamp Duty Paid By	:	IQVIA RDS INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	300 (Three Hundred only)

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Statutory Alert:

1. [illegible]

CLINICAL TRIAL AGREEMENT

The Clinical Trial Agreement ("**Agreement**") is made by and between:

- Mahatma Gandhi Mission's Medical College and Hospital, N-6 CIDCO, Aurangabad-431003, Maharashtra, India; (the "**Institution**"), and
- Dr. Bhosale Deepak Sadashiv , Mahatma Gandhi Mission's Medical College and Hospital, N-6 CIDCO, Aurangabad-431003, Maharashtra, India (the "**Investigator**"), and
- IQVIA RDS (India) Private Limited (formerly Quintiles Research (India) Private Limited), having a place of business at III Floor, Etamin Block, Prestige Technology Park, Sarjapur - Marathahalli Outer Ring Road, Bangalore – 560103, Karnataka, India ("**IQVIA**"),

Each a "**Party**" and together the "**Parties**".

Protocol Number:	CT/P015/CMR/16/03_01
Protocol Title:	A Phase III Randomized, Double Blind, Parallel Group, Placebo Controlled, Multi-centre, Multinational Study to Evaluate Efficacy and Safety of TRC150094 as an Add On to Standard of Care in Improving Cardiovascular Risk in Subjects with Diabetes, Dyslipidemia and Hypertension
Protocol Date:	17 Jul 2017
Sponsor:	Torrent Pharmaceuticals Limited
Country where Site is Conducting Study	India
Investigator:	Dr. Bhosale Deepak Sadashiv
Key Date:	**100 Calendar Days after Site Initiation Visit (being the date by which Site must enrol at least one (1) subject as more specifically set out in section 1.7 "Key Enrolment Date" below)**
IRB/IEC	Contact name: Dr. Manvendra Kachole (Chairperson) - +91 9225930400

The following additional definitions shall apply to this Agreement:

Protocol: the clinical protocol referenced above as it may be modified from time to time by the Sponsor (defined below).

Case Report Form or **CRF**: case report form (paper or electronic) to be used by Site to record all of the Protocol-required information to be reported to Sponsor on each Study Subject (defined below).

Study: the clinical trial that is to be performed in accordance with this Agreement and the Protocol for purposes of gathering information about the compound/medical device identified in the Protocol.

Study Subject: an individual who participates in the Study, either as a recipient of the Investigational Product (defined below) or as a control.

Study Staff: the individuals involved in conducting the Study under the direction of the Investigator.

Investigational Product: the compound/medical device identified in the Protocol that is being tested in the Study.

Good Clinical Practices or **GCPs**: International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) Harmonised Tripartite Guideline for Good Clinical Practice as amended from time to time and the principles set out in the Declaration of Helsinki as revised from time to time.

Sponsor: the sponsor of the Study.

Medical Records: the Study Subjects' primary medical records kept by the Institution on behalf of the Investigator, including, without limitation, treatment entries, x-rays, biopsy reports, ultrasound photographs and other diagnostic images.

MCI Regulations: Indian Medical Council (Professional Conduct, Etiquette and Ethics) (Amendment) Regulations, 2009 – Part -1, as may be amended from time to time or any replacement regulations.

Study Data: all records and reports, other than Medical Records, 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) required to be delivered to Sponsor pursuant to the Protocol and all records regarding inventories and dispositions of all Investigational Product.

Government Official: any officer or employee of a government or of any ministry, department, agency, or instrumentality of a government; any person acting in an official capacity on behalf of a government or of any ministry, department, agency, or instrumentality of a government; any officer or employee of a company or of a business owned in whole or part by a government; any officer or employee of a public international organization such as the World Bank or the United Nations; any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or any candidate for political office; any doctor, pharmacist, or other healthcare professional who works for or in any hospital, pharmacy or other healthcare facility owned or operated by a government agency, ministry or department.

Item(s) of Value: should be interpreted broadly and may include, but is not limited to, money or payments or equivalents, such as gift certificates; gifts or free goods; meals, entertainment, or hospitality; travel or payment of expenses; provision of services; purchase of property or services at inflated prices; assumption or forgiveness of indebtedness; intangible benefits, such as enhanced social or business standing (e.g., making donations to government official's favoured charity); and/or benefits to third persons related to government officials (e.g., close family members).

Dual Capacity: the capacity of holding a Government Official position and being a party to this Agreement.

Informed Consent: consent obtained from a Study Subject that complies with guidelines established by the Declaration of Helsinki, International Conference of Harmonization (ICH), and all the applicable laws, guidelines, or standards, governing the participation of Study Subject in trials.

RECITALS:

WHEREAS, IQVIA is providing clinical research organisation services to Sponsor under a separate contract between IQVIA and Sponsor. IQVIA' services include monitoring of the Study and contracting with clinical research sites;

WHEREAS, the Investigator has represented that he/she has the requisite expertise and resources for providing clinical trial and research services, and other services for the pharmaceutical industry;

WHEREAS, the Institution has represented that it has the necessary infrastructure and resources to carry out clinical trial services.

WHEREAS, the Institution and Investigator (hereinafter jointly the "**Site**") are willing to conduct the Study and IQVIA requests the Site to undertake such Study.

NOW THEREFORE, the following is agreed:

1. CONDUCT OF THE STUDY

1.1. Compliance with Laws, Regulations, and Good Clinical Practices

Site agrees that Site and Study Staff shall perform the Study at Institution in strict accordance with this Agreement, the Protocol, terms and conditions of the approval of the Independent Ethics Committee ("**IEC**"), any and all applicable local, national and international laws, regulations and guidelines, acceptable ethical and medical considerations, including in particular, but without limitation, GCPs and MCI Regulations and state and local tax and finance regulations. Site and Study Staff acknowledge that IQVIA and Sponsor, and their respective affiliates, need to adhere to the provisions of (i) the Bribery Act 2010 of the United Kingdom (Bribery Act); (ii) the Foreign Corrupt Practices Act 1977 of the United States of America (FCPA) and (iii) any other applicable anti-corruption legislation.

The Investigator shall ensure that neither administration of the Investigational Product to any Study Subject nor any other clinical intervention mandated by the Protocol takes place in relation to any such Study Subject until it is satisfied that all relevant regulatory and IEC approvals have been obtained

1.2. Informed Consent Form

Site agrees to use an informed consent form that has been approved by Sponsor and is in accordance with applicable regulations and the requirements of the Institutional Review Board ("**IRB**") or Independent Ethics Committee ("**IEC**") that is responsible for reviewing the Study. Site shall obtain the prior written informed consent of each Study Subject and same shall be maintained by the Investigator for record.

1.3. Medical Records and Study Data

1.3.1. Collection, Storage and Destruction: Site shall ensure the prompt, complete, and accurate collection, recording and classification of the Medical Records and Study Data.

Site shall:

(i) maintain and store Medical Records and Study Data in a secure manner with physical and electronic access restrictions, as applicable and environmental controls appropriate to the applicable data type and in accordance with applicable laws, regulations and industry standards and will also be kept confidential under the terms of Section 3 of this Agreement; and

(ii) protect the Medical Records and Study Data from unauthorized use, access, duplication, and disclosure. If directed by Sponsor or IQVIA, Site will submit Study Data using the electronic system provided by Sponsor or IQVIA or their designated representative and in accordance with Sponsor's instructions for electronic data entry. Site shall prevent unauthorized access to the Study Data by maintaining physical security of the electronic system and ensuring that Study Staff maintain the confidentiality of their passwords. Investigator agrees to collect all Study Data in Medical Records prior to entering it into the CRF. Site shall ensure the prompt submission of CRFs; and

(iii) take measures to prevent accidental or premature destruction or damage of these documents, for as long as required by applicable laws and regulations. Neither Institution nor Investigator shall destroy or permit the destruction of any Medical Records or Study Data without prior written notification to the Sponsor, and Institution shall continue to store Medical Records and Study Data, at the Sponsor's expense, for any period that the Sponsor may request in writing after retention is no longer required by any applicable law or regulation.

The Investigator shall ensure that the clinical samples required to be tested during the course of the Study are tested in accordance with the Protocol and at a laboratory approved by the Sponsor/ IQVIA.

If the Investigator leaves the Institution, then responsibility for maintaining Medical Records and Study Data shall be determined in accordance with applicable regulations but Institution will not in any case be relieved of its obligations under this Agreement for maintaining the Medical Records and Study Data.

1.3.2. Ownership. Institution shall retain ownership of Medical Records. The Institution and the Investigator hereby assign to Sponsor all of their rights, title and interest, including intellectual property rights, to all Confidential Information (as defined below) and any other Study Data.

1.3.3. Access, Use, Monitoring and Inspection. Site shall provide original or copies (as the case may be) of all Study Data to IQVIA and Sponsor for Sponsor's use. Site shall afford Sponsor and IQVIA and their representatives and designees reasonable access to Site's facilities and to Medical Records and Study Data so as to permit Sponsor and IQVIA and their representatives and designees to monitor the Study.

In the event the Sponsor or IQVIA reasonably believes there has been any research misconduct in relation to the Study at the Site, Institution and the Investigator shall provide all reasonable assistance to any investigation into any alleged research misconduct undertaken by or on behalf of the Sponsor. Site shall afford regulatory authorities reasonable access to Site's facilities and to Medical Records and Study Data, and the right to copy Medical Records and Study Data.

The Site agrees to cooperate with the representatives of IQVIA and Sponsor, and the Site agrees to ensure that the employees, agents and representatives of the Site do not harass, or otherwise create a hostile working environment for such representatives.

The Site shall immediately notify IQVIA of, and provide IQVIA copies of, any inquiries, correspondence or communications to or from any governmental or regulatory authority relating to the Study, including, but not limited to, requests for inspection of the Site's facilities, and the Site shall permit IQVIA and Sponsor to attend any such inspections. The Site will make reasonable efforts to separate, and not disclose, all Confidential Information that is not required to be disclosed during such inspections.

1.3.4. License. Sponsor hereby grants to Institution a perpetual, non-exclusive, non-transferable, paid-up license, without right to sublicense, to use Study Data (i) subject to the obligations set forth in section 3 "Confidentiality", for internal, non-commercial research and for educational purposes, and (ii) for preparation of publications in accordance with Section 5 "Publication Rights".

1.3.5. Survival. This section 1.3 "Medical Records and Study Data" shall survive termination or expiration of this Agreement.

1.4. Duties of Investigator

Investigator shall be responsible for obtaining and maintaining all the approvals from the relevant IEC for the conduct of the Study at the Institution. The Investigator is also responsible for the conduct of the Study at Institution and for supervising any individual or party to whom the Investigator delegates Study-related duties and functions. In particular, but without limitation, it is the Investigator's duty to review and understand the information in the Investigator's Brochure or device labelling instructions, to ensure that all informed consent requirements are met, to ensure that all required reviews and approvals by applicable regulatory authorities and IRBs or IECs are obtained, and to review all CRFs to ensure their accuracy and completeness.

If the Investigator and Institution retain the services of any individual or party to perform Study-related duties and functions, the Institution and Investigator shall ensure this individual or party is qualified to perform those Study-related duties and functions and shall implement procedures to ensure the integrity of the Study-related duties and functions performed and any data generated.

Investigator agrees to provide a written declaration revealing Investigator's possible economic or other interests, if any, in connection with the conduct of the Study or the Investigational Product.

Investigator agrees to provide a written declaration revealing Investigator's disclosure obligations, if any, with the Institution in connection with the conduct of the Study and the Investigational Product.

Investigator shall ensure that the clinical samples required to be tested during the course of the Study are tested in accordance with the Protocol and at a laboratory approved by the Sponsor.

Site agrees to provide prompt advance notice to Sponsor and IQVIA if Investigator will be leaving the Institution or is otherwise no longer able to perform the Study. The appointment of a new Investigator must have the prior approval of Sponsor and IQVIA

Investigator hereby warrants that:

a) Investigator has the necessary expertise to perform the Study. Investigator shall at all time keep Sponsor indemnified against any acts and or omissions from the Investigator.

b) Investigator is free to participate in the Study and there are no rights which may be exercised or by obligations owed to any third party which might prevent his performance of the obligations detailed in this Agreement.

c) Investigator is not involved in any regulatory or misconduct litigation or investigation by the food and drug authorities, the medicines and healthcare products regulatory agency, or other regulatory authorities in India or outside India which can affect the validity or any other way adversely affect the services provided under this Agreement. No report/ study produced by him/her in any previous clinical study has been rejected because of concerns as to its accuracy or because it was generated by fraud.

d) Investigator has considered and is satisfied that facilities to the Study are available to him/her at the Institution and that he/she is supported, and will continue to be supported, by medical and other staff of sufficient number and experience to enable Investigator to perform the Study efficiently and in accordance with his/her obligations under the Agreement.

e) Investigator carries out professional liability insurance (or the Institution carries professional liability insurance) for Study Subjects on such terms and conditions as required by the relevant rules and regulations applying for the performance of clinical studies and details and evidence of the coverage shall be provided to Sponsor and, on the Sponsor's request, to the competent ethics commission before commencement of the Study.

1.5. Adverse Events

The Site shall report adverse events and serious adverse events as directed in the Protocol and by applicable laws and regulations. The Site shall cooperate with Sponsor in its efforts to follow-up on any adverse events. The Site shall comply with its IRB/IEC reporting obligations. The Investigator shall be responsible for collating adverse events and including such data in the Study database.

Sponsor will promptly report to the Site, the Site's IRB/IEC, and IQVIA, any finding of which they become aware that could affect the safety of participants or their willingness to continue participation in the Study, influence the conduct of the Study, or alter the Site's IRB/IEC approval to continue the Study.

1.6. Use and Return of Investigational Product and Equipment

Sponsor or a duly authorized agent of Sponsor, shall supply Institution or Investigator with sufficient amount of Investigational Product as described in the Protocol.

The Site shall use the Investigational Product and any comparator products provided in connection with the Study, solely for the purpose of properly completing the Study and shall maintain the Investigational Product as specified in the Protocol and according to applicable laws and regulations, including storage in a locked, secured area at all times.

Upon completion or termination of the Study, the Site shall return or destroy, at Sponsor's option, the Investigational Product, comparator products, and materials and all Confidential Information (as defined below) at Sponsor's sole expense.

Institution and Investigator shall comply with all laws and regulations governing the disposition or destruction of Investigational Product and any instructions from IQVIA that are not inconsistent with such laws and regulations.

The Site shall return any equipment or materials (if any) provided by Sponsor for use in the Study unless Sponsor and Site have a written agreement for Site to acquire the equipment. Equipment provided to Site for the Study, if any, is listed on Attachment B hereto. If there are Site facility improvements provided by IQVIA or Sponsor in relation to the Study, then Site shall enter a separate written agreement with IQVIA s or Sponsor with respect to such facility improvements.

1.7. Enrolment of Study Subjects

Site shall not be permitted to screen potential Study Subjects, randomize Study Subjects, receive Investigational Product or receive any payment until the Effective Date of this Agreement is reached.

1.8. Key Enrolment Date

The Site understands and agrees that if Site has not enrolled at least one (1) Study Subject by the Key Enrolment Date then IQVIA may terminate this Agreement in accordance with Section 15 "Term & Termination" Sponsor/ IQVIA has the right to limit enrolment at any time.

If IQVIA requests Site's attendance at a Study start up meeting or other meeting necessary to provide information regarding the Study or Investigational Product, Site will be reimbursed for reasonable and necessary travel and lodging expenses (including meals) incurred to attend such meetings. Reimbursement will be as set forth in Attachment A.

2. PAYMENT

In consideration for the proper performance of the Study by Site in compliance with the terms and conditions of this Agreement, payments shall be made by IQVIA in accordance with the provisions set forth in Attachment A, with the last payment being made after the Site completes all its obligations hereunder, and IQVIA has received all properly completed CRFs and, if IQVIA requests, all other Confidential Information (as defined below).

3. CONFIDENTIALITY

3.1 Definition

"**Confidential Information**" means the confidential and proprietary information of Sponsor and includes (i) all information disclosed by or on behalf of Sponsor to Institution, Investigator or other Institution personnel, including without limitation, the Investigational Product, technical information relating to the Investigational Product, all Pre-Existing Intellectual Property (as defined in Section 4) of Sponsor, and the Protocol; and (ii) Study enrolment information, information pertaining to the status of the Study, communications to and from regulatory authorities, information relating to the regulatory status of the Investigational Product, and Study Data and Inventions (as defined in Section 4).

Confidential Information shall not include information that:

(i) can be shown by documentation to have been public knowledge prior to or after disclosure by Sponsor, other than through wrongful acts or omissions attributable to Investigator or Institution or any of its personnel;

(ii) can be shown by documentation to have been in the possession of Investigator, Institution or any of its personnel prior to disclosure by Sponsor, from sources other than Sponsor that did not have an obligation of confidentiality to Sponsor;

(iii) can be shown by documentation to have been independently developed by Investigator, Institution or any of its personnel; or

(iv) is permitted to be disclosed by written authorization from Sponsor.

3.2 Obligations

Site and Site's personnel, including Study Staff shall:

(i) have access to the Confidential Information on a need to know basis;

(ii) Not use Confidential Information for any purpose other than the performance of the Study; or
(iii) Not disclose Confidential Information to any third party, except as permitted by this Section 3 or by Section 5 "Publication Rights", or as required by law or by a regulatory authority or as authorized in writing by the disclosing party.

To protect Confidential Information, Site agrees to:
(i) limit dissemination of Confidential Information to only those Study Staff having a need to know for purposes of performing the Study;
(ii) advise all Study Staff who receive Confidential Information of the confidential nature of such information; and
(iii) use reasonable measures to protect Confidential Information from disclosure.

Nothing herein shall limit the right of Site to disclose Study Data as permitted by Section 5 "Publication Rights."

3.3 Compelled Disclosure
In the event that Institution or Investigator receives notice from a third party seeking to compel disclosure of any Confidential Information, the notice recipient shall provide Sponsor with prompt notice so that Sponsor may seek a protective order or other appropriate remedy. In the event that such protective order or other remedy is not obtained, the notice recipient shall furnish only that portion of the Confidential Information which is legally required to be disclosed, and shall request confidential treatment for the Confidential Information.

3.4 Return or Destruction
Upon termination of this Agreement or upon any earlier written request by Sponsor at any time, Site shall return to Sponsor, or destroy, at Sponsor's option, all Confidential Information other than Study Data.

3.5 Survival
This Section 3 "Confidentiality" shall survive termination or expiration of this Agreement for ten (10) years.

4. INTELLECTUAL PROPERTY

4.1 Pre-existing Intellectual Property
Ownership of inventions, discoveries, works of authorship and other developments existing as of the Effective Date and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "**Pre-existing Intellectual Property**"), is not affected by this Agreement, and no Party or Sponsor shall have any claims to or rights in any Pre-existing Intellectual Property of another, except as may be otherwise expressly provided in any other written agreement between them.

4.2 Inventions
For purposes hereof, the term "**Inventions**" means all inventions, discoveries and developments conceived, first reduced to practice or otherwise discovered or developed by a Party or Sponsor or any of such entity's personnel in performance of the Study. Sponsor shall own all Inventions, that are conceived, first reduced to practice or otherwise discovered or developed by the Institution, the Investigator or any of their personnel in performance of the Study.

4.3 Assignment of Inventions
Site shall, and shall cause its personnel to, disclose all Inventions promptly and fully to Sponsor in writing, and Site, on behalf of itself and its personnel, hereby assigns to Sponsor all of its rights, title and interest in and to Inventions, including all patents, copyrights and other intellectual property rights therein and all rights of action and claims for damages and benefits arising due to past and present infringement of said rights. Site shall cooperate and assist Sponsor by executing, and causing its personnel to execute, all documents reasonably necessary for Sponsor to secure and maintain Sponsor's ownership rights in Inventions.

4.4 License

Sponsor hereby grants to Institution a perpetual, non-exclusive, non-transferable, paid-up license, without right to sublicense, to use Inventions, subject to the obligations set forth in Section 3 "Confidentiality," for internal, non-commercial research and for educational purposes.

4.5 Patent Prosecution

Site shall cooperate, at Sponsor's request and expense, with Sponsor's preparation, filing, prosecution, and maintenance of all patent applications and patents for Inventions.

4.6 Survival

This Section 4 "Intellectual Property" shall survive termination or expiration of this Agreement.

5. PUBLICATION RIGHTS

5.1 Publication and Disclosure

5.1.1 The Sponsor agrees that Institution and Investigator shall be permitted to publish or present the results subject to this clause and any publication policy described in the Protocol, provided that such policy does not obstruct publication unreasonably. If it is a multi-centre trial, any publication based on result obtained at Institution (or a group of Trial Sites) shall not be made before the first multicentre publication unless otherwise agreed. If a publication concerns the analysis of subject data from a multi-centre clinical trial the publication shall make reference to relevant multi-centre publication(s).

5.1.2 Up on completion of the Study, and any prior publication of multi centre data, or when the Study Data is adequate (in Sponsor's reasonable judgement), the Investigator and Institute may prepare the data derived from the Study for publication. Such data will be submitted to the Sponsor for review and comment prior to publication. In order to ensure that the Sponsor will be able to make comments and suggestions where pertinent, material for public dissemination will be submitted to the Sponsor for a review at least thirty (30) days prior to submission for publication, public dissemination, or review by publication committee.

5.1.3 Institution and Investigator agree that all reasonable comments made by the Sponsor in relation to a proposed publication will be incorporated into the publication.
During the period for a review of proposed publication in clause 5.1.2 above, the Sponsor shall be entitled to make reasoned request to the Institution and Investigator that publication be delayed for a period of three (3) months from the date of first submission to the Sponsor in order to enable the Sponsor to take steps to protect its proprietary information/or intellectual rights and knowhow and Institute and Investigator shall not unreasonably withhold its consent to such request The Investigator, Institution as well as the SMO shall not issue a press release that references any Protocol or Study conducted by Sponsor, or that uses Sponsor's name or trademarks.

5.2 Confidentiality of Unpublished Data

Institution and Investigator acknowledges and agrees that Study Data that is not published, presented or otherwise disclosed in accordance with Section 5.1 or Section 5.2 ("**Unpublished Data**") remains within the definition of Confidential Information, and Institution and Investigator shall not, and shall require their personnel not to, disclose Unpublished Data to any third party or disclose any Study Data to any third party in greater detail than the same may be disclosed in any publications, presentations or disclosures made in accordance with Section 5.1 or Section 5.2.

5.3 Media Contacts

Institution and Investigator shall not, and shall ensure that its personnel do not engage in interviews or other contacts with the media, including but not limited to newspapers, radio, television and the Internet, related to the Study, the Investigational Product, Inventions, or Study Data without the prior written consent of Sponsor. This provision does not prohibit publication or presentation of Study Data in accordance with this Section.

5.4 Use of Name, Registry and Reporting

No Party hereto shall use any other Party's name, or Sponsor's name, in connection with any advertising, publication, promotion or news/press release without prior written permission, except that the Sponsor and IQVIA may use the Site's name in Study publications and communications, including clinical trial websites and Study newsletters. Sponsor will register the Study with a public clinical trials registry in accordance

with applicable laws and regulations and will report the results of the Study publicly when and to the extent required by applicable laws and regulations.

5.5 Survival

This Section 5 "Publication Rights" shall survive termination or expiration of this Agreement.

6. PERSONAL DATA

6.1 Study Team Member Personal Data

Both prior to and during the course of the Study, the Investigator and his/her teams may be called upon to provide personal data. This data falls within the scope of the law and regulations relating to the protection of personal data.

For the Investigator, this personal data may include names, contact information, work experience and professional qualifications, publications, resumes, educational background and information related to potential Dual Capacity conflict of interest, and payments made to Payee(s) under this Agreement for the following purposes:

(i) the conduct of clinical trials;
(ii) verification by governmental or regulatory agencies, the Sponsor, IQVIA, and their agents and affiliates;
(iii) compliance with legal and regulatory requirements;
(iv) publication on www.clinicaltrials.gov and websites and databases that serve a comparable purpose;
(v) storage in databases to facilitate the selection of investigators for future clinical trials; and
(vi) anti-corruption compliance.

Names of members of Study Staff may be processed in IQVIA" study contacts database for study-related purposes only.

6.2 Study Subject Personal Data

The Investigator shall obtain Study Subject written consent for the collection and use of Study Subject personal data for Study purposes, including the disclosure, transfer and processing of data collected in accordance with the Protocol, in compliance with applicable data protection provisions. The Investigator shall indemnify Sponsor against any claims arising from any breach by the Investigator or the Institution or the SMO of this Clause.

6.3 Data Controller

The Sponsor shall be the data controller for such personal data except that, if IQVIA deals with any personal data under this Agreement in the manner of a data controller, IQVIA shall be the data controller of such personal data to the extent of such dealings.

IQVIA may process "**personal data**", as defined in the applicable data protection legislation enacted under the same or equivalent/similar national legislation (collectively "**Data Protection Legislation**"), of the Investigator and Study Staff for study-related purposes and all such processing will be carried out in accordance with the Data Protection Legislation.

6.4 Survival

This Section 6 "Personal Data" shall survive termination or expiration of this Agreement.

7. STUDY SUBJECT INJURY

The Site shall promptly notify IQVIA and Sponsor in writing of any claim of illness or injury or death actually or allegedly due to an adverse reaction to the Investigational Product and cooperate with Sponsor in the handling of the adverse event.

Sponsor shall reimburse Institution for the direct, reasonable and necessary medical expenses incurred by Institution for the treatment of any adverse event experienced by, illness of or bodily injury to a Study Subject that is caused by treatment of the Study Subject in accordance with the Protocol, except to the extent that such adverse event, illness or personal injury is caused by:
(a) failure by Institution, Investigator or any of their respective personnel to comply with this Agreement, the Protocol, any written instructions of Sponsor concerning the Study, or any applicable law, regulation or guidance, including GCPs, issued by any regulatory authority, or
(b) negligence or wilful misconduct by Institution, Investigator or any of their respective personnel, or
(c) failure of the Study Subject to follow the reasonable instructions of the Investigator relating to the requirements of the Study.

This Section 7 "Study Subject Injury" shall survive termination or expiration of this Agreement.

8. IQVIA DISCLAIMER

IQVIA expressly disclaims any liability in connection with the Investigational Product, including any liability for any claim arising out of a condition caused by or allegedly caused by any Study procedures associated with such product except to the extent that such liability is caused by the negligence, wilful misconduct or breach of this Agreement by IQVIA.

This Section 8 "IQVIA Disclaimer" shall survive termination or expiration of this Agreement.

9. INDEMNITY

9.1 The Investigator shall indemnify Sponsor, its directors, officers, and employees (hereinafter collectively "**Sponsor Representatives**") for any and all damages, costs, expenses and other liabilities, including reasonable attorney's fees and court costs, incurred in connection with any third party (including the relevant regulatory/statutory authority and government/semi-government bodies) claim, action or proceeding or otherwise arising from the following :

(a) Investigator's negligence, malpractice, misconduct, improper acts or omissions of the Investigator and/or the employees or agents of the Investigator in the performance of Investigator's obligations hereunder or the instructions of the Sponsor;
(b) Non adherence or breach of any applicable law or non-compliance in accordance with the Agreement;
(c) deviation from the Protocol;
(d) unauthorized use of IMP.

9.2 Sponsor shall indemnify the Institution and its directors, trustees, authorized representatives and employees including the staff (collectively the Indemnitees) for any and all damages, costs, expenses and other liabilities, including reasonable attorney's fees and court costs, incurred in connection with any third party (including the relevant regulatory/statutory authority and government/semi-government bodies) claim, action or proceeding or otherwise arising by reason of personal injury, including death, to any person caused by or allegedly caused by the investigational medicinal product used in the Study, except where such claim has arisen from events mentioned in clause 9.1 (a) to 9.1 (d).

10. CONSEQUENTIAL DAMAGES

Neither IQVIA nor Sponsor shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages, nor shall Site be responsible to IQVIA or Sponsor for any lost profits, lost opportunities, or other consequential damages, except as stated below.

This Section 10 "Consequential Damages" shall survive termination or expiration of this Agreement.

11. DEBARMENT

The Site represents and warrants that neither Institution nor Investigator, nor any of Institution's or Investigator's employees, agents or other persons performing the Study at Institution, have been debarred, disqualified or banned from conducting clinical trials or are under investigation by any regulatory authority for debarment or any similar regulatory action in any country, and the Site shall notify IQVIA immediately if any such investigation, disqualification, debarment, or ban occurs.

This Section 11 "Debarment" shall survive termination or expiration of this Agreement.

12. FINANCIAL DISCLOSURE AND CONFLICT OF INTEREST

Upon Sponsor's or IQVIA request, Site agrees that, for each listed or identified investigator or sub-investigator who is directly involved in the treatment or evaluation of Study Subjects, it shall promptly return to IQVIA a financial and conflict of interest disclosure form that has been completed and signed by such investigator or sub-investigator, which shall disclose any applicable interests held by those investigators or sub-investigators or their spouses or dependent children.

IQVIA may withhold payments if it does not receive a completed form from each such investigator and sub-investigator.

Site shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one (1) year after Study completion.

Site agrees that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, IQVIA, and their agents, and the Site consents to such review.

The Site further consents to the transfer of its financial disclosure data to the Sponsor's country of origin and to the U.S., even though data protection may not exist or be as developed in those countries as in the Site's own country.

This Section 12 "Financial Disclosure and Conflict of Interest" shall survive termination or expiration of this Agreement.

13. ANTI-KICKBACK AND ANTI FRAUD

Institution and Investigator agree that their judgment with respect to the advice and care of each Study Subject will not be affected by the compensation they receive from this Agreement, that such compensation does not exceed the fair market value of the services they are providing, and that no payments are being provided to them for the purpose of inducing them to purchase or prescribe any drugs, devices or products.

If the Sponsor or IQVIA provides any free products or items for use in the Study, Institution and Investigator agree that they will not bill any Study Subject, insurer or governmental agency, or any other third party, for such free products or items.

Institution and Investigator agree that they will not bill any Study Subject, insurer, or governmental agency for any visits, services or expenses incurred during the Study for which they have received compensation from IQVIA or Sponsor, or which are not part of the ordinary care they would normally provide for the Study Subject, and that neither Institution nor Investigator will pay another physician to refer subjects to the Study.

14. ANTI-BRIBERY

Institution and Investigator agree that the fees to be paid pursuant to this Agreement represent fair compensation for the services to be provided by Site. Institution and Investigator represent and warrant that payments or Items of Value received pursuant to this Agreement or in relation to the Study will not influence

any decision that Institution, Investigator or any of their respective owners, directors, employees, agents, consultants, or any payee under this Agreement may make, as a Government Official or otherwise, in order to assist Sponsor or IQVIA to secure an improper advantage or obtain or retain business.

Institution and Investigator further represent and warrant that neither they nor any of their respective owners, directors, employees, agents, or consultants, nor any payee under this Agreement, will, in order to assist Sponsor or IQVIA to secure an improper advantage or obtain or retain business, directly or indirectly pay, offer or promise to pay, or give any Items of Value to any person or entity for purposes of (i) influencing any act or decision; (ii) inducing such person or entity to do or omit to do any act in violation of their lawful duty; (iii) securing any improper advantage; or (iv) inducing such person or entity to use influence with the government or instrumentality thereof to affect or influence any act or decision of the government or instrumentality.

In addition to other rights or remedies under this Agreement or at law, IQVIA may terminate this Agreement if Site breaches any of the representations or warranties contained in this Section or if IQVIA or Sponsor learns that improper payments are being or have been made to or by Institution or Investigator or any individual or entity acting on its or their behalf.

15. INDEPENDENT CONTRACTORS

The Investigator and Institution and Study Staff are acting as independent contractors of IQVIA and Sponsor and shall not be considered the employees or agents of IQVIA or Sponsor.

Neither IQVIA nor Sponsor shall be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Investigator or Institution or their staff.

16. TERM & TERMINATION

16.1 Term

This Agreement will become effective on the date of approval of the Study by Drugs Controller General India or the date on which it is last signed by the parties, whichever is later (the "**Effective Date**") and shall continue until completion or until terminated in accordance with this Section 15 "Term & Termination". IQVIA shall attach a copy of the approval from the Drugs Controller General India approving the Study to this Agreement as Attachment B, and the Parties agree that such approval shall be incorporated by reference herein. If such approval has not been received as of the date the Parties sign this Agreement, IQVIA shall keep the original signed Agreements until receipt of such approval, and upon receipt of such approval, IQVIA shall attach a copy of the approval to each original Agreement as Attachment B and forward an original Agreement to each other Party thereafter, while retaining one original Agreement in its files. If such approval was received prior to the signatures of the Parties, IQVIA shall attach a copy of the approval hereto as Attachment B, and upon signature of all Parties, each Party shall receive an original of the Agreement, which shall include such approval as Attachment B.

16.2 Termination

IQVIA may terminate this Agreement for any reason effective immediately without any onus or additional remuneration upon written notice. The Site may terminate upon written notice if circumstances beyond the Site's reasonable control prevent completion of the Study, or if it reasonably determines that it is unsafe to continue the Study. Upon receipt of notice of termination, the Site shall immediately cease any subject recruitment, follow the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs, and IQVIA shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in Attachment A; provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all CRF pages and all data clarifications issued and satisfaction of all other applicable conditions set forth herein. If a material breach of this Agreement appears to have occurred and termination may be required, then, except to the extent that Study Subject safety may be

jeopardized, IQVIA may suspend performance of all or part of this Agreement, including, but not limited to, subject enrolment.

16.3 Consequences of Termination

In the event this Agreement is prematurely or orderly terminated, Site shall provide IQVIA with all Study data including any work product, final result report and CRF in relation to the Study relating to the period from the commencement of the Study until termination of the Agreement. The Investigator reserves a right to retain one copy of all the material as the result of the Services performed, which will remain subject to the confidentiality provisions herein, and to be used only if a dispute arises regarding the Services performed by the Investigator hereunder.

17. NOTICE

Any notices required or permitted to be given hereunder shall be given in writing and shall be delivered
(a) in person,
(b) by certified mail, postage prepaid, return receipt requested,
(c) by e-mail of .pdf/scan or other non-editable format notice with confirmed transmission report, or
(d) by a commercial overnight courier that guarantees next day delivery and provides a receipt, and such notices shall be addressed as follows:

To Sponsor:	Name: Dr. Deepa Joshi, Vice President, Discovery Research & Clinical Development Address: Torrent Research & Development Centre, Ahmedabad-Gandhinagar Highway, Bhat P.O., Gandhinagar, Gujarat - 382 428 Tel: +91 079 23969100
To IQVIA	Name: Kapil Jhawar Sr. Clinical Project Manager Address: IQVIA RDS (India) Private Limited (formerly Quintiles Research (India) Private Limited)having its office at B-101-106, Shapath IV, Opp. Karnavati Club, S G Road, Ahmedabad- 380 051, India
To Institution	Name: Mahatma Gandhi Mission's Medical College and Hospital
To Investigator	Name: Dr. Bhosale Deepak Sadashiv Address: Mahatma Gandhi Mission's Medical College and Hospital, N-6 CIDCO, Aurangabad-431003, Maharashtra, India

18. FORCE MAJEURE

The performance by either Party of any obligation on its part to be performed hereunder shall be excused by floods, fires or any other Act of God, accidents, wars, riots, embargoes, delay of carriers, inability to obtain materials, failure of power or natural sources of supply, acts, injunctions, or restraints of government or other force majeure preventing such performance, whether similar or dissimilar to the foregoing, beyond the reasonable control of the Party bound by such obligation, provided, however, that the Party affected shall exert

its reasonable efforts to eliminate or cure or overcome any of such causes and to resume performance of its obligations with all possible speed.

19. MISCELLANEOUS

19.1 Entire Agreement

This Agreement, including its attachment(s), constitutes the sole and complete agreement between the Parties and replaces all other written and oral agreements relating to the Study.

Any change in the terms of this Agreement shall be valid only if the changes are made in writing, agreed and signed by the Parties.

19.2 No Waiver/Enforceability

Failure to enforce any term of this Agreement shall not constitute a waiver of such term.

If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect.

19.3 Assignment of the Agreement

This Agreement shall be binding upon the Parties and their successors and assigns.

The Site shall not assign or transfer or subcontract any rights or obligations under this Agreement without the written consent of IQVIA and Sponsor.

Upon Sponsor's request, IQVIA may assign this Agreement to Sponsor or to a third party, and IQVIA shall not be responsible for any obligations or liabilities under this Agreement that arise after the date of the assignment, and the Site hereby consents to such an assignment. Site will be given prompt notice of such assignment by the assignee.

19.4 Third Party Beneficiary

The Parties agree that Sponsor shall have the right to enforce any of the provisions of this Agreement as a third party beneficiary.
Each Party to this Agreement acknowledges that except for the Sponsor, there are no third party beneficiaries with any rights to enforce any of the provisions of this Agreement.

19.5 Applicable Law and Dispute Resolution

This Agreement shall be interpreted under the laws of the state or province and country in which Site conducts the Study.

Any dispute arising out of or in connection with this Agreement will be finally settled through courts of the state or province in which the Site, is located.

19.6 Survival:

The terms of this Agreement that contain obligations or rights that extend beyond the completion of the Study shall survive termination or completion of this Agreement, even if not expressly stated herein.

THIS SECTION IS INTENTIONALLY LEFT BLANK

ACKNOWLEDGED AND AGREED BY IQVIA RDS (INDIA) PRIVATE LIMITED (FORMERLY QUINTILES RESEARCH (INDIA) PRIVATE LIMITED):

By: Tanuka Ganguly

Title: Director, Site and Patient Networks

Signature: Tanuka Ganguly

Date: 17/Jan/2019

ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:

By: Dr. Bhosale Deepak Sadashiv

Title: Principal Investigator

Signature: _____

Date: 21/Jan/2019

ACKNOWLEDGED AND AGREED BY Mahatma Gandhi Mission's Medical College and Hospital
By: Dr. Rajendra Bohra

Title: DEAN

Signature: _____ 21/01/2019.

Date: _____

M.G.M.'s Medical College Aurangabad

ATTACHMENT A
BUDGET & PAYMENT SCHEDULE

PAYMENT TERMS

A. PAYEE DETAILS

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

Payee Name	MGM Medical College
Payee Address	Mahatma Gandhi Mission's Medical College and Hospital N-6 CIDCO, Aurangabad-431003, Maharashtra, India
Email Address	mgmmca@themgmgroup.com
Bank Name	IDBI Bank
Bank Account IBAN Number or branch number	0376104000000
IFSC Code	IBKL0000376
GST Registration Number	Not Applicable
VAT/GST/Tax ID Number	Pan Number: AAATM4256E
PAYMENT METHOD	Electronic Fund Transfer

In case of changes in the Payee's bank details, Site is obliged to inform IQVIA in writing. The parties agree that in case of changes in bank details which do not involve a change of Payee/Bank Account Name or change of country location of bank account, no further amendments are required.

The Parties acknowledge that the designated Payee is authorized to receive all of the payments for the services performed under this Agreement.

If the Investigator is not the Payee, then the Payee's obligation to reimburse the Investigator, if any, is determined by a separate agreement between Investigator and Payee, which may involve different payment amounts and different payment intervals than the payments made by IQVIA to the Payee.

Investigator acknowledges that if Investigator is not the Payee, IQVIA will not pay Investigator even if the Payee fails to reimburse Investigator.

B. PAYMENT DISPUTE

Site will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

C. PAYMENT TERM

IQVIA will pay the Payee monthly (or every three (3) months), on a completed visit per subject basis in accordance with the attached budget. Ninety percent (90%) of each payment due, including any Screening Failure that may be payable under the terms of this Agreement, will be made based upon prior month (or prior 3 months) enrolment data confirmed by subject CRFs received from the Site and data verification supporting subject visitation

The balance of monies earned, up to ten percent (10%), will be pro-rated upon verification of actual subject visits, and will be paid by IQVIA to the Payee upon final acceptance by Sponsor of all CRFs pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by IQVIA and/or Sponsor, the return of all unused supplies to IQVIA, and upon satisfaction of all other applicable conditions set forth in the Agreement.

Any expense or cost incurred by Site in performing this Agreement that is not specifically designated as reimbursable by IQVIA or Sponsor under the Agreement (including this Budget and Payment Schedule) is Site's sole responsibility

Subject to the provisions of the following paragraph, neither IQVIA nor Sponsor shall be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Site.

IQVIA is obligated to, and will withhold tax, as applicable, in accordance with Country Name tax laws, as amended from time to time.

Site shall be responsible 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 that relate to the Investigator, the Institution and its employees and/or collaborators.

Site represents that the services it provides under this Agreement are taxable services under the laws governing Good and Services tax ("**GST**") in India, and that it is required to charge GST for the services rendered to IQVIA at the prevailing rate. Site represents that it is entitled to require such payment of the GST under the laws of India. Site undertakes to provide IQVIA with an invoice, to be sent to IQVIA at the address mentioned in Section F of this Attachment A, in respect of such taxable services and such invoice shall be in accordance with the applicable legislation as may be amended from time to time or any successor legislation.

All amounts specified in this Agreement are in Indian Rupees (INR) and are inclusive of all overhead fees. For the avoidance of doubt, overhead fees include any applicable overhead fees.

Major, disqualifying Protocol violations are not payable under this Agreement

D. DISCONTINUED OR EARLY TERMINATION

Reimbursement for discontinued or early termination subjects will be prorated based on the number of confirmed completed visits.

E. INVOICES

Original Invoices pertaining to this Study for the following items must be submitted to IQVIA for reimbursement at the following address:

IQVIA RDS (India) Private Limited (formerly Quintiles Research (India) Private Limited), Bangalore
Attn: **Finance PSC – Accounts Payable (Investigator Payments)**
Address:
III Floor, Etamin Block,
Prestige Technology Park,
Sarjapur - Marathahalli Outer Ring Road
Bangalore – 560103, India

Please note that invoices will not be processed unless they reference the Sponsor name, Protocol number, Investigator name, Site number and Payee GST registration number. Upon receipt and verification of the invoices, reimbursement for invoices will be included with the next regularly scheduled payment.

F. EC/IRB/IEC FEES

EC/IRB/IEC costs will be reimbursed on a pass-through basis upon receipt of a formal invoice issued by the EC/IRB/IEC and are not included in the attached Budget. Payment will be made directly to the EC/IRB/IEC. Any subsequent re-submissions or renewals, upon approval by IQVIA and Sponsor, will be reimbursed upon receipt of appropriate documentation.

G. **H. MEETING ATTENDANCE: [IF SITE'S ATTENDANCE IS NOT REQUIRED AT A STUDY MEETING, BE SURE IT'S STATED EXPLICITLY]** Necessary travel and lodging expenses (including meals) incurred by the Site when attending Study start up meetings or other meetings necessary to provide information regarding the Study or Investigational Product will be reimbursed on a pass-through basis upon receipt of supporting invoices from a third party vendor.

- **RECORD STORAGE FEE**
  A record storage payment will be made to Site at the completion of the Study subject to receipt of a document storage quotation and upon Sponsor/CRO approval. The record storage fee will not be provided in the event where a third party vendor has been contracted by Sponsor to perform record storage.

  In accordance with Sponsor's Protocol requirements, Institution shall maintain all Site Study records in a safe and secure location to allow easy and timely retrieval, when needed.

- **SCREENING FAILURE**

  Reimbursement for screen failures will not exceed Five (5) screen failure(s) paid per One (1) subject randomized.

  To be eligible for reimbursement of a screening visit, completed screening CRF pages must be submitted to IQVIA along with any additional information, which may be requested by IQVIA to appropriately document the subject screening procedures.

NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED

All payments for this Study in accordance with the attached budget will be paid by IQVIA by wire transfer.

H. **MINIMUM ENROLMENT GOAL**

Site acknowledges that Site's minimum enrolment goal is **30** subjects and that Site will use best efforts to reach the enrolment goal within a reasonable time after commencement of the Study at Site. If Site fails to adhere to this principle IQVIA may reconsider Site's suitability to continue participation in the Study.

I. **BUDGET TABLE**

VISIT	*AMOUNT (INR) (INCLUSIVE OF OVERHEAD 25%)
SCR	10315
D0	5416
W4	7898
W12	10257
W24	10257
W36	7898
W50	7712
FUP	8239
TOTAL COST PER PATIENT	**67992**

The cost per patient is inclusive of patient travel expense.

UNSCHEDULED VISIT PROCEDURES Unscheduled visits should only take place if there is an immediate risk to subject safety, or in the event that the additional visit is pre-approved by IQVIA in writing, and not to exceed 2 visits per subject per visit. To be eligible for reimbursement for unscheduled visits, completed CRF pages

must be submitted to IQVIA within 5 days of visit with any additional information which may be requested by IQVIA to appropriately document the subject visit.

PROCEDURES	AMOUNTS (Inclusive of Overhead 25%)
Patient Reimbursement, Expenses, Patient Travel - Per Visit	500
Office or other outpatient visit for the evaluation and management of an established patient, which requires at least 2 of these key components: A comprehensive history; A comprehensive physical examination; Vital signs, weight, height; Medical decision making of high complexity.	2297
Vital signs, weight, height	342
12-lead ECG: Includes tracing, interpretation and report	186
Combined: Blood Draw, venipuncture, phlebotomy specimen collection with lab handling and shipping; Simple	279
Collection of specimen; urine, urine collection	62
Ambulatory blood pressure monitoring, 24 hours or longer (AMBP) (ABPM); utilizing a system such as magnetic tape and/or computer disk: Includes recording, scanning analysis, interpretation and report	2359

ATTACHMENT B
EQUIPMENT (*optional*)

The Site will be supplied with/ by:
• Ambulatory Blood Pressure Monitoring machine (ABPM)

All materials and equipment provided ("Equipment") by the Sponsor or IQVIA /vendors contracted by the Sponsor shall remain the sole property of the Sponsor/ IQVIA /vendor, as the case may be.

Therefore, it is hereby agreed that such Equipment shall:
a) be subject to removal at any time upon the Sponsor's or, IQVIA' demand provided that such removal does not prevent the Site from conducting the Study and carrying out their obligations under this Agreement;
b) be used only for the purposes of the Study;
c) be used in accordance with any manuals or instructions while in possession of the Site;
d) shall remain in the same condition, ordinary wear and tear excepted. As long as the Equipment are in the possession of the Site, it is liable for maintenance or any risk of loss in connection with the Equipment during the conduct of the Study;
e) be clearly identified as the sole property of the Sponsor/ IQVIA /vendor, as applicable, by clearly stating "BELONGS TO "Name of legal owner" in order to notify any third parties, including creditors, that the legal owner retains title thereto; and
f) upon completion or termination of the Study, IQVIA, together with Site assistance, shall arrange the return of all equipment provided for the Study within one (1) month of request to return, or if requested by the Sponsor or IQVIA in writing, arrange for the disposal of the Equipment as soon as reasonably practicable.

ATTACHMENT C
APPROVAL LETTER