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Certificate of Stamp Duty

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Certificate Issued Date	:	18 Aug 2020 10.40 AM
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Unique Doc. Reference	:	SUBIN-GJGJ13207711878006563525995
Purchased by	:	CADILA PHARMACEUTICAL LTD
Description of Document	:	Article 5(h) Agreement (not otherwise provided for)
Description	:	Not Applicable
Consideration Price (Rs.)	:	0 (Zero)
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Stamp Duty Amount(Rs.)	:	300 (Three Hundred only)

THIS E-STAMP CERTIFICATE FORMS AN INTEGRAL PART OF THIS CLINICAL TRIAL AGREEMENT DATED 18th August, 2020 BY AND BETWEEN

1) CADILA PHARMACEUTICALS LTD.
2) DR. D. HIMANSHU
3) KING GEORGE'S MEDICAL UNIVERSITY

R.P. ASTIK ADVOCATE & NOTARY GULBAI TEKRA BRANCH

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VOID

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CLINICAL TRIAL AGREEMENT

This CLINICAL TRIAL AGREEMENT ("Agreement") is made effective as on this 18th August 2020 (the Effective Date);

Cadila Pharmaceuticals Ltd., a Company incorporated under the Companies Act 1956, having its registered office at "Cadila Corporate Campus", Sarkhej – Dholka Road, Bhat, Dist. Ahmedabad and it's Contract Research Operations Division (hereinafter referred to as "Cadila CRO") situated at, 1389, Trasad Road, Dholka-382225, Dist: Ahmedabad, Gujarat, India.

And

Dr. D. Himanshu, as the Investigator at the Institution, working **Department of Medicine, King George's Medical University, Shahmeena Road, Chowk, Lucknow-226003**(hereinafter the "Investigator") of the SECOND PART;

And

King George's Medical University, Shahmeena Road, Chowk, Lucknow-226003 represented by it Faculty In-charge (hereinafter the "Institution"), which term unless repugnant to the context and meaning thereof be deemed to include its affiliates, successors, assigns and legal representatives of the THIRD PART

'Cadila CRO, 'Institution' and 'Investigator' hereinafter are collectively referred to as the "Parties" and individually as the "Party".

Recitals

A. WHEREAS, CPL is a renowned pharmaceutical company of India and engaged in the development, manufacturing and marketing of pharmaceutical and allied products.

WHEREAS Cadila CRO, intends to conduct a multi-center clinical study of Ashwagandha for the Prophylaxis against SARS-CoV-2 Infection: A Randomized Hydroxychloroquine Controlled Clinical Trial in Health Care Providers (hereinafter referred to as "Clinical Study").

B. WHEREAS, the Institution has represented that it has appropriate facilities, personnel and other resources and the Investigator (as defined above) having the requisite qualification, training, knowledge and experience necessary to conduct the above said clinical study and laboratory test evaluations.

NOW THEREFORE, in consideration of the mutual covenants contained in this Agreement, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:

1. Scope of Work.

1.1 The Investigator agrees to conduct the Clinical Study subject to the terms of this Agreement, Protocol Number (AYUSH-CSIR-HCP-01) the "Ashwagandha for the Prophylaxis against SARS-CoV 2 Infection: A Randomized Hydroxychloroquine Controlled Clinical Trial in Health Care Providers"), which shall be deemed to have been incorporated by reference to this clause and the investigator's brochure for the investigational Product (the "Investigator's Brochure") provided by the Cadila CRO, under Investigational New Drug (IND) applications filed with the Drugs Controller General of India (DCGI). The Investigator agrees to conduct the Clinical Study strictly in accordance with the Protocol approved by the local Ethics Committee as amended from time to time. Investigator will conduct the Study in strict accordance with the terms and conditions of this Agreement, the Protocol and any amendments thereto, and in compliance with all federal, state and local laws and regulations as applicable to the territory in which the Study is being conducted including but not limited to (a) The revised and applicable versions of the Declaration of Helsinki Directive, as amended from time to time; (b) New Drug Clinical Trial Regulations, 2019 , as amended from time to time, (b) the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use Topic E6 Guidelines on Good Clinical Practice and Directive 75/318/EEC, as amended from time to time ("ICH-GCP"); (c) all regulations and laws as applicable to clinical trials in India (d) the Prevention of Corruption Act, 1988. The Clinical Trial Annual report to be submitted to Ethics Committee every year

2. The Investigator.

2.1 For sake of clarity, the Investigator is an employee of Institution and will be named in Appendix A. The Investigator represents and certifies to have read and understand the Investigator's Brochure. Prior to the commencement of the Clinical Study, the Investigator shall deliver to Cadila CRO true, complete and correct copies of the Investigator's statement as mentioned in New Drug Clinical Trial Regulations, 2019 , as amended from time to time and curriculum vitae, each of which shall be signed by the Investigator. During the Clinical Study, the Institution shall immediately notify Cadila CRO in writing at such time as it becomes aware that the Investigator plans to leave the Institution or shall be unable to complete the Clinical Study. If the Institution and Cadila CRO are unable to agree on an acceptable substitute investigator within fifteen (15) business days following such notice, Cadila CRO may terminate this Agreement pursuant to Section 16.

3. Representations and Covenants.

3.1 The Institution and (to the extent that such representations and covenants relate to the Investigator) the Investigator each represents certifies and covenants to Cadila CRO, as follows

(a) The Investigator is, and at all times during the course of the Study shall be, qualified by training and experience with appropriate expertise to conduct the Study,

(b) The Institution and the Investigator have, and at all times during the course of the Clinical Study shall have, the appropriate licenses, approvals and certifications necessary to safely, accurately and lawfully perform the Clinical Study;

(c) None of the Institution, the Investigator, or any other person who assists in performing the Clinical Study is subject to any conflicting obligations or has any financial or other interest in the outcome of the Clinical Study or has entered into any contract with respect to the Clinical Study that might interfere with the performance of the Clinical Study or that might impair the

acceptance of the resulting data by the regulatory authority or that might create a conflict of interest;

(d) The Institution and the Investigator have been selected to conduct the Clinical Study because of their experience, expertise and resources and not, in any way, as an inducement to, or in return for, past, present or future prescribing, purchasing, recommending, using, dispensing or granting preferential formulary status for any Cadila CRO's Product.

4. Facilities.

4.1 The Institution and the Investigator shall conduct the Clinical Study at the facilities situated as mentioned first herein and identified above, or such other facilities as Cadila CRO and the Institution may agree in writing, The Institution shall make available it's personnel, facilities and resources as may be necessary to perform its obligations efficiently and expeditiously under this Agreement.

5. Subject Enrollments and Informed Consent

5.1 Subject Enrollment: The Investigator shall enroll such nos. of subjects into the Clinical Study as mentioned in Appendix A annexed herewith and forming integral part of this Agreement (each, a **"Subject"**). The Investigator shall use all reasonable efforts to complete enrollment of all Subjects by Enrollment Closing Date set forth in Appendix A or otherwise by such other date as may be notified in writing to the Investigator by Cadila CRO. The Study period may be extended or shortened and the number of Subjects the Institution/Investigator may enroll in the Clinical Study may be changed at Cadila CRO's sole discretion. The Institution/Investigator acknowledges that the Clinical Study is part of the Multi-Center Study, and agrees that when the enrollment goal for the Multi-Center Study as a whole is reached, enrollment will be closed at all sites, including the Institution, regardless of whether the Institution or any other site has reached its individual enrollment goal.

5.2 Informed Consent: The Investigator shall obtain the informed consent form of each Subject prior to any screening or participation in the Clinical Study using the Informed Consent Materials (as defined in Section 7.6) and in compliance with Applicable Laws. Each Subject shall complete an informed consent form that has been reviewed and approved in advance by IEC of the Institution in compliance with the requirements of applicable laws. Investigator has to ensure that the Informed Consent is only voluntary and the study participant has the rights to withdraw from the trial at any time during the Clinical Study.

5.3 Investigator shall report any death, life threatening, or serious adverse event, or other event as specified by the Protocol to the Institutional Ethics Committee with a copy to Cadila CRO. Such notification shall be given promptly, and in no instance later than 24 (twenty-four) hours of occurrence of such an event and shall be made in accordance with New Drug Clinical Trial Regulations, 2019 , as amended from time to time and the procedures outlined in the Protocol concerning the reporting of adverse events.

5.4 Compensation. In consideration of the services to be rendered hereunder by the Institution and Investigator, Cadila CRO shall pay to the Institution such amounts in a manner stipulated in the payment schedule set forth in Annexure – A of Appendix A annexed herewith and forming an integral part of this Agreement. The parties acknowledge that the amounts to be paid by Cadila CRO under this Agreement are reasonable compensation for the work performed and that neither the Institution nor the Investigator has received any other compensation or other inducement in connection with this Agreement for its participation in the Clinical Study. Any amounts, if any, paid by Cadila CRO to the Institution for services that have not been performed, or expenses that have not been incurred, under this Agreement shall be promptly refunded to Cadila CRO upon the completion of the Clinical Study or expiration or termination of this Agreement, or earlier at the written request of Cadila CRO except with respect to those expenses reimbursable under Sections 14.2. The Institution acknowledges and agrees that the

payments made by the Cadila CRO under this Section represent Cadila CRO's total monetary obligations under this Agreement, and fully cover the costs of conducting the Clinical Study. Accordingly, the Institution shall not submit claims to, or otherwise seek reimbursement from any other third party paid or, whether public or private, for any costs covered by payments made or goods or services provided by Cadila CRO under this Agreement or otherwise incurred for conducting the Clinical Study. Cadila CRO shall ensure compensation for the SAE period over and above covering / reimbursement of the research injury due to SAE as per protocol specifications read with New Drug Clinical Trial Regulations, 2019, as amended from time to time.

5.5 In the event INVESTIGATOR screens and/or enrolls very few patients, through no fault of the Cadila CRO, Cadila CRO may close enrollment at the Institution without liability thereof. If circumstances or events have occurred or will occur that will substantially delay or are likely to substantially delay the progress of recruitment or enrolment of the Subjects, the Institution shall immediately inform the Cadila CRO in writing. In each such event, the Parties shall discuss the consequences of the delay and if reasonable, as determined by Cadila CRO, each Party shall undertake reasonable endeavors to agree on measures to overcome such a delay.

6. Ownership and Control of Study Drug.

6.1 All Study Drug supplied to the Institution shall remain the exclusive property of CSIR-AYUSH (**hereinafter** referred to as "**Sponsor**") until administered or dispensed to Subjects during the course of the Clinical Study. The Study Drug shall only be used for the purpose and manner as described in the Protocol and in compliance with Applicable Laws. Upon termination or completion of the Clinical Study, the Institution shall, at Sponsor's direction and expense, either return to Sponsor or Cadila CRO or dispose of any quantities of unused Clinical Study Drug, in accordance with Cadila CRO's written instructions. The Institution shall maintain complete and accurate records relating to the disposition of the Study Drug supplied to the Institution as set forth in Section 7.1.

6.2 Institution shall own all original hospital records, clinical and office charts, laboratory notes, evaluation checklists developed by Institution, pharmacy dispensing records, recorded data from automated instruments, copies or transcriptions certified after verification as being accurate copies, photographic negatives, microfilm or magnetic media, x-rays, CT scans, MRI scans, PET scans, ultrasounds, subject files, and records kept at the pharmacy, at the laboratories involved in the Clinical Study in accordance with Applicable Law (collectively, "Source Documents"); however, Institution shall bound to provide the source documents to Cadila CRO as and when demanded by it for the purpose of evaluation and records of the study and its outcome, or any other reason.

7. Records; Reports; and Regulatory Assistance.

7.1 <u>Study Documentation</u>: The Institution and the Investigator shall be jointly liable to prepare, maintain and retain complete, current, accurate, organized and legible Study Documentation in a manner acceptable for the collection of data for submission to, or review by regulatory or governmental authorities, and in full compliance with the Protocol and all Applicable Laws. However, on a case-by-case basis, Cadila CRO may at its sole expense request, in writing, longer periods of retention times for Study Documentation. For purposes of this Agreement, "Study Documentation" includes all records (related to the Study Drug or Protocol), accounts, notes, reports and data, collected, generated or used in connection with the Study, whether in written, electronic, video or other tangible form, including all records, original observations and notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the Clinical Study. The Investigator or designee will conduct data entry activities, which shall include entry of Subject data after Subject visit within 3 working days after a visit and Investigator shall respond to all data queries within 7 (seven) days from the date of such request.

The CRF instructions will also provide the Study site with data entry instructions. A duplicate copy of the CRF will be archived at the Study site for 15 years after the study completion.

7.2 The Cadila CRO will review the facilities at the Site to ensure adequate infrastructure required for Clinical Study at the site. INVESTIGATOR shall ensure that the Institution shall maintain at all time an adequate facilities for the duration of the Study (i.e. at a minimum, are safe, secure, hygienic, include adequately-maintained and calibrated equipment, and provide for secure and accessible storage of Study materials and records). Study Records will be retained by Investigator for 2 (two) years following the date a marketing application is approved for the Investigational Product for the indication under investigation in the Study, or if no application is to be filed, or if the application is not approved for such indication, until 3 (three) years after the study is complete and FDA / DCGI is notified, or any longer retention period mandated by Applicable Law.

7.3 The Investigator agrees to limit access to the Investigational Product to only qualified and delegated Clinical Study staff and shall personally ensure, administer, instruct administration, or supervise the administration or instruction of administration of Investigational Product (whether active or placebo) to Clinical Study patients in accordance with the Protocol; and shall not chemically, physically or otherwise modify Investigational Product; and shall handle, store, and ship or dispose of Investigational Product with due and appropriate care and in compliance with manufacturer's instructions and all Applicable Laws, rules and regulations, including, but not limited to, those governing hazardous substances.

7.4 The Investigator agrees to limit access to the Biological sample, specific marker sample, surrogate marker sample and or sample / test as per protocol to only qualified and delegated staff and shall personally ensure sample collection, processing, storage, transport, handling and or concercn activities in accordance with protocol and timeline.

7.5 Provisions of Data and Reports: The Institution shall provide to Cadila CRO original case report forms for each Subject participating in the Clinical Study and such other reports as and when required by the Protocol or under Applicable Laws.

7.6 Institutional Review Board: The Institution shall provide to the Cadila CRO documentation verifying review and approval by the IRB of the information to be provided to potential Subjects of the Clinical Study to secure their informed consent, including information about any compensation being provided to Subjects for participation in the Clinical Study ("Informed Consent Materials"), the Protocol, the Investigator's Brochure and amendments to any of the foregoing.

7.7 Regulatory Assistance: At the request and expense of Cadila CRO, the Investigator or his representative shall: (a) assist Cadila CRO in the preparation and submission of investigational new drug applications, new drug applications, any other premarket or marketing applications relating to the Clinical Study or the Investigational Drug, and any amendments or supplements; (b) attend meetings with regulatory or governmental authorities regarding such applications and the associated approvals; and (c) provide such other reasonable assistance as the Cadila CRO may request in connection with regulatory matters relating to the Study or the Study Drug.

7.8 Sponsor shall timely arrange the Investigational Product to Cadila CRO who shall deliver the same at SITE of the Institution, in sufficient quantities for use in the Study. Title to these materials delivered by Cadila CRO shall remain solely and exclusively with Sponsor, and the materials shall be used solely and exclusively by Investigator for purposes of carrying out the Study.

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8. Audit and Review:

8.1 Cadila CRO or its authorized representatives shall have the right upon advance written notice at Cadila CRO's expense, and during regular business hours, to: (a) audit all Facilities of the Institute being used in performance of the Clinical Study; (b) monitor the conduct of the Study and ensure to send monitoring follow up report promptly; (c) review, copy and audit all Study Documentation, any other books, records, data and Work Product (as defined below) relating to the Study or the IRB, and all required licenses, certificates and accreditation; and (d) interview the Investigator and other persons who assisted in performing the Study. Subject's medical records are for review purposes only. (e) Cadila CRO to send the DSMB report (if applicable)and its timely submission to EC. (f) Cadila CRO to notify to the Institution, up to two years post study closure, relevant safety findings from the study data.

9. Changes to the Protocol.

9.1 No change in the Protocol shall be made by the Institution or the Investigator, subject to any Applicable Laws relating to the safety of Subjects that require a deviation from the Protocol, in which case the Institution shall promptly notify Cadila CRO and the Institution Review Board of the nature of the deviation and the facts necessitating such deviation as soon as the facts are known to the Institution. Cadila CRO may at any time make changes in the Protocol upon five (5) days' advance written notice to the Institution; provided, however, that, unless the changes are required by Applicable Laws, do not materially increase the cost of performance of the Clinical Study by the Institution or are otherwise agreed to by the Institution, otherwise the Institution may mutually discuss with Cadila CRO on the material increase of the cost for performing Clinical Study due to change in Protocol.

10. Regulatory Inspections.

10.1 If any governmental or regulatory authority (a) contacts the Institution or the Investigator with respect to the Study, (b) conducts, or gives notice of its intent to conduct, an inspection at any facility or (c) takes, or gives notice of its intent to take, any other regulatory action with respect to any activity of the Institution, the IRB or the Investigator that could reasonably be expected to impact any data or clinical activity under the Study, then the Institution shall promptly notify Cadila CRO of such contact or notice. Cadila CRO shall have the right to be present at and to participate in any such inspection or regulatory action with respect to the Clinical Study. The Institution shall provide Cadila CRO with copies of all pertinent information and documentation issued by any governmental or regulatory authority and any proposed response. Cadila CRO shall have the right in advance to review and comment on any responses that pertain to the Study. No such response shall contain any false or misleading information with respect to the Clinical Study, the Study Drug or Cadila CRO.

11. Confidential Information

11.1 For purposes of this Agreement, "Confidential Information" means any information of Cadila CRO, whether of a technical, business or other nature, including information that relates to Cadila CRO's trade secrets, products, Study Drug, chemical structure, promotional material, developments, proprietary rights or business affairs, together with any Inventions, Work Product and all other written information, data and results collected, prepared, developed or generated by the Institution, the Investigator and any other person pursuant to or in contemplation of this Agreement, including, subject to applicable laws and regulations, this Agreement. Confidential Information does not include any information, if the Institute and Investigator can demonstrate that the information:

(a) Is already in their possession and known prior to the date of this Agreement;

(b) The Institution or the Investigator can prove that they have lawfully obtained from a third party without breach of any obligation of confidentiality;

(c) is or becomes part of the public domain through no act or violation of any obligation of the Institution or the Investigator; or (For the avoidance of doubt, when Cadila CRO lists or discloses any non-confidential information relating to the Study Drug or the Study in a clinical trial registry or clinical results database, any aspects or details of Confidential Information concerning the Study Drug or the Study that are not listed or disclosed in such registry or database shall not be deemed to be or become part of the public domain.)

11.2 The Institution and the Investigator shall not, without Cadila CRO's prior written consent or as may be permitted by this Agreement, disclose to any third party any Confidential Information, and shall use such Confidential Information solely for purposes of performing its obligations under this Agreement. The Institution shall restrict the access of Confidential Information to only those persons within the Institution who have a need to know, and shall ensure that they are aware of the obligation of confidentiality required by this Agreement. The Institution and the Investigator shall use at least the same care and discretion in maintaining the confidentiality of the Confidential Information as each uses with its most sensitive confidential information. The Institution or the Investigator, as applicable, shall notify Cadila CRO promptly upon the Institution or the Investigator's discovery of any loss or compromise of the Confidential Information. Upon the termination or expiration of this Agreement or upon Cadila CRO earlier written request, the Institution or the Investigator shall promptly return to Cadila CRO all Confidential Information at Cadila CRO reasonable expense, provided that the Institution shall have the right to retain, copies of each Subject's primary medical records for archival purpose only.

12. Publication and Presentations

12.1 Neither the Institution, the Investigator, nor any other person who assists in performing the Study shall issue any press release or other publicity materials or make any presentation or announcement, private or public, which refers the name of Sponsor/Cadila CRO or the name of Test Product, without prior written consent of Sponsor. There shall be no publication based on Trial unless Sponsor shall have given its prior written approval. Sponsor may require that Institution publish results jointly with them and others.

13. Use of name:

13.1 Subject to Applicable Laws, none of the Institution, the Investigator or Cadila CRO shall mention or otherwise use the name, trademark, trade name or logo of any other Party in any publication, press release or promotional material with respect to the Study without the prior written approval of such other Party except for the purpose as expressed herein this Agreement; provided, however, that for non-commercial, internal purposes, Cadila CRO shall have the right to identify the Institution as the site at which the Study was conducted and to identify those individuals responsible for conducting the Study. The Institution may use the name of Cadila CRO and the title of the Study for internal purposes, including, but not limited to, acknowledging the Investigator's work.

13.2 Advertising. Neither the Institution nor the Investigator shall issue to the public any information or statement through the press or any other media, including advertisements for the enrollment of Study Subjects, without the prior written permission of Cadila CRO and ethics committee and the review and approval of the IRB.

14. Indemnification and insurance:

14.1 Indemnification.

(a) Except as set forth below, Cadila CRO shall defend, indemnify and hold harmless the Institution, officers, agents, and employees, including the Investigator and the Institution's other employees and any physician, nurse, nurse's aide, study coordinator or other healthcare

personnel providing services to the Institution in connection with its conduct of the Study (collectively, the "Institutional Indemnified Parties") from and against any and all liability, claim, loss, damages and expense (collectively "Losses") incurred by them in connection with any and all suits, investigations, claims or demands by or on behalf of Subjects taking part in the Study (or their dependents) against any Institutional Indemnified Party for personal injury (including death) to Subjects to the extent arising out of direct result of the intake or use of the Investigational Products, including (a) the administration of the Study Drug in accordance with this Agreement, the Protocol and any other written instructions of Cadila CRO or (b) the performance of any test or procedure that is required by the Protocol to which the Subjects would not have been exposed but for their participation in the Study, or the use by Cadila CRO of the results of the Study, provided that, in each case (a) or (b), the Institution and the Investigator have (i) used reasonable medical judgment in the conduct of the Study (including the enrollment of Subjects for which participation in the Study is medically appropriate) and (ii) otherwise acted in conformity with generally accepted standards of the medical community in which they practice.

(b) Notwithstanding anything contained herein to the contrary, the Cadila CRO and/or its directors, officers, employees, consultants and advisors shall not be liable to the Institution, officers, agents, and employees, including the Investigator and the Institution's other employees and any physician, nurse, nurse's aide, study coordinator or other healthcare personnel, in any manner whatsoever and howsoever arising under this Agreement:

(i) for any special, non-compensatory, consequential, indirect, incidental loss, damage, including without limitation, for loss of profits, loss of sales, loss of revenue and/or loss of use, regardless of the form of action, manner whether in contract, tort, negligence, strict liability, or otherwise except provided here in this Agreement under clause "Indemnification";

(ii) arising out of or relating to the negligence, wilful, malfeasance or wrongful acts or omissions of any Institutional Indemnified Party, or by the negligence or failure of any Institutional Indemnified Party to comply with the provisions of this Agreement, the Protocol or any written instructions of Cadila CRO concerning the Study;

(iii) to the extent that such Loss arises out of or relates to the Investigator's or the Institution's negligence or failure to promptly report to Cadila CRO any significant or alarming developments that may occur during the Clinical Study, including any Subject adverse experiences or Serious Adverse Events (as both such terms are defined in the Protocol).

14.2 Reimbursement of Medical Expenses: Cadila CRO shall reimburse the Institution for the direct, reasonable and necessary medical expenses incurred by the Institution for the treatment of any personal injury that is a direct result of (a) the administration of the Study Drug, in accordance with this Agreement, the Protocol and any other written instructions of Cadila CRO or (b) any performance of any test or procedure that is required by the Protocol to which the Subjects would not have been exposed but for their participation in the Clinical Study if (i) the Institutional Indemnified Parties have complied with this Agreement, the Protocol and any written instructions of Cadila CRO concerning the Clinical Study and (ii) all the requirements of informed consent have been complied with in accordance with Section 5.2. Cadila CRO will not provide compensation for lost wages or for any other damages, expenses or losses, or for medical expenses that have been covered by a Subject's medical or other insurance, provided, however, Cadila CRO understands and agrees that Subject is not required to file an insurance

claim. Cadila CRO shall ensure compensation over and above SAE management /reimbursement with the exceptions. Sections 14.1 and 14.2 shall not apply to any Loss:

15. Insurance:

15.1 The Cadila CRO will have an insurance policy for an appropriate amount adequate to cover the risks of its obligations under this agreement. A copy of such policy shall be provided to the institution on their request, if any. Policy will be used by the Party, for any personal/bodily injury suffered by the person involved in the study as specified under this Agreement.

16. Termination:

16.1 Right to Terminate or Suspend Clinical Study: The Clinical Study may be terminated or suspended by Cadila CRO immediately upon written notice to the other Parties on safety concerns or as otherwise required under the Applicable Laws. Further, Cadila CRO may terminate or suspend the Clinical Study if the Multi Center Study is terminated or suspended.

16.2 Right to Terminate Agreement by Cadila CRO: Cadila CRO may suspend and/or terminate this Agreement, in its sole discretion, on ten (10) business days' advance written notice to the Institution and Investigator. The Cadila CRO or the Institution may terminate this Agreement in the event of material breach by the parties to this Agreement, provided that the written notice is explaining the nature of the default and an opportunity to cure such default within a period of 30 business days after the giving of notice. The Institution may terminate this Agreement, on written notice to Cadila CRO, if the Clinical Study is suspended or terminated and not recommenced within ninety (90) days.

16.3 Right to Terminate Agreement by Institute: The Institute can terminate the clinical study on the following reason:

(a) if the Principal Investigator becomes incapacitated or terminates his/her relationship with the Institution and a replacement suitable and agreeable to Cadila CRO cannot, after reasonable efforts by the Institution, be found;

(b) if Institution has indication of serious physical harm being suffered by any of the Trial Subjects at its site, it may immediately suspend enrollment of Trial Subjects at its site.

16.4 Transition upon Termination: Upon notice of termination of the Clinical Study or this Agreement, the Institution shall immediately cease enrollment of Subjects into the Study and, at the discretion of Cadila CRO, shall: (a) terminate the Study with respect to the enrolled Subjects in an orderly and prompt manner, to the extent medically permissible, and pursuant to consultation with Cadila CRO's clinical monitor, including, without limitation, any required follow-up treatment with previously enrolled Subjects or (b) transfer the enrolled Subjects to another clinical site in accordance with Cadila CRO's instructions. Cadila CRO or its designee shall have the right to assume full control of the terminated Study and the Institution shall turn over all Study Documentation and materials in its possession associated with the Study, including all Work Product, Inventions and Materials, as expeditiously as possible, shall handle the Study and shall provide such other assistance as is necessary to ensure a smooth and orderly transition of the Study that will not involve any disruption of the Protocol. Upon notice of suspension of the Study, the Institution shall immediately cease enrollment of Subjects into the Study. Cadila CRO shall reimburse Institution for all expenses incurred from such transition except for such transitions required due to an uncured breach of this Agreement by Institution.

16.5 Payment Owed: Except in the case of termination of this Agreement as a result of an uncured breach of this Agreement by the Institution, upon termination of the Study or this Agreement, Cadila CRO shall,

upon receipt of applicable invoices and other supporting documentation satisfactory to Cadila CRO: (a) reimburse the Institution for its reasonable and verifiable Study costs and reasonable un-cancelable Study costs or expenses incurred in connection with transfer of Subjects pursuant to Section 16.4 and (b) with respect to Subjects who have not completed the Study at the date of the termination, make payments to the Institution in accordance with appendix A for work already performed in accordance with the Study.

16.6. Final Accounting: Within thirty (30) days after the termination of this Agreement, each party will settle its account and the Institution shall deliver to Cadila CRO a final accounting of all Subjects participating in the Study and the visits completed in accordance with the Study during the term of this Agreement, and all reasonable direct costs incurred in connection with any transfer of the Study as agreed and mentioned in the payment schedule annexed herewith. Within thirty (30) days of delivery or receipt of the final accounting, either the Institution shall refund to Cadila CRO any excess amounts paid by Cadila CRO or Cadila CRO shall pay any additional amounts due to the Institution, as the case may be. Cadila CRO or its designee shall have the right for a period of two (2) years after the payment of any transfer costs to audit the Institution's books and records with respect to such accounting.

17. Miscellaneous:

17.1 Independent Contractor. In undertaking to perform the respective services hereunder, Cadila CRO, the Institution and the Investigator are doing so as independent contractors, and not as employees or agents of other Parties.

17.2 Assignment. No Party shall assign this Agreement or any rights or obligations hereunder without the prior written consent of the other Parties, except that Cadila CRO, without the consent of any other party hereto, may assign this Agreement and its rights and obligations hereunder (a) to any successor in interest (whether by merger, acquisition, asset purchase or otherwise) to all or substantially all of the business to which this Agreement relates, (b) in connection with the transfer, whether by license or otherwise, or sale of all or substantially all of its rights to the Study Drug or (c) to any direct or indirect affiliate of Cadila CRO.

17.3 Severability. If any provision of this Agreement is held to be invalid, illegal or unenforceable, in any respect, then, to the fullest extent permitted by applicable law and if the rights or obligations of any party will not be materially and adversely affected: (a) such provision will be given no effect by the parties and shall not form part of this Agreement, (b) all other provisions of this Agreement shall remain in full force and effect and (c) the parties will use their best efforts to negotiate a provision in replacement of the provision held invalid, illegal or unenforceable that is consistent with applicable law and achieves, as nearly as possible, the original intention of the parties. To the fullest extent permitted by applicable law, the Parties waive any provision of law that would render any provision in this Agreement invalid, illegal or unenforceable in any respect.

17.4 Notices. Any notice, request or other communication permitted or required under this Agreement shall be in writing, shall refer specifically to this Agreement and shall be deemed given only if hand delivered or sent by an internationally recognized overnight delivery service, costs prepaid, email or by facsimile (with transmission confirmed), addressed to the parties at the below mentioned address of the Parties:

If to Cadila CRO to:
Dr. Manjul Joshipura,
Sr. Vice President
Address: 1389, Trasad Road,
Dholka, Dist: Ahmedabad- 382225,
Gujarat, India

If to Principle Investigator to:

Dr D. Himanshu,
Department of Medicine.
King George's Medical University,
Shahmeena Road, Chowk, Lucknow-226003

If to the Institute:

Faculty In-chatge
King George's Medical University,
Shahmeena Road, Chowk, Lucknow-226003.

17.5 Business Communications.

The parties consent to receive communications sent via mail, e-mail and/or fax at the Investigator mailing address, e-mail address and fax number set forth in this agreement.

17.6 Entire Agreement. This Agreement, together with the appendices hereto constitute the entire agreement among the Parties hereto with respect to the subject matter of this Agreement. This Agreement supersedes all prior agreements, whether written or oral, with respect to the subject matter of this Agreement. Each party confirms that it is relying on the representations, warranties or covenants of other party as set out in this Agreement. Nothing in this Agreement is intended to limit or exclude any liability for fraud; misrepresentation, gross negligence, willful misconduct or false statement.

17.7 Period of Performance. The performance of this Agreement shall be commenced from the Effective Date and shall continue valid and in full force till the completion of the Clinical Study or termination of the Clinical Study by Cadila CRO or termination of this Agreement, whichever is ealier.

17.8 Amendment. Any amendment or modification to this Agreement must be in writing and signed by authorized representatives of each Party.

17.9 Waiver. A party's failure to enforce, at any time or for any period of time, any provision of this Agreement, or to exercise any right or remedy shall not constitute a waiver of that provision, right or remedy or prevent such Party from enforcing any or all provisions of this Agreement and exercising any rights or remedies. To be effective any waiver must be in writing.

17.10 Inconsistency. In the event of any inconsistency between this Agreement and the Protocol, the terms of the Protocol shall prevail with respect to the conduct of the Clinical Study and the treatment of Subjects in connection therewith; in all other respects, the terms of this Agreement shall prevail.

17.11 Construction. Except where the context requires otherwise, whenever used the singular includes the plural, the plural includes the singular, the use of any gender is applicable to all genders, the word "or" has the inclusive meaning represented by the phrase "and/or" and the term "including" or "includes" means including, without limiting the generality of any description preceding such term. Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The headings of this Agreement are for convenience of reference only and do not define, describe, extend or limit the scope or intent of this Agreement or the scope or intent of any provision contained in this Agreement. A reference in this Agreement to a Section or appendix is to the referenced Section or

CADILA PHARMACEUTICALS LIMITED

appendix of this Agreement. The wording of this Agreement shall be deemed to be the wording mutually chosen by the parties and no rule of strict construction shall be applied.

17.12 Counterparts. This Agreement may be executed in two counterpart copies, each of which shall be deemed an original and all of which taken together shall be deemed to constitute one and the same instrument.

17.13 Governing Law, Jurisdiction and Dispute Resolution. This agreement shall be governed by applicable laws of India and is subject to exclusive jurisdiction of the Courts Situated at Ahmedabad, India. Any dispute arising out of or in connection with this agreement, shall be first solved amicably by the Parties within 30 days of the dispute arises, failing which the same shall be referred to the sole arbitrator mutually decided by the Parties or each Party to nominate its Arbitrator and thereof; the two Arbitrator will nominate the Presiding Arbitrator, in accordance with Indian Arbitration and Conciliation Act 1996, its amendments and rules and regulations thereof. The seat and venue of arbitration will be at Ahmedabad, India.

17.14 Survival Clauses. Clause 3 (Representations and Covenants), Clause 11 (Confidentiality), Clause 14 (Indemnification), Clause 17.13 (Governing Law, Jurisdiction and Dispute Resolution), shall survive termination or expiration of this Agreement for infinite period unless otherwise specifically provided in this Agreement, in addition to any other provisions that by their content are intended to survive the performance, termination, expiration or cancellation of this Agreement.

THIS AGREEMENT IS EXECUTED by the authorized representatives of Cadila CRO, Investigator and the Institution as of the date first written above.

For: CADILA PHARMACEUTICALS LTD. Name: Dr. Manjul Joshipura Designation: Sr. Vice -President Place: Ahmedabad Date:	For: INVESTIGATOR Name: Dr. D. Himanshu Designation: P.I Place: Lucknow Date:
  Name : Mr. Vinod Jain Designation : Chief Financial Controller	For King George's Medical University, Name: Dr R.K. Garg Designation: Faculity-In-Charge
  Name: Ms. Sanjeev K Singh Designation: GM – Legal	

Annexure I

STUDY TITLE: Ashwagandha for the Prophylaxis against SARS-CoV-2 Infection: A Randomized Hydroxychloroquine Controlled Clinical Trial in Health Care Providers.

Terms of Payment:

1. Fixed Cost as Investigators (Both) fees: Cadila Pharmaceuticals Limited, India will pay maximum up to Rs. 12,000/- per patient upon achieving the below milestones.

Milestone	Payment
Baseline- Visit 1	3000
Visit 2	3000
Visit 3	3000
Visit 4	3000

2. Maximum up to Rs. 2000/-per patient will be paid to Site Coordinator as per the below milestones.

Milestone	Payment
Screening - Visit 1	500
Visit 2	500
Visit 3	500
Visit 4	500

3. Patient compensation will be provided Rs. 500/- per visit per patient.
4. Administrative cost (for stationary, courier, telephone, fax, internet) will be paid Rs. 10,000/- for entire study.
5. Study medications will be provided by sponsor. (As mentioned in protocol)
6. As per new regulations, GST is applicable over and above of total budget.
7. Screen failure charges will be paid Rs. 500/- to Investigator with laboratory charges on actual basis not exceeding as per below table of laboratory charges, per screen failed patient up to a maximum of 10 % of enrolled subjects.
8. Laboratory charges will be paid as per actual upon submission of original bills or as per the below milestones whichever is higher

Sr. No.	Visit	Test Name	INR
1	Baseline	CBC, LFT,RFT, Blood Sugar, Urine Routine, C-Reactive Protein, Nasal and throat Swab, Serum for IgG and IgM for COVID 19, Lipid profile and UPT	5700
2	Visit 2	Nasal and throat Swab	2500
3	Visit 3	Nasal and throat Swab	2500
4	Visit 4	CBC, LFT,RFT, Blood Sugar, Urine Routine, C-Reactive	5600

CADILA PHARMACEUTICALS LIMITED AHMEDABAD

		Protein, Nasal and throat Swab, COVID 19 specific Serum for IgG and IgM, Lipid profile	

9. Reimbursement of related Adverse Events/SAE medication management cost on actual as per DCGI Guidelines. In most situations where AE/SAE is prima facie unrelated, medical management cost will not be paid unless meeting all criteria of detailed DCGI guidelines.
10. 25 % Institutional Over Head will be applicable on PI fees only.
11. Rs. 30,000/- will be given for archiving the documents for 15 years.

Investigator has to complete below information:

Payment Cheque required in favour of/payable to:

"Vice Chancellor of KGMU, Lucknow"
Account No.: **50287351562**
Bank Name: **Allahabad Bank**
IFSC Code: **ALLA0211028**

Address where payment Cheque would be sent:

Dr D. Himanshu, Kalam Center, Room No. 505, 5Th Floor, KGMU, Lucknow-226003.

PAN Number or TAN Number, if applicable: **PAN No. AAAAK4509K**
Service Tax No.:
GST No.: **09AAAAK4509K**

By signing this FINANCIAL AGREEMENT, Cadila CRO, Ahmedabad, Investigator and the Institute agree to adhere to the terms and conditions mentioned in the CLINICAL TRIAL INVESTIGATOR's AGREEMENT.

For: CADILA PHARMACEUTICALS LTD. Name: Dr. Manjul Joshipura Designation: Sr. Vice -President Place: Ahmedabad Date:	For: INVESTIGATOR Name: Dr D. Himanshu, Designation: P.I Place: Lucknow Date:
  Name : Mr. Vinod Jain Designation : Chief Financial Controller	For. King George's Medical University, Name: Dr R.K. Garg Designation: Faculity-In-Charge
  Name: Ms. Sanjeev K Singh Designation: GM – Legal	R.K Garg Member Secretary IEC

Research Cell
King George's Medical University

100/-

ABHYUDAYA CO-OP. BANK LTD.
VASHI BRANCH,
ABHYUDAYA BANK BUILDING,
SECTOR 17, VASHI,
NAVI MUMBAI-400 705.

भारत 99627 163350 महाराष्ट्र
FEB 14 2019 12:56
INDIA STAMP DUTY MAHARASHTRA

CLINICAL TRIAL AGREEMENT BETWEEN ACCUTEST, PRINCIPAL INVESTIGATOR & INSTITUTE
(PI Name: Dr. Shiv Rajan, Site Name: King George Medical University Protocol Number: EIL-E7389-CT01-012)

For ABHYUDAYA CO-OP. BANK LTD.
AJIT GHETYE
Authorised Signatories
Vashi Br. Navi Mumbai - 400 703

CLINICAL TRIAL AGREEMENT

This clinical trial agreement is made by and between the following three parties:

1)ACCUTEST:	2) PRINCIPAL INVESTIGATOR:
Accutest Research Lab. (I) Pvt. Ltd. A-77, Khairne MIDC, TTC Industrial Area, Khairne, Navi Mumbai, 400 709, Tel.: +91 22- 2778 0718/19 Fax: +91 22- 2778 0720 Email ID: Rajendra.Talele@accutestgloabal.com **Hereinafter "ACCUTEST"**	Name: Dr. Shiv Rajan Address: Department of Surgical Oncology, King George Medical University, Shatabdi Building, Chowk, Lucknow- 226003, Uttar Pradesh, India. Tel.: +91 94555 83068 Email ID: shivrajan.194@gmail.com **Hereinafter "PRINCIPAL INVESTIGATOR"**

3) INSTITUTE:

Name of the Authorized Signatory: Prof. R. K. Garg
Designation: Member Secretary
Name of the Institute: King George Medical University
Address Department of Surgical Oncology, King George Medical University, Shatabdi Building, Chowk, Lucknow- 226003, Uttar Pradesh, India.

Hereinafter "INSTITUTE."

Initial-1 (ACCUTEST):

Initial-2 (PI):

Initial-3 (INSTITUTE):

Confidential

ACCUTEST RESEARCH LABORATORIES (I) PVT. LTD. NAVI MUMBAI

This clinical trial agreement is effective from the date of last signature ("**Effective Date**")

Accutest is engaged in the business of clinical trials management as a contract research organization and intends to carry out a clinical study ("the Study") with "**Post Marketing Trial (Phase IV) on the Safety, Tolerability And Efficacy of Eribulin Mesylate in Treating Patients with Locally Advanced or Metastatic Breast Cancer**"("the **Protocol EIL-E7389-CT01-012**") for the purpose of obtaining data for the application of the Study Drug.

The Study Protocol Number: EIL-E7389-CT01-012

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

Section 1: Study Protocol

The nature and scope of the Study are ensured from the Protocol. The Protocol precisely and exhaustively describes the clinical research activities and responsibilities for careful execution by the Principal Investigator. Any changes to the Protocol are subject to Accutest's prior written consent which the Principal Investigator shall obtain, and the approval/notification of the competent ethics committee and the Drug Controller General of India ("**DCGI**"). The Protocol, including any amendments, constitutes an integral part of this Agreement ("The **Agreement**") and shall be valid upon signature of this Agreement. In the case of any inconsistency between this Agreement and the Protocol, this Agreement shall prevail. The Principal Investigator warrant that they have received the Protocol.

Section 2: Rules for the Conduct of the Study

2.1 Legal framework

The parties agree that the duties and obligations of the provisions of the Declaration of the Helsinki World Medical Association Recommendations Guiding Physicians in Biomedical Research Involving Human Subjects including amendments as set out in the Protocol of the "ICH Harmonised Tripartite Guideline, Guideline for Good Clinical Practice", the applicable national legislation on public health and pharmaceuticals including the Central Drugs Standard Control Organization's Good Clinical Practice Guidelines ("**GCP Guidelines**")valid at the time of the performance of this Agreement; and all other pertinent rules and regulations shall be applicable including but not limited to Schedule Y to the Drugs and Cosmetics Rules, 1945 ("**Schedule Y**"), and that the Agreement shall be construed accordingly.

2.2 General Duties and Obligations

The Principal Investigator shall carry out the Study in a professional, competent manner in accordance with the Protocol and the terms of this Agreement.

The Principal Investigator hereby warrants that they have sufficient resources with regard to time, adequate personnel and facilities for the performance of the Study. Unless expressly agreed otherwise, the responsibility for services of third parties (including, but not limited to sub-investigators and satellite sites) remains with the Principal Investigator. The Principal Investigator shall ensure that all personnel and third parties are bound by and comply with the terms of the Protocol and this Agreement.

The Principal Investigator will inform Accutest, about all changes of personnel, facilities and clinical research methods at the Institute that may affect the Study.

ACCUTEST RESEARCH LABORATORIES NAVI MUMBAI

In the event the Principal Investigator becomes either unwilling or unable to perform the duties required by this Agreement, Principal Investigator will inform Accutest within 3 days of the Principal Investigator being unwilling or unable to perform the duties. The Principal Investigator shall continue to be bound by the provisions referred to in Section 5.2.

The Principal Investigator is an employee, of the Institute and Investigator guarantees the proper performance by him following all obligations hereunder.

2.3 Ethics Committee / Review Board / Regulatory Authority Approval / Notifications

Accutest shall undertake the necessary notifications to authorities in accordance with applicable laws. The Study shall not commence until the Principal Investigator is informed by Accutest that the authorities have given authorization.
Accutest will provide the Principal Investigator with all the documentation required for submission to the pertinent ethics committee. Institute/Principal Investigator will obtain the written approval of the appropriate ethics committee prior to the commencement of the Study and will furnish Accutest or its designate with the ethics committee's letter of approval and a list of all ethics committee meeting attendees.

The Study shall not commence until receipt of the ethics committee written approval and shall follow any conditions of approval imposed by the ethics committee, and the time interval has been observed and all regulatory documents that are necessary according to the ICH – GCP,Schedule Y, and other applicable pharmaceutical regulations are available.

Should the ethics committee express objections to the content or the performance of the Study, the parties will collectively develop modifications that accommodate the objections. Should the ethics committee approval be unobtainable nonetheless, the parties shall be entitled to mutually terminate this Agreement. Amendments to the Protocol must be submitted by the Principal Investigatorto the pertinent ethics committee.

2.4 Subject Information and Informed Consent

The Principal Investigator shall ensure that during informed consent process, information to the subjects is provided individually and not in a group (in accordance with the provisions specified in Section 2.1 above) in a language that is best understood by the subject about the nature, significance and consequences of the Study, its expected duration, and the potential benefits and risks involved in Study participation.The explanation shall at least include all points listed in the ICH-GCP and Schedule Y.The Principal Investigator should obtain written Informed consent fromthepatient, record necessary source data (like IC-EC, ECG, Physical Examination, Vital,etc.) and submit verify the eligibility criteriaprior to enrolling the patient in the study.The Principal Investigator shall conduct complete Informed Consent process as per current regulatory requirement and also document the written consent prior to the Study on a prepared Informed Consent Form (ICF) and shall hand out a copy of the ICF and subject information document to each subject. In accordance with the provisions specified in Section 2.1 above, Principal Investigator shall ensure that consent of the governing local health authorities and/or subject for the submission of ICF mentioned above anonymous data to and/or appropriate regulatory authorities, is obtained.

All the study related documents should be preserved safely after the completion/termination of the study for at least a period of 5 years if it is not possible to maintain the same permanently, if applicable.

Each subject will be informed accordingly, and his/her consent will be obtained

RESEARCH LABORATORIES

- that he/she is enrolled in the Study,
- that the subject's insurance has been effected and that each subject has obligations arising from the general insurance conditions; in particular these are:
- during the course of the Study the subject must immediately inform the Principal Investigator about any other medical treatment he/she undergoes;
- any health damage, which may be attributable to participation in the Study, must be immediately reported to the insurance company;

- that the necessary documentation of the subject's health and personal data and its distribution to Accutest, the competent health authorities, and other Institutes, as legally required, may take place.

In the event the patient or his/her legally acceptable representative is unable to read/write, an impartial witness will remain present during the entire informed consent process and who must append h s/her signatures to the Study informed consent form. The Principal Investigator will obtain prior approval from the relevant ethics committee in the event of any amendments to the Study informed consent form

2.5 Enrolment Period

The recruitment phase may not commence until the written positive decision of the ethics committee has been obtained.

The Principal Investigator will recruit a maximum of **20 subjects** for the Study, as the enrollment is competitive amongst the investigative sites.

The Principal Investigator is aware that for this multicentre study, a competitive recruitment will apply. Should the total number of subjects enrolled in the study be met prior to the end of the anticipated enrolimert period, Accutest shall have the right to end further enrolment of subjects; no payment will be made for any such additionalsubjects.

2.6 Study Documents and Drug Supplies

Accutest's designee shall ensure appropriate and timely supply of the documents and Study Drugs necessary for the performance of the Study. All supplies shall be returned to Accutest by the Principal nvestigator/Institutein a timely manner throughout the performance of this Study, as outlined in the Protocol or when Accutest otherwise requests delivery of data, unused Drug, and clinical specimens.

The Principal Investigator hereby warrants that he/she shall:

a) account for all clinical supplies furnished by Accutest and keep a written inventory of any equipment supplied by Accutest according to guidelines provided by Accutest;

b) use the Study Drug solely for the Study, documenting each usage and to return all used and unused clinical or other supplies provided by Accutest upon conclusion of the Study;

c) collect data properly and report to Accutest all relevant information and data obtained under the Protocol;

d) submit to Accutest signed CRFs/eCRFs resulting from the Study in a timely manner;

e) retain all necessary records and documents about the Study as required by applicable regulatory requirements, this Agreement, and/or the Protocol;

Moreover the Principal Investigator shall update/maintain the investigator study file provided at the time of Site Initiation Visit (SIV) andas per ICH-GCP all relevant essential documents which are necessary for the conduct of the Study including but not limited to following:

a) Signed Protocol and amendments;
b) Investigator's Brochure and updates (If applicable);
c) Ethics Committee composition, approval(s)/opinion correspondence/reporting;
d) Notifications/Approval of regulatory authorities;
e) CVs and signature sheet for key study personnel (e.g. investigators);
f) Approved and signed informed consent forms;
g) CRFs/eCRFs (investigator's copy) (If applicable);
h) Serious adverse events documentation and related correspondence/reporting;
i) Instructions for handling of Study Drug;
j) Screening, enrollment, and monitoring logs and subject identification code list;
k) Study related correspondence with Accutest

2.7 Adverse Events

The Principal Investigator is obliged to document and manage all Adverse Events (AEs) in accordance with the Protocol and to notify Accutest of all Serious Adverse Events according to the study instructions ("Serious Adverse Event Reporting") within the timeline specified in the Protocolor as per current regulatory requirement

Section 3: Documentation and Monitoring

3.1 Documentation and CRF/eCRFs handling

The Principal Investigator shall keep all original medical files (paper and print-outs of electronic files) of every subject participating in the Study in addition to the Case Report Forms(CRFs)/electronic Case Report Forms (eCRFs). The medical file is the documentation containing all demographic and medical data of a subject. This medical file will clearly identify each Study subject and where the medical files are termed the source; entries on the CRFs/eCRFs must be traceable to entries in the medical file. In the course of the Study, the Principal Investigator undertakes to express medical data in writing using medical terminology where necessary, the status of the Study for the respective subject and be completed expeditiously following a subject visit. The Principal Investigator must sign all eCRFs/CRFs. The Principal Investigator should inform the general practitioner and, if applicable, any other physicians, treating the subject about his participation in this clinical Study. The Principal Investigator warrants that all eCRFs/CRFs submitted to Accutest are true, complete and correct and accurately reflect the results of the Study with respect to each person participating as a subject.

The Principal Investigator undertakes to cooperate with Accutest and acknowledges Accutest's right, upon a request, to be granted direct access to all requested trial-related records (including patient medical files).

3.2 Monitoring

The parties agree to frequent monitoring visits to the institute by Accutest. The monitor (CRA) will visit the Institute to discuss study progress with the Principal Investigator who will allow inspection of all study data including medical files requested by the monitor.

The CRAs will check the data entered in the eCRFs/CRFs. CRAs and possibly representatives of Accutest shall perform source data verification, comparing the CRFs/eCRFs with the medical records to validate the data. Despite the CRA's and other representatives' efforts, the Principal Investigator remain primarily responsible for the accurate and complete data entry in the CRFs/ eCRFs. Al persons who obtain knowledge of medical records are subject to professional secrecy.

Such monitoring will be carried out during the study, but may also be demanded by the pertinent regulatory authorities after completion of the study. The Principal Investigator are obliged to inform Accutest immediately of any notification of an inspection by the pertinent regulatory authorities.

3.3 Audit and Regulatory Inspection

Audits or inspections may be carried out during the Study, but may also be demanded by the regulatory authorities after completion of the Study. In the event that Accutest or authorities perform an audit, the Institute, Principal Investigator will allow access to the facilities, make documents available and if necessary provide information. Should a governmental or regulatory authority request or carry out an inspection of the Institute's or Principal Investigator's facilities, Principal Investigator has to immediately notify Accutestby telephone, mail or fax and allow Accutestto be present. The Principal Investigator shall provide to Accutest copies of all materials, correspondence, statements, forms and records that Principal Investigator receives, obtains, or generates pursuant to any such inspection.

Section 4: Confidentiality and Subject Data

4.1 Protection of Subject Data

On the CRFs/eCRFs, which will be used for evaluation of the Study, patient data will be documented in anonymous form only, i.e. without naming the subject, and passed on to Accutest and the DCGIand/or foreign regulatory authorities. The name of the subject, as well as other person-related data, will not be divulged by the Principal Investigator, or by Accutest. Accutest shall ensure that the protection of the data concerning subjects is safeguarded.

When, for reasons ofthefulfilment of professional obligations or verification purposes, person-related data concerning the Principal Investigator or the subjectare stored or handled, reliable organizational measures must be employed to ensure that these data are not divulged to unauthorized third parties.

Exception: When IEC or DCGI or any other regulatory authorities require the subject details then Principal investigator shall share photocopy and maintain the record in the file.

4.2 Confidentiality

Principal Investigator shall receive copies of the Study documents and the investigator site file. Principal Investigator/Institute is obliged to retain the documents facilitating identification of the Study patients, and all other Study Documentation disclosed by Accutest, for at least 15 years after the end or the premature termination of the Study or as communicated during site close-outvisit.Institute has no part to play in the closeout of the trial.Accutest is responsible for informing the Principal Investigator when it is no longer necessary to conserve all the Study documentation (ICH 4.9.5).

The Principal Investigator/Institute is obliged to maintain the secrecy of all information related to the Study and the Study Drug ("the **Information**"). The Principal Investigator shall procure that any co-workers assisting the Principal Investigator in the Study shall keep all such Information secure and strictly confidential as well. The Principal Investigator agrees not to use the Information for any purpose other than the performance of the Study.

The information shall not include:

- Information that enters the public domain and only then where this has occurred other than through unauthorized disclosure by the Principal Investigator or his co-workers.
- Information that is properly requestedforby the ethics committee responsible for approvngthe Study may proceed or is requested by the pertinent regulatory authorities in accordance with prevailing legislation, provided that the Principal Investigator shall give prior written notice to Accutest of any such request for disclosure.

The above obligations of confidentiality shall remain in full force and effect.

4.3 Proprietary information

All documents, data, know-how, formulas and unused Study Drug provided to the Principal Investigator for purposes of the Study ("**Data**") are and will remain Accutest's property and will be returned to Accutest or their respective designates upon request. Notwithstanding the preceding, Accutest shall retain full ownership rights in and to all templates, programs and other materials developed or licensed by Accutest prior to or apart from the commencement of this Agreement, regardless of whether such materials are used in connection with this Agreement. The Principal Investigator hereby transfers and assigns to Accutest the Principal Investigator's worldwide right and title to all Data in perpetuity and agrees to undertake such actions reasonably requested by Accutest to give effect to such ownership and agrees to sign, execute, affirm all documents, including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose.

4.4 Rights to results

Accutest shall have the right to use the results of the Study in any manner deemed appropriate to Accutest's business interests. All data attained during the performance of the Study are Accutest's property. The Principal Investigator assign worldwide rights and title to alldata obtained in the Study in perpetuity to Accutest and agree to undertake such actions reasonably requested by Accutest to give effect to such ownership and agree to sign, execute, affirm all documents, including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose. Principal Investigator shall notify Accutest of the results immediately, separately and in writing.

4.5 Intellectual Property

Neither the Principal Investigator nor hisemployees or agents shall acquire any rights of any kind whatsoever with respect to the Study Drug as a result of their performance under this Agreement. All inventions, discoveries, and technology relating to the Study Drug conceived by the Institute or its Principal Investigator, solely or jointly with others as a result of work done under this Agreement, shall be, and remain, at all times the sole and exclusive property of Accutest (subject to the right expressly reserved under Section 4.3).

The Principal Investigator hereby assign worldwide rights and title to the Intellectual Property in perpetuity to Accutest and agree to undertake such actions reasonably requested by Accutest to give effect to such ownership and agree to sign, execute, affirm all documents, including, without limitation, all applications, forms, instruments of assignment and supporting documentation and perform all other acts as may be required for this purpose.

The Principal Investigatorwarrant, by the execution of this Agreement that they have not entered, and will not enter into any contractual agreement or relationship which would in any way conflict with or compromise Accutest's rights to, any inventions, discoveries, or technology arising out of or related to their performance thereunder.

4.6 Publications

It is the general policy of the ARL & Sponsor to encourage publication of results of Clinical Trial on a case to case basis. However, according to good scientific practice, no interim data should be published by the Principal Investigator/ Institute unless agreed by the Parties in writing. It is further agreed that when the Principal Investigator/ Institute request for publications, the manuscript shall be based on final report of the Study and before any publication it shall be sent to the ARL &Sponsorfor its perusal, comments, and approval. The ARL or Sponsor may at its discretion either refuse the publication or forward it to the Principal Investigator/ Institute/ along with its comments or modifications which shall be final and binding on the Principal Investigator/ Institute.

4.7 Publicity

No party to this Agreement shall use Accutest's name or the name of any party hereto in connection with any advertising or promotion of any product or service without the prior written permission of such party or Accutest, as appropriate.

Section 5 Term and Termination of the Agreement

5.1 This Agreement commences on the Effective Date provided that Accutest has received from the pertinent ethics committees and the DCGI, as required by law, approval to carry out the Study. This Agreement shall remain in force to the full conclusion of the Study according to the Study Protocol unless terminated prematurely. Accutest may terminate this Agreement immediately upon written notice to the Institute/Principal Investigator

5.2 Termination of this Agreement by any party shall not affect the rights and obligations of the parties accrued prior to the effective date of termination of this Agreement.

Neither termination of this Agreement, however, effectuated, nor the end of the term shall cause the parties hereto to be released from their rights and obligations under Sections 3, 4, 6, 7 and 8, or under any other provisions of this Agreement that by their terms are understood to survive termination.

Upon completion of the Study, the Principal Investigator and the Institute shall return to Accutest, or its designee, all unused Study Drug, compounds, Comparator Drugs (when used), equipment as specified in Section 2.6 that were furnished to the Institute other than the Investigator site file documents

5.3 Should the Principal Investigator recognise within reasonable discretion that continuation of the Study is no longer possible, due to unexpected results medically not justifiable, due to severity of serious adverse events not justifiable or efficacy of the treatment with the Study Drug insufficient.

he/she will immediately notify Accutest as well as the ethics committee. Should continuation not be justifiable, the Principal Investigator may arrange for immediate termination of the Study. In the event that the Study is terminated with the consent of Accutest, the Principal Investigator shall receive payment pro rata temporis basis for the efforts of the Study, in accordance with Appendix A.

5.4 Accutest may terminate its cooperation with the Principal Investigator prematurely, providec that:

a) one month after shipment of the Study material, no subjects have been enro ied or the Principal Investigator recruits no subjectsor recruits such a low number of subjectsthat it can be assumed that the agreed number of patients will not be reached during the planned recruitment phase,

b) Accutest terminates the Study for the Study Drug or the indication is discontinued,

c) it is proved that the dosage used for the Study does not seem to be justified any more,

d) regulatory authorities or other pertinent institutions decide to terminate the Study in this center or as a whole,

e) the Principal Investigator fails to sufficiently adhere to the conditions of the Protocol and the need to exact and complete data documentation and the GCP Guidelines and Schedule Y.

5.5 Consequences of Termination: Upon the effective date of termination, the Principal Investigator shall:

a) terminate all services as efficiently and quickly as possible, except to the extent Institute/Principal Investigator is required to continue to follow the procedures and perform such services with respect to the ongoing Study, as may be necessary, until the appointment by Accutest of another Institute/Principal Investigator for the purpose of continuing the Study;

b) within 7 business days, provide copies of all information, data, documents (including but not limited to IPs, ICFs (blank copies), CRFs/eCRFs, Study related material & documents, and any clinical samples obtained with regard to the Study) prepared, conceived, generated or delivered by Principal Investigator as a result of or in connection with the concuct of the Study;

c) Provide an accounting of all clinical supplies, which is subject to verification by Accutest. If Accutest objects to any charge, the parties shall use reasonable efforts to resolve expeditiously any disagreement.

Section 6: Payment Terms and Conditions

It shall be the Principal Investigator's/ Institute'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 Institute, and its employees and/or collaborators.

Payment of investigator grants on behalf of Accutest will be equatedwith respect to the number of subjectsrecruited and the services performed as set out in detail in the APPENDIX-I & II entitled "Investigator Grants."

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Inthecase of any inconsistency between this Agreement and the APPENDIX, this Agreement shall prevail. For the avoidance of doubt, if any obligation is specified in one of these documents but not in the other, this shall not constitute an inconsistency.

In the event thatAccutest or the Principal Investigator/Institute terminates the Agreement prematurely in accordance with Section 5.4, Accutest shall not pay grants for performance on subjects that do not conclude the Study provided that:

- where a subject has been recruited to the Study in violation of the Protocol, there shall be no obligation of payment;
- where failure by a subject to complete the Study is due to the omission of tests or assessments by the Principal Investigator, there shall be no obligation of payment
- where failure by a subjectto complete the Study is due to adverse effect, lack of effect, concomitant illness, non-compliance or non-attendance, provided that full data is available up to the time of the subject's dropout and the event is satisfactorily recorded, payment shall be made in accordance with the above-referenced APPENDIX proportionately according to the amount of work carried out by the Principal Investigator pursuant to the Protocol;
- any sums advanced to the Principal Investigator prior to termination of this Agreement will be taken into account in calculating any sum due to the Institute or Principal Investigator and any balance outstanding and due to Accutest shall be paid to by the Principal Investigator;
- "Completed Patients" are subjectswho have completed the Study in accordance with the Protocol, and for whom full case report forms and any ancillary documentation required have been completed by the Principal Investigator to Accutest's satisfaction.

Section 7: Standard of Care, Insurance, Indemnity

7.1 Subject Insurance

Thishas been obtained and will be provided to the site personnel before the initiation of the trial.

7.2 Product liability

Study Insurance will be provided to the site personnel before the initial of the trial.

7.3 Standard of care

In no event shall Accutest be held responsible for any controversy, demand or claim for the payment of damages deriving from Principal Investigator for-

(a) injuries or damages incurred if they are the result of or are alleged to be the result of negligence or willful misconduct on the part of the Instituteor agents or the Principal Investigator;

(b) activities contrary to the Protocol;

(c) unauthorized warranties made by the Principal Investigator concerning the product being tested;

(d) in any case, in which written, informed consent was not obtained for the subjectinvo vedin accordance with the Protocol.

Initial (ACCUTEST): Initial (PI): Initial (INSTITUTE):

The Principal Investigator hereby represent and warrant that they have obtained a professional liability insurance policy from a reputed and creditworthy insurance company, covering their liability for any damage, which may be caused as a result of fault or negligence, which they may commit in the performance of this Agreement. The Principal Investigator shall provide evidence of its insurance upon request by Accutest. The Principal Investigator shall be liable under this Agreement for direct damages resulting from negligence or wilful misconduct in the execution of the Study.

The Principal Investigator shall defend and hold harmless, and be responsible for losses suffered byAccutestand any agent and employees of Accutest from any and all liabilities, claims, actions or suits for personal injury or death directly arising out of the improper or negligent administration or use of the Study Drug during the course of the Study.

The Principal Investigator shall also indemnify, defend, and hold Accutest and its affiliates directors, officers, employees and other representatives ("Accutest Indemnified Parties") harmless from and against any and all loss, costs, claims, actions, liability and/or suits, including without limitation, interest, penalties and reasonable attorneys' fees ("Accutest's Claims"), incurred by Accutest that arose from or was a result of following:

(a) any material breach by Principal Investigator under this Agreement;

(b)the failure, or act, error, deviation, omissions, negligence, gross negligence or intentional misconduct of the Principal Investigator in connection with its performance of the services, obligations, responsibilities and undertakings under this Agreement;

(c) Principal Investigator's violation of any and all applicable laws rules and regulations of India;

(d) Principal Investigator's breach or default in performance of its obligations in connection with the Study

(e) Principal Investigator's material deviation from the Protocol;

(f) Principal Investigator's failure to complete the Study and any such delay attributable solely to Principal Investigator's willful misconduct, or failure to comply with its obligations under this Agreement.

Section 8: Parties

8.1 Conflict of Interests

ThePrincipalInvestigatorwarrant that they, as well as all their support personnel, are not presently under any agreement or obligation which conflicts with the duties and obligations owed to Accutest under this Agreement, and further agree not to undertake any such obligations or agreement during the course of the Study

Where (if applicable) it is intended that the Study Drug will be the subject of a submission to the regulatory authorities for a New Drug Application, the Principal Investigator certifies that he/she shall, in any form or manner reasonably requested by Accutest, disclose, and shall use his/her reasonable best efforts to cause any sub-investigators for the Study to disclose, all of the following that they and their spouses, domestic partners and dependent children own or possess directly, indirectly, or equitably (all collectively "Financial Interests"):

(a) All compensation, payments (including other research grants, consulting or director's fees, honoraria, speaking and meeting travel fees and reimbursement) and items or services of value provided by or on behalf of Accutest (excluding compensation received under this Agreement);

(b) All licenses, assignments or other conveyances of rights or interests in real personal or intellectual property ofAccutest or relating to the Study Drug,

(c) All forms of interests in the equity (including stock, options, and warrants) or debt of Accutester of other entities having a financial interest in the Study Drug; and

(d) All other financial interests payments, and other compensation.

During the conduct of the Study and for one (1) year after its completion the Principal Investigator agrees to execute and update such forms, disclosures, and certifications now or subsequently required by Accutest related to the Financial Interests. The Principal Investigator hereby warrants that he/she has implemented a "Conflicts of Interests" disclosure and management policy and program that complies with the requirements and regulations issued or administered by the pertinent regulatory authorities, and the Principal Investigator warrants that he/she has and will continue to comply with such policies and programs.

8.2 Independent Contractor, Employees

The Institute and the Principal Investigatorshall perform services under this Agreement only as independent contractors for Accutest, and nothing contained herein shall be construed to be inconsistent with that relationship or status. The Principal Investigator and his respective employees shall not be considered employees or agents of Accutest. This Agreement shall not create a business organization of any kind

The parties agree that they shall not directly or indirectly solicit for employment, employ or otherwise retain staff of the other party during the term of this Agreement or within the period of three (3) years following termination of this Agreement.

The Study is performed independently from any business transactions and decision on supply purchases with Accutest. The InstituteandthePrincipal Investigatorwill not receive any benefits from the conduct of the Study beyond the remuneration agreed here in.

8.3 Assignment

Principal Investigatorshallnotassign hisrights or obligations out of this Agreement to any third parties without Accutest's prior written consent. The InstituteandthePrincipal Investigator understand and agree that this Agreement is being entered into to perform services forAccutest and that accordingly, Accutest may freely assign its rights and obligations out of this Agreement.

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

Section 9: Communications

The Parties undertake to notify each other of all cases that influence the performance of this Agreement Correspondences shall be made to the following addresses

Initial (ACCUTEST)

Initial (PI)

Initial (INSTITUTE)

1)ACCUTEST:	2) PRINCIPAL INVESTIGATOR:
Accutest Research Lab. (I) Pvt. Ltd. A-77, Khairne MIDC, TTC Industrial Area, Khairne, Navi Mumbai, 400 709, Tel.: +91 22- 2778 0718/19 Fax: +91 22- 2778 0720 Email ID: Rajendra.Talele @accutestgloabal.com	Name: Dr. Shiv Rajan Address: Department of Surgical Oncology, King George Medical University, Shatabdi Building, Chowk, Lucknow- 226003, Uttar Pradesh, ndia. Tel.: +91 94555 83068 Email ID: shivrajan.194@gmail.com
3) INSTITUTE: Name of the Authorized Signatory: Prof. R. K. Garg Designation: Member Secretary Name of the Institute: King George Medical University Address: Department of Surgical Oncology, King George Medical University, Shatabdi Building, Chowk, Lucknow- 226003, Uttar Pradesh, India.	

Section 10: Contractual

10.1 Entire Agreement

This Agreement (including the Protocol and the APPENDIX) 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 all parties and refers to this Agreement.

10.2 Applicable Law, Place of Venue

The parties agree that this Agreement shall be governed by Indian Law, without regard to the conflicts of laws provisions thereof.

The parties will endeavor to settle amicably any dispute having its origin in this Agreement. In case a dispute is brought before a court of law, the courts of Mumbai, India will have sole jurisdiction over the litigation

10.3 Severability

Should any of the provisions of this Agreement be declared entirely or in part invalid or unenforceable by the pertinent authorities according to the applicable laws, the remaining terms of this Agreement shall not be affected by such declaration. Such invalid provision shall be replaced by a valid provision reflecting - to the extent possible - the intent of the original provision.

10.4 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.

Section 11: Miscellaneous

Initial (ACCUTEST): Initial (PI): Initial (INSTITUTE)

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Principal Investigator/Institute hereby confirms,

A. that he/she has never been subject to debarment proceedings indicted, convicted, or otherwise engaged in conduct for which a person can be debarred by law,

B. To have received a copy of the Investigator's Brochure and to be informed of its contents.

The Investigator consents that his/her contact data, as well as information about the conduct of the Study, may be stored and processed for evaluation purposes during and after the completion of the Study by Accutest.

1) ACCUTEST: For Accutest Research Lab. (I) Pvt. Ltd: Signature and Date 15-Feb-2018 **Mr. Rajendra Talele, Head- Clinical Development Services**	**2) PRINCIPAL INVESTIGATOR:** Signature and Date Shiv Rajan. 18/4/18 **Dr. Shiv Rajan**
3) INSTITUTE: For Signature and Date RKGOrg 17/8/18 **Name & Designation: Prof. R. K. Garg, Member Secretary**	

R.K.Garg
Member Secretary IEC
Research Cell
King George's Medical University
U.P. Lucknow

RKGOrg

Initial (ACCUTEST):

Initial (PI):

Initial (INSTITUTE):

APPENDIX

Financial Support for Investigator:

(a) **Total payment, compliance, completed patients, inclusion Criteria:**

Payment of remuneration will only be made under the condition that the Study is conducted in accordance with the Protocol, the Study documentation is complete and evaluable, can be verified from the subject medical files, and is submitted to Accutest at the stipulated points in time. Should these prerequisites not be fulfilled, the remunerations are forfeited, particularly for patients who are included in the Study despite non-compliance with the inclusion or exclusion criteria.

Unless expressly agreed otherwise in writing, total payment will not exceed the amount set out below.

For each evaluable patient who completes the study visits in accordance with the Protocol, GCP, and application regulatory requirement, Accutest will compensate the Investigator remuneration as specified in Appendix II.

Payments for any costs not expressly specified herein, including but not limited to hospital overhead fees, staff costs, pharmacy fees, other tests,(if applicable) and travel costs, must come from the per patient enrolment fee.

(b) **Payments will be made based upon the completed CRF/eCRFs collected by Accutest**

(Please refer Appendix II for payment detail).

(c) **Pro rata temporis payment**

Should the Study be prematurely discontinued, the remuneration will be calculated on a pro rata temporis basis. For patients who do not complete the Study, remuneration may be paid on pro rata temporis basis. Payment will include only those patients participating in the Study whose date of joining the Study is not later than the date of the premature termination of the Study.

(d) **Protocol violators, exclusion**

For Protocol violators due to missed or delayed visits or in the event of a violation on the part of a patient of a Protocol resolution or the Regulations for Good Clinical Practice, no compensation will be paid for that patient /payment may be made at Accutest's sole discretion.

(e) **Income tax**

All the payments made to the payee are subject to Tax Deducted at Source (TDS) as per the applicable existing tax laws in the country. Accutest will deduct the tax at the time of making payments unless a valid certificate (Form 15 AA – for no TDS) from tax authority is made available in advance.

(f) Payment details

Accutest, on behalf of the Sponsor, shall pay the relevant cost and fee as set out in this Payment Agreement to following payees through A/C Payee Cheque as agreed by all signatories.Full of the grant shall be paid to the PI/ institute according to the payment milestones provided in APPENDIX II.

PI/ Institute payment
Payee Name: Vice Chancellor, K.G.M.U, Lucknow, U.P.
PAN number: AAAAK4509K
GST Number: 09AAAAK4509K1ZJ

Note:

1. Provide legible scan/photocopy of the PAN cards at the time of the signing of this agreement.
2. All local investigations (local lab tests, CT scans,any diagnostic assessments etc.) would be done to the payee mentioned for "PI/ institute payment" without deducting TDS. (A separate bill for patient payment should submitted).

1) ACCUTEST:	2) PRINCIPAL INVESTIGATOR:
For Accutest Research Lab. (I) Pvt. Ltd: Signature and Date Rajendra Talele 15-Feb-2018 Mr. Rajendra Talele, Head - Clinical Development Services	Signature and Date Shiv Rajan 18/4/18 Dr. Shiv Rajan
3) INSTITUTE: For Signature and Date R K Garg 17/5/18 Name & Designation: Prof. R. K. Garg, Member Secretary R.K.Garg Member Secretary IEC Research Cell King George's Medical University U.P.	

R K Garg 2

Initial (ACCUTEST): Initial (PI): Initial (INSTITUTE):

ACCUTEST RESEARCH LABORATORIES

APPENDIX II

Visit	Amount(INR)
Screening	10000
Day 15 (Cycle 1)	5000
Day 15 (Cycle 3)	4000
Day 15 (Cycle 6)	6000
Study Termination Visit	7000
Total PI Grant (a)	32000
Institutuional overhead (20%) (b)	6400
TOTAL (a-b)	38400
GST 18% (c)	6912
Patient Travel Reimbursement for 6 Cycles (d)	6000
Grand Total (a+b+c+d)	51312
TOTAL PI GRANT	51312

Payment Details & Milestone:

1. Principal Investigator Fees will be **INR 51312/-** per completed patient (inclusive of institutional overhead and goods and service tax and/or other taxes if applicable). The taxes may be revised and shall be applicable as per the Government norms from time to time.

   All local investigations (local lab tests, CT scans,any diagnostic assessments etc) wil be paid to the payee mentioned for "PI/ institute payment"on Actuals on Production of the Bills/Invoice/Proof

   The above payment also includes following charges:

   a. Investigator(s) and other team members fees
   b. Stationary, cupboard, courier, telephone, fax, internet and electricity bills, etc.
   c. Patient recruitment
   d. Electronic Case Report Form/Case Report Forms (CRF/ eCRFs) completion and correction
   e. Data Clarification Form (DCF) resolution
   f. Consultation charges
   g. Document archival

2. Ethics Committee fee will be paid on actual on the production of Bill/proof/invoice.
3. Institutional Overhead will be paidon production of Bill/proof/invoice
4. Per patient cost will be paid as mentioned above upon confirmation by site monitor of receipt of legible and accurately completed CRF/eCRF for a properly qualified subject.
5. INR 4000/- for one screen failure patient.

RKGMC

ARCH LABORATORIES (I) PVT. MUMBAI

6. Expense towards the medical management of serious adverse events will be made as per actual.

The following are the milestone for the payments:

1. Every month from SIV, site personnel is supposed to raise invoice.
2. Invoice should be 90% of the SDV completed at the site by the ARL monitor
3. Rest 10% of study payment will be made after study close out visit once all documents and activities (related to site) are completed.

NOTE: *If above milestones are not achieved than proportionate amount will be paid based on patient randomized and visit completed bythepatient.*

Principal Investigator agrees that before incurring any of the aforesaid expenses it shall obtain prior written approval from the Sponsor. Sponsor will generally provide procedural material required bytheprotocolfor the study. However, in the event Sponsor requires Principal Investigator to procure aforesaid items, it shall reimburse the actual cost incurred by Principal Investigator in connection in addition to that.

The parties hereto agree as follow on the basis of the Clinical Trial Agreement:

a) Accutest will pay a sum for every complete and evaluable patient.

b) A complete and evaluable patient is defined as follows:

- All procedures must be performed according to the protocol
- A patient will only be included according to the inclusion/exclusion criteria
- All data are documented completely and accurately

c) All payments will be on a pro rata basis as mentioned in budget above. For patients who do not complete (early termination, drop-out, etc.), the budget will be evaluated according to the number of days completed as per protocol. If any investigation is not performed during a visit, then an equivalent amount mentioned in the above budget will be decucted.

d) An invoice will be generated/ requested for payment onamonthly basis according to the actual work performed (after source data verification and CRF/eCRFs review for completed visits). An invoice will be generated/ requested according to days completed bythepatient as specified above.

e) If the patient was randomized in the study deviating from protocol inclusion and exclusion criteria (withoutawaiver, if applicable), then payment will not be made for such wrong rancomization and subsequent visits, however screening visit can be paid, if performed according to protocol.

f) Patient conveyance/ compensation will be paid by Accutest on behalf of the Sponsor and is included in thebudget as mentioned. The TDS will not be deductedon payment released for patient compensation.

g) The investigator grant includes payment of meals provided to patient and patient's relative (if applicable) during the study.

h) If the trial terminates prematurely, any payments made by Accutestexceeding the amount earned will be promptly refunded to Accutest(minus Ethics Committee fees, and patient conveyance/compensation).

i) Payment would be doneon the basis of invoices generated by the site in consultation with site CRA on every monitoring after checking the CRF/eCRF completion.

NOTE: Site should generateamonthly invoice and should consider completed milestone from above at the time of invoicing.

1) ACCUTEST: For Accutest Research Lab. (I) Pvt. Ltd: Signature and Date Rajendra Talele 15-Feb 2018 **Mr. Rajendra Talele, Head- Clinical Development Services**	2) PRINCIPAL INVESTIGATOR: Signature and Date Shiv Rajan 18/4/18 **Dr. Shiv Rajan**
3) INSTITUTE: For Signature and Date R K Garg 17/5/18 **Name & Designation: Prof. R. K. Garg, Member Secretary** R.K.Garg Member Secretary IEC Research Cell King George's Medical University	

R K Garg 17/5/18

Initial (ACCUTEST): Initial (PI): Initial (INSTITUTE):

महाराष्ट्र MAHARASHTRA ◐ 2020 ◐ YA 807850

प्रधान मुद्रांक कार्यालय, मुंबई
प.मु.वि.क. ८०००० ९०
16 MAR 2021
सक्षम अधिकारी

श्री. सी. टि. अंधेकर

CLINICAL TRIAL AGREEMENT

This contract (hereinafter "**the Contract**") is made as of the **26-03-21** (hereinafter "**the Effective Date**"), by and among:

Dr R N Srivastava, Professor, Dept of Orthopaedic Surgery, Shatabdi Phase II, 6th Floor, King George's Medical University, Chowk, Lucknow, UP, INDIA

Hereinafter "the **INVESTIGATOR**",

AND

King George's Medical University, Shah Mina Road, Lucknow- 226003

Hereinafter "the **INSTITUTION**" study site

AND

Alkem Laboratories Limited, having its registered office at **Alkem House, Senapati Bapat Marg, Lower Parel, Mumbai 400013, India.**

Hereinafter "the **SPONSOR**"

Dr. R N Srivastava
Professor
Dept. of Orthopaedic Surgery
K.G. Medical University
Lucknow

ALKEM LABORATORIES LTD.

Initials INVESTIGATOR Initials INSTITUTION Initials SPONSOR

6406

ALKEM LABORATORIES LTD.
"ALKEM HOUSE", Devashish,
Senapati Bapat Marg,
Lower Parel, Mumbai-400 013

परिशिष्ट - क Annexure [illegible]

मुद्रांक विकत घेणाऱ्याचे नाव ____________________

मुद्रांक विकत घेणाऱ्याचे रहिवासी पत्ता ____________________

मुद्रांक विक्रीच्या नोंद वहीतील अनु. क्रमांक ________ दिनांक ________

मुद्रांक विकत घेणाऱ्याची सही   परवानाधारक मुद्रांक विक्रेत्याची सही

परवाना क्रमांक : ८००००१०

मुद्रांक विक्रेत्याचे नाव/पत्ता : श्री. कल्पेश प्रेमजी गाला

रुम नं.४, भाग्योदय बिल्डींग, ७९ नगिनदास मास्टर रोड, फोर्ट, मुंबई-४०० ००१.

22 MAR 2021

शासकीय कार्यालयासमोर/न्यायालयासमोर [illegible] मुद्रांक खरेदीची आवश्यकता नाही. 22 MAR 2021 [illegible]

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

The INVESTIGATOR, the INSTITUTION and the SPONSOR are hereinafter individually referred to as a "**Party**" or collectively referred to as the "**Parties**".

WITNESSETH:
WHEREAS, the SPONSOR is to perform a clinical trial (hereinafter the "**Study**") to evaluate its product [**ADA1**] (hereafter the "Investigational Product") in accordance with a protocol of SPONSOR entitled 'A prospective, multicenter, randomized, double blind, Phase III study to compare the efficacy and safety of Biosimilar Adalimumab injection of Enzene Biosciences Ltd. with HUMIRA® (adalimumab) injection in subjects with active Ankylosing spondylitis (AS).' [**ALK20/ENZ129-ADA1**] and its amendments (hereinafter collectively the "Protocol"),

AND WHEREAS, the INSTITUTION and the INVESTIGATOR having each reviewed the Protocol for the Study, the Clinical Investigator Brochure and sufficient information regarding the Investigational Product to evaluate their interest in participating in the Study, wish to participate in the Study and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Study.

In consideration of the undertakings and commitments set forth herein, the Parties agree to enter into the Contract, which provisions shall apply in compliance with those of the Protocol.

ARTICLE 1. PROTOCOL

The Study shall be performed in strict compliance with the Protocol a copy of which has been provided and signed by the INVESTIGATOR, INSTITUTIONand SPONSOR, as such Protocol is submitted to the registered Institutional Ethic Committee (**"IEC/IRB"**) for favorable opinion/ approval and as the Protocol may be amended from time to time thereafter.

Any amendment to the Protocol shall be notified to the relevant IEC/IRB according to regulation & guidelines mentioned in section 3.1. All the terms of the Protocol and any further amendments to the Protocol are incorporated hereunder and are part of the Contract.

To the extent that there may be any inconsistency between this Contract and the Protocol, this Contract shall control, except with respect to medical or clinical matters for which the provisions of the Protocol shall take precedence.

ARTICLE 2. STUDY SITE

The Study shall be performed at the INSTITUTION (hereinafter the "**Study Site**"). The INVESTIGATOR and the INSTITUTION shall be responsible for obtaining any authorization from the representatives of the Study Site where the Study is performed.

For the avoidance of doubt, the sums paid under Exhibit 1 of the Contract to the INVESTIGATOR and/or the INSTITUTIONinvolves compensation for the performance of the Study carried out at the Study Site.

The INVESTIGATOR hereby represents, warrants and covenants that he/she has and shall maintain all necessary authorizations from the Study Site representatives to perform the Study and that he/she shall take responsibility for the payment of any cost incurred by the Study Site in connection with the Study, the amount and terms of which shall be directly and exclusively handled by the INVESTIGATOR and the Study Site.

ARTICLE 3. COMPLIANCE

3.1 The Study shall be performed in accordance with (i) the Protocol (ii) all applicable Central, State and Local laws, rules and regulations in India including the Ethical Guidelines for Biomedical Research on Human Subjects issued by the Indian Council of Medical Research and the Indian GCP Guidelines, (iii) the Guideline for Good Clinical Practice of the International Conference on Harmonization (hereinafter the "**ICH–GCP**"), (iv) the principles laid down by the 18th World Medical Assembly (Helsinki, 1964) and all applicable amendments laid down by the World Medical Assemblies, and (v) the specific procedures provided by the SPONSOR applicable for conducting the Study.

3.2 The INVESTIGATOR and the INSTITUTION shall ensure that all procedures defined in the Protocol are complied with, so that all data coming from the Study Site are reliable and have been processed correctly (especially the randomization lists, and the blind character of the Study as the case may be) and will ensure that the content of the case report form (CRF)/electronic case report form (e-CRF) will accurately reflect source documents.

3.3 The INVESTIGATOR and the INSTITUTION shall submit CRF/e-CRF to the SPONSOR.

Prof.R.N. S... Dept. of Orthopaedics K.G.Medical University

ARTICLE 4. TERM

This Contract is being entered into force from the Effective Date and shall expire upon receipt by the SPONSOR of all data generated by the INVESTIGATOR and after completion of the close-out visit for the Study Site.

The Parties estimate that the whole Study will take approximately Eighteen months from the first visit of the first Subject to the last visit of the last Subject.

ARTICLE 5. ITEMS SUPPLIED BY THE SPONSOR

5.1 The SPONSOR shall provide the INVESTIGATOR and/or the INSTITUTION with all necessary information, documents and materials, including but not limited to :

- the Investigator's Brochure (IB)
- the Protocol,
- the Informed Consent Form
- the CRF/e-CRF
- the Investigational Product manufactured in accordance with the applicable regulations and/or the Good Manufacturing Practice (GMP), suitably packaged and labeled and in sufficient quantity to conduct the Study.

5.2 The INVESTIGATOR, the Collaborators and the INSTITUTION shall use the information, documents and Investigational Product provided by the SPONSOR, solely for the purpose of the Study or to fulfill their own regulatory obligations, to the exclusion of any use for their own or for a third party's account.

For the purpose of the Contract, the term "Collaborator(s)" shall mean any person involved in the Study including but not limited to research associates, sub-investigators, biologists, assistants and nurses.
Unless otherwise instructed by the SPONSOR or required by applicable laws and regulations, the information, documents and Investigational Product shall be returned or made available to the SPONSOR upon completion of the Study.

The INVESTIGATOR shall bind the Collaborators with obligations at least as stringent as those provided for in the Contract. Therefore, the INVESTIGATOR shall be held liable should any of the Collaborators fail to comply with any of the obligations provided for in this Contract.

The Investigational Product will not be released until the SPONSOR has received a copy of the written and dated approval/opinion of the IEC/IRB and DCGI for the study.

5.3 The INVESTIGATOR / INSTITUTION or its designee shall ensure that an accurate record of the quantity of Investigational Product received and dispensed to each patient is maintained. The INVESTIGATOR/INSTITUTION shall ensure that the Investigational Product is stored and dispensed in accordance with the SPONSOR's specifications and applicable laws and regulations.

5.4 The INVESTIGATOR/INSTITUTION agrees to take responsibility for the safeguarding of such materials and to notify SPONSOR promptly in case of any loss damage, or failure of these materials.

5.5 Upon termination or completion of the Study, all unused Study Drug, compounds, drugs devices, case report forms, whether or not completed, and other related materials that were furnished to the INVESTIGATOR/INSTITUTION by or on behalf of the SPONSOR shall be returned to the SPONSOR.

ARTICLE 6. SUBJECTS' RECRUITMENT

6.1 The INVESTIGATOR has estimated that he/she may require to recruit a maximum of 20 (Twenty) Subjects (the "**Subjects**"), within nine months of commencement of the Study. This target of recruitment can be increased only upon written agreement of the SPONSOR. In addition, SPONSOR may establish a threshold number of Subjects and rate of accrual of Subjects (e.g, x Subjects per day/week/month) to allow for appropriate monitoring of the Study and will communicate this information to the INVESTIGATOR. The INVESTIGATOR undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by the SPONSOR.

6.2 A minimum of five patients must be enrolled within Two months of initiating the Study at the STUDY SITE. If no subjects are enrolled over a period of nine months, the SPONSOR may decide at its discretion to discontinue the Study at the STUDY SITE.

6.3 The SPONSOR reserves the right to request the INVESTIGATOR to limit the recruitment of further Subjects or cease the recruitment, notably in case the recruitment target for the Study has been reached. In such case, the SPONSOR shall inform the INVESTIGATOR to stop the recruitment of any subject who

has not yet signed informed consent. The INVESTIGATOR shall upon receipt of the written notice stop immediately further recruitment of Subjects. Payments shall only be made according to the number of Subjects recruited up to the date of receipt of the notice by indicating no further recruitment. The SPONSOR will not take any responsibility and make any payment for the Subjects recruited after this date.

ARTICLE 7. CONSENT OF THE SUBJECTS

7.1 Before any Subject's participation in the Study, the INVESTIGATOR shall fully inform any subject and/or, as the case may be, her/his legal representative, in language understandable to them, of all pertinent aspects of the Study in accordance with the requirements stipulated under Indian laws/regulations (Article 3.1).

7.2 The INVESTIGATOR shall ensure that all Subjects participating in the Study and/or their legal representative (i) have received a copy of the Subject information leaflet, and (ii) have expressed their prior consent by signing the informed consent form, in such format as approved by DCGI or Other Authority, without the undue influence or coercion of any person directly involved in the Study, and only after having been duly informed.

7.3 The INVESTIGATOR&/ INSTITUTION shall ensure that the entire informed consent process referred to in Article 7.2 above be video recorded if the same is applicable as per local regulations and/or made applicable by Institutional Ethics Committee. The INVESTIGATOR &/ INSTITUTION should ensure that the confidentiality of the recorded files is appropriately maintained.

ARTICLE 8. MONITORING OF THE STUDY

8.1 The SPONSOR shall appoint monitor(s) from their end or from Clinical Research Organization (CRO), bound by a professional confidentiality obligation, who will work with the INVESTIGATOR and the INSTITUTION to ensure proper conduct of the Study (hereinafter the "**Monitor(s)**"). The INVESTIGATOR and the INSTITUTION agrees to fully cooperate with the SPONSOR's monitoring procedures and maintain all necessary patient information

8.2 The Monitor shall be entitled to visit the Study Site and be regularly informed about the performance of the Study and shall collect all the documents and information about the Study in accordance with the Protocol and the ICH-GCP. He/she shall have access to all records on the Subjects and all information pertaining to the Study, as well as, copies thereof, if needed.

ARTICLE 9. DUTY OF INFORMATION

The INVESTIGATOR and/or the INSTITUTION shall immediately inform the SPONSOR, Licensing Authority & Ethics Committeeof any serious adverse event ("**SAE**") or other events as defined in the Protocol.

ARTICLE 10. FINANCIAL TERMS AND CONDITIONS

10.1 In consideration for the proper performance by the INVESTIGATOR and the INSTITUTION of their obligations under the Contract, the SPONSOR shall compensate the INVESTIGATOR and/or the INSTITUTION in compliance with the payment terms defined in Exhibit 1. Payment terms may be modified only upon prior written consent of the Parties. Likewise, non-emergency additional tests or services (tests or services non-required by the Protocol or performed in excess of Protocol requirement) shall not be reimbursed hereunder without the prior written consent of the SPONSOR.

ARTICLE 11. CONFIDENTIALITY AND RESTRICTED USE

11.1 All information disclosed or provided by the SPONSOR or produced during the Study, including but not limited to the Protocol, the Investigator's brochure and CRF/e-CRF, the results obtained during the course of the Study, the financial terms of the Contract (hereafter the "**Confidential Information**"), is confidential. The INVESTIGATOR and the INSTITUTION agree to keep confidential and not to disclose the Confidential Information to any third party without the prior written approval of the SPONSOR. The INVESTIGATOR and the INSTITUTION shall use the Confidential Information solely for the purposes of the Study.

11.2 Furthermore, the Parties agree to adhere to the principles of personal data confidentiality in relation to the Subjects, the INVESTIGATOR, the INSTITUTION and the Collaborators involved in the Study. Each Collaborator shall be subject to these obligations of confidentiality and restricted use. The INVESTIGATOR shall inform the Collaborators of the confidential nature of the Study and will only

provide them with the Confidential Information that is strictly necessary for the accomplishment of their acts.

11.3 Confidential Information shall not include information that: (1) is at the time of disclosure, or thereafter becomes, publicly available through no fault of the INVESTIGATOR or the INSTITUTION; (2) is disclosed to the INVESTIGATOR or to the INSTITUTION by a third party entitled to disclose such information in a non-confidential manner; (3) is known to the INVESTIGATOR or to the INSTITUTION prior to disclosure under this Contract, as shown by the INVESTIGATOR's or the INSTITUTION's prior written records; (4) can be documented to have been independently developed by Study Site's personnel without reliance on Confidential Information; or (5) is required by applicable law to be disclosed, provided that the INVESTIGATOR or the INSTITUTION give the SPONSOR prompt notice of such fact so that it may obtain a protective order or other appropriate remedy concerning any such disclosure, cooperate fully with the SPONSOR in connection with its efforts to obtain any such order or other remedy, and disclose, where disclosure is necessary, only the information legally required to be disclosed.

11.4 The obligations of confidentiality and restricted use contained herein are applicable during the term of the Contract and shall survive for 10 (ten) years from its date of termination or expiry whichever is later.

ARTICLE 12. RECORD RETENTION

The INVESTIGATOR and the INSTITUTION through the Study Site shall retain and preserve one (1) set only of all original data generated in the course of the Study for 5 years from the date of the last visit of SPONSOR to the Study Site after the Study is completed ("**Retention Period**").

The SPONSOR must be informed in writing of any change of address or relocation of the Study files and of the INVESTIGATOR /the INSTITUTION during this period.

Following the Retention Period, as instructed by the SPONSOR, the INVESTIGATOR and/or the INSTITUTION will either forward such records to the SPONSOR at the SPONSOR's expense, retain such records for a reasonable additional charge to be mutually agreed , or destroy the records, and send the SPONSOR proof of such destruction. Subject files should be retained as per GCP requirements as defined in the Protocol and in compliance with local regulations.

ARTICLE 13. DATA PROTECTION

13.1 The Subject data, the INVESTIGATOR's data, the INSTITUTION's data and Collaborators' data, which may be included in the SPONSOR's databases, shall be treated by the Parties in compliance with all applicable laws and regulations.

13.2 The SPONSOR also collects specific data regarding the INVESTIGATOR and the Collaborators which may be included in the SPONSOR's databases, shall be treated by both Parties in compliance with all applicable laws and regulations.

13.3 When archiving or processing data pertaining to the INVESTIGATOR, the Collaborators, the INSTITUTION and/or the Subjects, the SPONSOR shall take all appropriate measures to safeguard and prevent access to this data by unauthorized third party.

ARTICLE 14. PUBLICATIONS AND COMMUNICATIONS

14.1 The INVESTIGATOR and the INSTITUTION undertakes not to make any publication or release pertaining to the Study and/or results of the Study without the SPONSOR's prior written consent, being understood that the SPONSOR will not unreasonably withhold its approval.

14.2 The INVESTIGATOR and the INSTITUTION shall not use the name(s) of the SPONSOR and/or of its employees in advertising or promotional material or publication without the prior written consent of the SPONSOR. The SPONSOR shall not use the name(s) of the INVESTIGATOR, the INSTITUTION and/or the Collaborators in advertising or promotional material or publication without having received their prior written consent(s).

14.3 The SPONSOR has the right at any time to publish the results of the Study.

ARTICLE 15. PROPERTY RIGHTS

15.1 All Confidential Information, documents, materials, Investigational Product and equipment provided by the SPONSOR (hereinafter collectively "**Information**") are and shall remain the sole and exclusive property of the SPONSOR.

The INVESTIGATOR and INSTITUTION shall not and shall cause the Collaborators not to mention any Information in any application for a patent or any other intellectual property rights whatsoever.

15.2 All the results, data, documents, discoveries and inventions which arise directly or indirectly from the Study in any form, shall be the immediate and exclusive property of the SPONSOR or its designee. For this purpose, the INVESTIGATOR, the Collaborators and the INSTITUTION presently assign to the SPONSOR (or its designee) all intellectual property rights (including all patents, copyrights, databases and any application or right to apply for registration of any of those rights) which may arise directly or indirectly from the Study and all existing or future materials created in relation to the Study.

15.3 The SPONSOR may use all the results at its own discretion, without any limitation to its property right (territory, field, continuance, etc.), and without any additional payment. The SPONSOR shall be under no obligation to patent, develop, market or otherwise use the results of the Study issued under this Contract.

ARTICLE 16. LIABILITY – INDEMNIFICATION – INSURANCE

16.1 The SPONSOR agrees that it has subscribed to a liability insurance policy to cover its liability as required by applicable law. The SPONSOR will provide the INVESTIGATOR and/or the INSTITUTION with a certificate of insurance.

16.2 The insurance subscribed to by the SPONSOR does not release either the INVESTIGATOR or the INSTITUTION from their obligation to maintain their own liability insurance policies.

16.3 The SPONSOR agrees to indemnify, hold harmless and defend the INVESTIGATOR, the INSTITUTION, and the Collaborators ("**Indemnitees**") from and against any and all claims and suits, including reasonable attorneys' fees incurred in the defence thereof, arising out of an injury to a Subject (including death) caused by the administration of the Investigational Product or the performance of any procedure required under the Protocol as per Indian laws, except to the extent such claim or suit is attributable to:

(1) a failure to adhere to the terms of this Contract, the Protocol or any written instructions from the SPONSOR regarding the administration of the Investigational Product or the performance of any required procedure;

(2) a failure to comply with any applicable laws, regulations and government requirements (including, without limitation, obtaining informed consents); or

(3) the negligence or wilful malfeasance of the Indemnitees.

The SPONSOR shall have no obligation under this Article, however, unless: (i) the SPONSOR is promptly notified of any such claim or suit; (ii) the Indemnitees cooperate fully in the handling thereof; and (iii) the SPONSOR has sole control over the disposition of such claim or suit, including the selection of counsel and any settlement thereof, provided, however, that no settlement shall include an admission of liability on the part of the Indemnitees without their prior written consent, which consent shall not be unreasonably withheld.

ARTICLE 17. AUDITS AND INSPECTIONS

17.1 For the purpose of ensuring compliance with the Protocol, Good Clinical Practice and applicable regulatory requirements, the INVESTIGATOR and the INSTITUTION shall permit audits by or on behalf of the SPONSOR and inspections by applicable regulatory authorities.

The INVESTIGATOR agrees to allow the auditors and/or inspectors to have direct access to his/her Study records and to Subjects files for review, being understood that this personnel is bound by professional secrecy, and as such will not disclose any personal identity or personal medical information.

17.2 The INVESTIGATOR and the INSTITUTION shall devote their best efforts to facilitate the performance of any audit and inspection and shall give to the SPONSOR or to any person designated by the SPONSOR access to all necessary facilities, data and documents.

17.3 As soon as either the INVESTIGATOR or the INSTITUTION is notified of a future inspection by the authorities, they shall inform the SPONSOR and authorize the SPONSOR to participate to this inspection. The information that arises from the inspections by the regulatory authorities will be immediately communicated by the INVESTIGATOR and/or INSTITUTION to the SPONSOR.

Prof. R. [illegible] Dept. of [illegible] K.G. Medical [illegible]

Initials SPONSOR | Initials INSTITUTION | Initials INVESTIGATOR

17.4 The INVESTIGATOR and the INSTITUTION shall take appropriate measures required by the SPONSOR to take corrective actions without delay in order to solve all problems found during the audits or inspections.

17.5 It is expressly agreed between the Parties that the SPONSOR will not compensate the INVESTIGATOR and/or the INSTITUTION for the audits and inspections and that the assistance and availability of the INVESTIGATOR or the INSTITUTION for the audits and inspections, if any, is includec in the amount mentioned in Exhibit 1.

17.6 The rights and obligations under this Article shall remain in effect for a period of five (5) years after the end of the Study.

ARTICLE 18. TERMINATION OF THE CONTRACT

This Contract may be terminated: (1) by a mutual written consent of the SPONSOR, INVESTIGATOR and the INSTITUTION on immediate basis; or (2) by the SPONSOR upon serving thirty (30) days prior written notice to the INVESTIGATOR and the INSTITUTION.

In the event this Contract is terminated, the SPONSOR will be responsible for compensating INVESTIGATOR and/or the INSTITUTIONfor actual activities performed hereunder in accordance with the terms of this Contract and reasonable non-cancellable expenses incurred prior to notice of termination if such expenses were required under the Protocol and contemplated within Exhibit 1. Any funds paid in advance will be prorated and any excess funds will be returned to the SPONSOR. The INVESTIGATOR shall provide the SPONSOR with all documentation required by the Protocol and applicable laws and regulations and any equipment provided by the SPONSOR in connection with the Study no later than ninety (90) days after the completion or early termination of the Contract.

The terms and conditions of Articles 11,13,14,15,19 shall survive the expiration or earlier termination of this Contract.

ARTICLE 19. DEBARMENT AND SENTENCING FOR MALPRACTICE

The INVESTIGATOR and the INSTITUTION represent and warrants that neither he/she nor any Collaborators /INSTITUTION involved in conducting the Study nor any member of the staff of the INSTITUTION, has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial, or perform services in connection with the evaluation of a pharmaceutical product under any laws, regulations or professional code of conduct.0.

The INVESTIGATOR shall immediately notify the SPONSOR should he/she or any Collaborators involved in conducting the Study, be so debarred, excluded, disqualified or restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Contract and during the thriteen months following the expiration or termination of the Contract.

ARTICLE 20. CONFLICT OF INTERESTS AND FINANCIAL DISCLOSURE

The INVESTIGATOR shall ensure that he/she and the Collaborators involved in this Study at the INVESTIGATOR's Study Site provide the SPONSOR with the appropriate financial disclosures required for compliance with DCGI, on such forms as the SPONSOR may supply or approve.

ARTICLE 21. MISCELLANEOUS

21.1 The Protocol, the Contract and all others documents exchanged between the Parties constitutes the whole undertaking of the Parties. All appendices attached hereto shall be deemed to be incorporated herein.

21.2 Any work performed by the INVESTIGATOR, the Collaborators and/or the INSTITUTION under this Contract shall be considered to be performed by them as independent contractors and not as employees, partners or agents of the SPONSOR. No Party shall have the authority, either express, implied or apparent, to bind the other Party, except to the extent that same may be consistent with the performance of that Party's obligations in accordance with the terms of this Contract.

21.3 Except as otherwise expressly mentioned hereinabove, any notification shall be made by mail or fax.

21.4 If either Party is prevented from fulfilling its obligations in accordance with the terms of this Contract due to force majeure (as defined by competent law and/or competent court), this Party shall be released from performance to the extent that it is so prevented from doing so for the duration of the intervening circumstances. The Party wishing to claim relief on the grounds of the said circumstances shall notify the other Party in writing without delay on the intervention or cessation thereof. The Party so prevented from

fulfilling its obligation shall devote its best endeavors to remove or avoid the impediment as soon as possible. If the Party is prevented from fulfilling its obligations under this Contract due to force majeure for a period exceeding two (2) running months, each Party shall have the right to terminate this Contract by registered mail with acknowledgment of receipt. The termination will become effective forthwith.

21.5 No indulgence granted by either Party to the other in relation to any term hereof shall be deemed a waiver of such term or prejudice the later enforcement of that or any other term hereof.

21.6 Should a provision of this Contract in any manner whatsoever contravene any applicable laws and regulations, such provision shall be deemed to be severable and shall not affect any other provision of this Contract, nor affect the enforceability of those remaining provisions which are not in contravention of any law and regulation.

21.7 The Contract is concluded by the SPONSOR intuitu personae. Hence, the INVESTIGATOR and the INSTITUTION shall not be allowed to transfer totally or partially the obligations the SPONSOR charged them with, nor to subcontract them without the prior written consent of the SPONSOR. The INVESTIGATOR and the INSTITUTION shall, where applicable, transmit to the Collaborators the Contract and shall cause them to abide by its terms and conditions. The SPONSOR may transfer this Contract to a successor in interest to its business by reason of any merger, acquisition, partnership, license agreement or otherwise, provided that the assignee is subject to the terms and obligations provided in this Contract.

21.8 This Contract constitutes the entire agreement between the Parties relative to the subject matter hereof and supersedes all representations, warranties, agreements or undertakings previously made relative to such subject matter, and no such representations, warranties, agreements or undertakings shall be any force and effect unless contained herein. No variation of any terms and conditions of this Contract will be binding upon the Parties unless committed in writing and signed by them respectively.

21.9 This Contract shall be governed by the laws of India. Prior to taking any legal action, the Parties shall endeavor to settle by amicable arrangement any disputes arising between them regarding this Contract. Should the Parties fail to reach an amicable settlement, the Parties agree to submit to the exclusive jurisdiction of the courts of Mumbai and they waive any other forum to which they may be entitled by reason of their present or future address or for any other reason.

21.10 No Party may assign or novate its rights, interests, liabilities or obligations under this Contract or any part thereof without the prior written consent of the other Parties, such consent not to be unreasonably withheld or delayed.

IN WITNESS WHEREOF, the Parties hereto have caused this Contract to be duly executed on their behalf in three counterparts, each of which shall be deemed to be an original, as of the Effective Date.

ALKEM LABORATORIES LIMITED

ALKEM LABORATORIES LTD. MUMBAI, INDIA

Name: Dr. Akhilesh Sharma
Designation: President & Chief Medical Officer

INVESTIGATOR

Prof. R.N. Srivastava, Prof. & Head, Deptt. of Orthopaedic Surgery, K.G. Medical University, U.P. Lucknow

Name: Dr R N Srivastava
Designation: Principal Investigator

INSTITUTION

Name:
Designation:

Member Secretary, Institutional Ethics Committee, King George's Medical University U.P. Lucknow

Prof. K.N. Srivastava, Prof. & Head, Deptt. of Orthopaedic Surgery, K.G. Medical University, U.P. Lucknow

EXHIBIT 1

1) The SPONSOR will provide grants to the institute as per below table for 20 subjects included in accordance with the Protocol and who has completed the Study and does not participate in pK study, this includes principal investigator, site coordinator and subject transportation fees for all visits.

	Adalimumab budget	
	Buoget for patients	**20**
	Heads	**Amount**
1	All protocol specific investigations (including screen failure)	As per actuals
2	Adcitional investigations (if required)	As per actuals
3	AE and SAE Management	As per actuals
4	Patient travel cost: INR 500 per visit X 20 pts. X 8 visits (additional charges will be included for extra visit)	80000
5	Research Coordinators fees (for 12 Months)	240000
	SUBTOTAL	320000
	Institutional overhead 25%	80000
	Total cost	**400000**

The payment shall be made as per below listed milestone.

	Milestones for payment	
Sr No	**Milestone**	**Amount**
1	Advance 10%	40000
2	10% @ Five subject randomized	40000
3	10% @ Ten Subject randomized	40000
4	20%@ Fifteen Subject randomized	80000
5	20%@ Twenty Subject randomized	80000
6	20% @ All subjects competed visits	80000
7	10%@ Site close out	40000
	Total	**400000**

The Total budget is calculated on assumption that 20 patients will be enrolled (10 in PK study and 10 non PK stucy). In case 20 Subjects not randomized then the final payments will be based number of subjects completed study at the site and the milestones will be adjusted considering per patient grant as Rs. 20000/-

2) Ethics Committee fees will be based on actuals.

3) Charges of protocol specific local laboratory test, including repeated local laboratory test done in case of adverse event will be reimbursed on actual i.e. upon presentation of invoices.

4) Institutional overheads will be 25% on patient visit fees as listed in above table.

5) A subject is considered as having completed the study when he/she has completed the specified study period, and is evaluated as per the Protocol.

6) In case of subjects recruited but not having completed the study, the amount to be paid will be calculated according to the fees of the visits actually performed by that subject. No payment will be made for an ineligible subject incorrectly randomized into the study or in case the subject did not complete the study due to negligence, malpractice, breach of protocol, willfully wrong act or omission on the part of the INVESTIGATOR/INSTITUTION.

7) The payment for recruited Subjects will be made to the INSTITUTION upon presentat on of the invoices within 45 days on the following account:

ALKEM LABORATORIES LTD. MUMBAI, INDIA

Prof.R.N. ... Prof ... Dept. of C...hol... K.G.Medical Uni... LUCKNOW

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR

KGMU Research Fund	
Payment through Cheque:	
Name of Payee:	KGMU Research Fund
Address of Payee:	King George Medical University, KGMU, Lucknow
PAN / TAN Number:	AAAAK4509K
GST No.	09AAAAK4509KZJ
Payment through wire transfer:	
Beneficiary's Account Name:	KGMU Research Fund
Beneficiary's Account Number:	50287351562
Bank Name:	Indian Bank
Bank Address:	KGMU Campus Branch Chowk, Lucknow-226003
IFSC:	IDIB000K656

8) Goods and Service Tax shall be added to invoiced amount as per indian tax regulations.

9) All payments made shall be subject to tax deducted at source, except for reimbursement.

10) The final payment will occur only after:

- The delivery and review of the final data of the study, provided that they shall be ready for statistical analysis;
- The completion of all CRF, including resolution of all DRF and after the positive opinion on the part of the SPONSOR regarding their filling;
- Receipt of all responses to the DRF from the INVESTIGATOR/INSTITUTION;
- The INVESTIGATOR has returned all remaining Investigational Product and applicable study material, if any.

THE DECCAN MERCHANT CO-OP BANK LTD. DADAR (W), KESHAVJI NAIK BUILDING, FIRST FLOOR RANADE ROAD, DADAR (WEST) MUMBAI - 400 028

Authorised Signatory

भारत 06895 136287 SPECIAL ADHESIVE महाराष्ट्र MAR 26 2019 13:17

INDIA STAMP DUTY MAHARASHTRA Rs.0000200/- PB6584

CLINICAL STUDY AGREEMENT

This Clinical Agreement ("**Agreement**") is entered into as of 27 MAR 2019 ("Effective Date") between **Novartis Healthcare Private Limited, a company registered under the Companies Act, 1956** and having its registered office at The Inspire – BKC, 7th Floor, G-Block, BKC Main Road, Bandra Kurla Complex, Bandra East, Mumbai 400051 ("**Novartis**") which expression shall mean and include its successors and assigns of the ONE PART;

AND

King George's Medical University, ("**Institution**") registered under the provisions of the Uttar Pradesh Chhatrapati Shahuji Maharaj Medical University Act, 2002 (U.P. Act No.8 Of 2002) and having its address at Erstwhile Chhatrapati Shahuji Maharaj Medical University, Chowk, Shah Mina Road, Lucknow-226003, Uttar Pradesh, India , which expression shall mean and include its successors and assigns of the SECOND PART;

AND *Dr. Sudhanshu Kumar Dwivedi* 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 prevelance 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 *15-April-2019*, subject to the compliance of Section 3 prior to this date. The Institution shall use its best efforts to complete the Study and to perform its obligations under this Agreement by *23-September-2021* 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 22-Mar-2019 ('Effective Date') and shall expire upon 21-Mar-2022 (both days inclusive) 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 **King George's Medical University, Chowk, Lucknow - 226003, India**: (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 enrolment 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 enrolment 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.

(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 6.7 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 on the Study 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 ***90 days from site initiation.***

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 dia ("Novartis") which expression shall mean and include its successors and assigns o 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;

(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
Novartis Healthcare Private Limited

Murugananthan K,
The Inspire – BKC,
7th Floor, G-Block,
BKC Main Road,
Bandra Kurla Complex,
Bandra East, Mumbai 400051

Telephone: +91 -22 50243000
Fax: +91-22-50243005

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

By: _____

Name: Sachin Singh

Title: Trial Monitoring - Head CTO

Date: 21st March 2019

KING GEORGE'S MEDICAL UNIVERSITY

By: _____

Name: R. K Garg

Title: Member Secretary IEC

Date: 20/6/19

R.K.Garg
Member Secretary IEC

Research Cell
King George's Medical University
U.P. Lucknow

PRINCIPAL INVESTIGATOR

By: _____

Name: Dr. Sudhanshu Kumar Dwivedi

Title: Principal Investigator

Date: 3/JUN/2019

ANNEX 1: PAYMENT SCHEDULE

STUDY NUMBER: CTQJ230A12001

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

Investigator s Name: Dr. Sudhanshu Kumar Dwivedi

Institute Name: King George's Medical University

Payee Name: Vice Chancellor, KGMU

Pan Card Number: AAAAK4509K

GSTIN: 09AAAK4509K1ZJ

Committed Number of Study Subjects: 100

Payment Schedule:

Visit name	1
Study Payment	5500
CRC Fees	1000
Institutional Overhead @ 10 %	550
Total Per Patient Visit	7,050 INR

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.
- The total payment to the institution will vary depending upon the total number of eligible patients enrolled. For each eligible patient with completed CRF the institution would be paid @ INR 5500/- only.
- Institutional Overhead charges will be paid as 10% of the CRF fee to the Institution.
- Study coordinator fees of INR 1,000 per patient shall be paid to the Institution upon completion of CRF.
- For enrolled patients, laboratory charges for LDL-C & Lp(a) examination will be reimbursed as per actuals to the institution on the receipt of original invoices only. It is the Investigators responsibility to liaise with the hospital laboratory.
- 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.
- 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 stucy. 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 co not give my permission to disclose my personal data in connection with the Grant Plan database.

Place and Date: Lucknow - 3 | JUN | 2019

Name: Dr. Sudhanshu Kumar Dwivedi

Principal Investigator

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, acaptation 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.

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

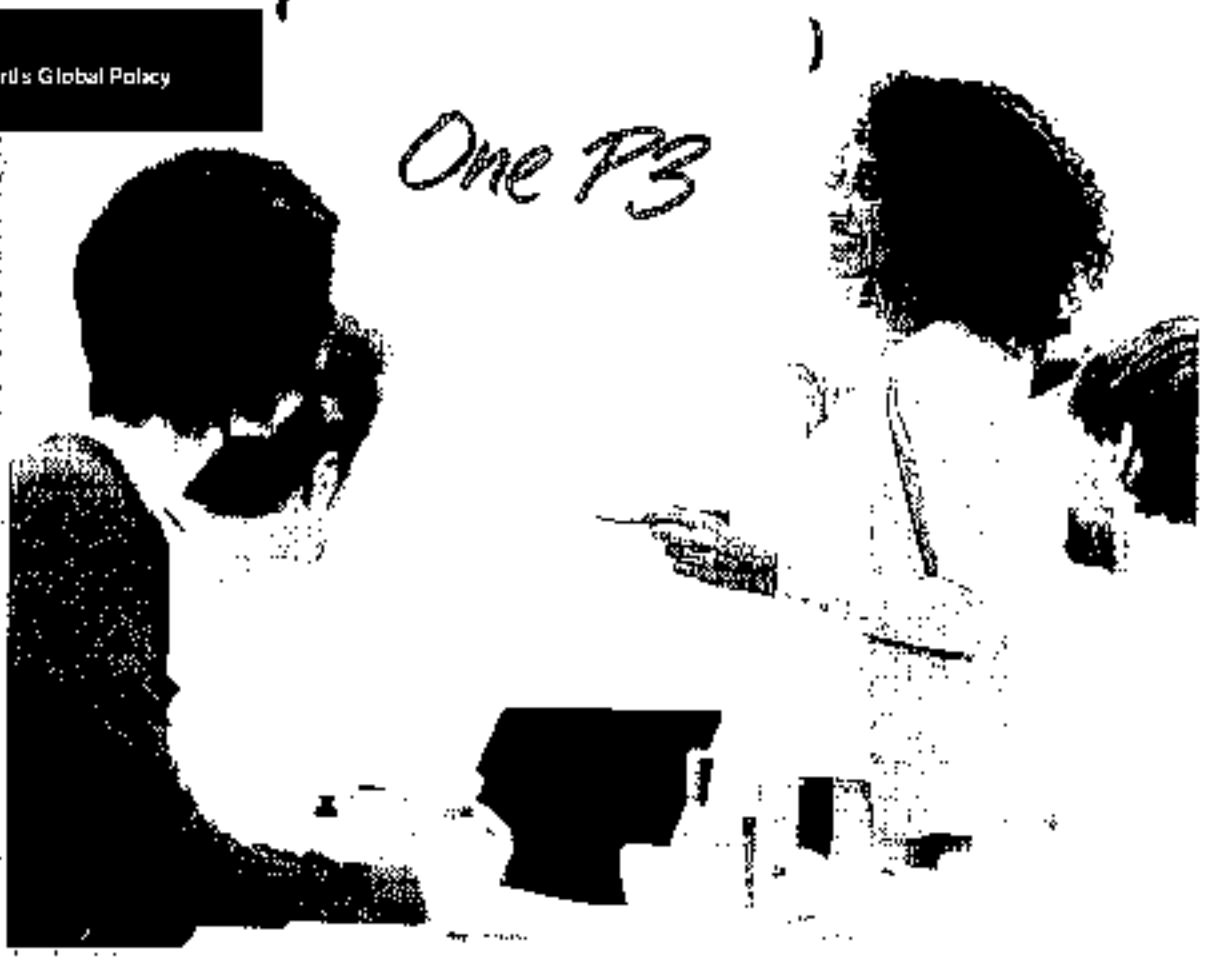
I / We, have read the policy (ies) understood its meaning and shall comply with the same.

[NAME OF INSTITUTION]	[PRINCIPAL INVESTIGATOR]
By: _____	By: _____
Name: R. K Garg	Name: Dr. Sudhanshu Kumar Dwivedi
Title: Member Secretary IEC	Title: Professor
Date: 30/1/19	Date: 31 JAN 2019

R.K.Garg
Member Secretary IEC

Research Cell
King George's Medical University
U.P. Lucknow

Novartis Global Policy



Professional Practices Policy (P3)

Novartis Global Policy

March 1st, 2018

Version GIC102V1.EN

NOVARTIS

Contents

1 Introduction

Purpose

Novartis' vision is to be a trusted leader in changing the practice of medicine. Consistent with this vision, Novartis is committed to the same high standard of ethical business conduct wherever it does business. Novartis has therefore adopted a single set of ethical principles that should be applied in daily decision-making by all Novartis Associates in any customer interaction and professional practice-related activity, including those not specifically covered by this Policy or related documents.

Scope and applicability

This Policy applies to all Novartis Associates as well as all professional practice-related activities conducted by third parties on behalf of Novartis. All such activities must be conducted in accordance with local laws, regulations and industry codes, which may be more stringent than the requirements outlined in this Policy.

This Policy serves as the foundation for P3 Guidelines ("Guidelines") and local standard operating procedures ("SOPs") all of which provide additional requirements for expected behaviors. As a result, this Policy should be read and applied in conjunction with the Guidelines and other references included in Section 5 of this document.

This Policy is effective as of March 1, 2016 and must be implemented by all Novartis affiliates. It replaces the existing versions of the divisional Professional Practices Policies.

The owner of this Professional Practices Policy (P3) is Group Integrity & Compliance.

2 Principles

Put patients first

All interactions with our customers must ultimately benefit patients by enhancing the standard of care, raising awareness about diseases and their treatment options, or otherwise contributing to the ethical delivery of healthcare.

We will treat patient information with respect, protect confidentiality, where required obtain informed consent, and be transparent with patients at all times.

We must protect patient safety. If an Associate becomes aware of a product-related risk or complaint (e.g., adverse event, manufacturing defect or product failure) related to Novartis products (approved or investigated) it must be reported in a timely manner.

Fund responsibly

External funding, including grants, donations and sponsorships, must only be given to legitimate organizations and provided in a way that protects our reputation, aligns with society's expectations, and is consistent with the Novartis Mission to discover new ways to improve and extend people's lives.

The same rules apply for external in kind support.

Act with clear intent

As trusted partners in healthcare, all of our activities must have clear and transparent objectives that are accurate, truthful, not misleading, and appropriate for their intended context.

Novartis may conduct promotional and non-promotional activities throughout the product lifecycle. These activities ensure that products are developed to meet the needs of patients, to advance scientific understanding of disease, including disease management and treatment outcomes, and to discuss the appropriate use of products.

Non-promotional activities should never be conducted in a way that are intended or perceived to be promotional.

Engage appropriately

Associates must not offer, approve, or provide anything of value with the intent or consequence of inappropriately influencing or rewarding our customers for the use of Novartis products.

Novartis may choose to engage healthcare professionals or other customers to provide necessary and legitimate services to help us research, develop, and/or promote our products. Any compensation must be for a bona fide service, consistent with fair market value, properly documented and accounted for, and disclosed where required.

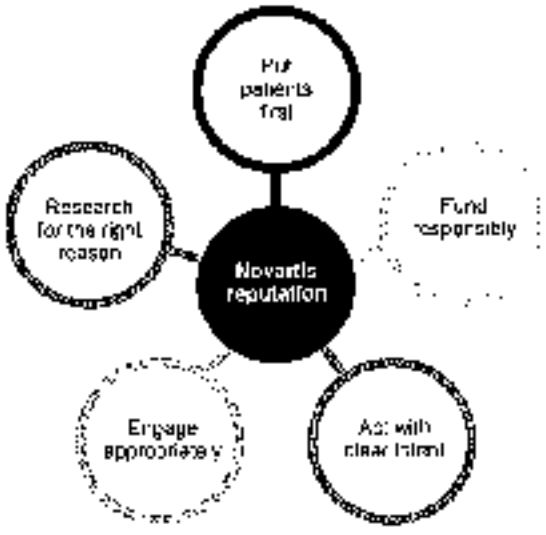
Allowable items of value, when provided to customers, must be modest, reasonable, infrequent, free from actual and perceived conflicts of interest, and disclosed where required.

Research for the right reason

Research and development must only be conducted to address valid medical or scientific questions aimed at enhancing patient care. We must always respect and protect the rights, safety and well-being of patients and animals and safeguard the integrity and validity of the data obtained.

Research and development activities must follow established ethical and scientific standards and be conducted by qualified investigators.

Research and development activities must never be promotional in nature.



3 Policy

3.1 Clinical Research

Novartis must conduct clinical **research for the right reasons**. Research must be conducted only if it is scientifically valid and designed to answer relevant medical, scientific, or health economic questions. It must follow the *Novartis Position on Clinical Study Transparency* and the *Novartis Quality Manual*.

Novartis Associates must always **put patients first** and protect their safety. If an Associate becomes aware of an adverse event related to any study or product, he/she must report it according to *Novartis Global Adverse Event Reporting Standard*.

Novartis supports the publication of study results in a timely manner and must not withhold or suppress data. We must protect confidential and/or patentable information, and personal information. Where required by local laws, regulations and/or industry codes, Novartis must disclose and report any payments or transfer of value made to HCPs and/or their institutions for research studies and third party medical writing support for publications. All publications must follow *Novartis Guidelines for the Publication of Results from Novartis-Sponsored Research*.

3.2 Pricing and Market Access

Novartis may interact with individuals, including HCPs, involved in recommending or deciding product reimbursement or purchase of Novartis products. However, these interactions **must not interfere with their independent judgment** or be perceived as improperly influencing them. Interactions may include proactive discussions to understand the needs of governments, payers and public health organizations (e.g., budgetary impact of new therapies) or responding to specific request for information (e.g., providing economic data or pipeline information that is in the public domain). All such discussions must be truthful and accurate. If these interactions are with public officials they may be subject to additional laws, regulations and industry codes. Engagement of HCPs for professional services who are formulary committee members must be disclosed according to local laws, regulations and industry codes. Discounts, rebates and other payments must be accurately and appropriately recorded in our books and records.

3.3 Pre-Approval Communication and Scientific Exchange

Products must only be **promoted consistent with approved labeling**.

Novartis supports the right of the scientific community and the public to be informed concerning scientific and medical progress. Therefore, where allowed by local laws, regulations and industry codes, Novartis may exchange scientific information. This may include communications at scientific events, public disclosure of information to investors/ shareholders, governments, reimbursement agencies or their agents and public health organizations.

Novartis may receive unsolicited requests for information on unapproved drugs and indications (off-label) from HCPs, patient organizations, and other stakeholders. Only the Medical function may provide such information in response to these requests. Novartis Associates who receive unsolicited requests for off-label information must forward such requests to the Medical function. The response provided by the Medical function, including any materials, must be accurate, not misleading, not promotional in nature, related solely to the subject matter of the request, and in compliance with local laws, regulations and industry codes. The Medical function should maintain written documentation of unsolicited requests and responses.

Novartis Medical Scientific Liaisons (MSLs) may interact with HCPs throughout the lifecycle of a product for the purpose of exchanging scientific information. Interactions must not be promotional in any way and must have **clear intent and transparent objectives**.

3.4 Promotional Interactions

Upon receipt of marketing authorization, Novartis may interact with customers, either directly or via a third party, to promote Novartis products, related features, and benefits. All interactions must have clear intent, transparent objectives, and must not interfere with the independence of customers.

Products must only be promoted consistent with approved labeling, as approved by the local regulatory authorities. Anyone promoting a Novartis product must be trained and have sufficient knowledge of the product to provide full and accurate product information.

Any materials used for purposes of the interaction must be approved in accordance with the *P3 Guideline on Promotional and Non-Promotional Materials* and local laws, regulations and industry codes.

3.5 Promotional Content

Novartis may produce and disseminate content (printed, electronically, and orally) to inform, educate, or promote its products. All content must be accurate, fair, balanced, truthful and not misleading, based on adequate substantiation and consistent with the scope of the relevant product's marketing authorization. Content must be reviewed, approved and updated, as required in accordance with the *P3 Guideline on Promotional and Non-Promotional Materials* and local laws, regulations and industry codes.

3.6 Items of Medical Utility and Cultural Acknowledgements

Novartis must engage appropriately with all customers. Where permitted by local laws, regulations and industry codes, items of medical utility and cultural acknowledgements may be offered or provided to HCPs if such items are modest, reasonable in value, offered on an occasional basis and according to the *P3 Guideline on Items of Medical Utility and Cultural Acknowledgements*.

Gifts (including personal gifts) or promotional aids, whether branded or unbranded, must not be provided to HCPs or their family members. This includes payments in cash or cash equivalents (such as gift certificates). Items made available to HCPs for use during Novartis meetings (such as pens and note pads) must not include any Novartis product or company branding.

Novartis Associates must not use their own personal funds to provide gifts to HCPs.

3.7 Samples, Demonstration and Evaluation Devices

Where permitted by local laws, regulations, and industry codes, free samples of Novartis pharmaceutical products may be provided to HCPs authorized to prescribe that product in order to enhance patient care or provide experience with the product. Pharmaceutical samples must be permanently labeled as samples, and managed with systems of control and accountability. They must never be resold or otherwise misused.

Over the counter (OTC) product samples may be distributed directly to customers where permitted by local laws, regulations, and industry codes.

Demonstration and evaluation devices may be provided free of charge to an HCP or HCO for a limited and agreed-upon duration. Devices provided must be labeled appropriately and must not be provided prior to receipt of marketing authorization for their intended use in that market. Title to the device must remain with Novartis for the entire duration of the evaluation and devices must not be stored at any HCP or HCO facility when not under evaluation.

3.8 Events

Novartis may organize events or fund events organized by third parties throughout the product lifecycle with the objective to provide scientific information or educate customers about our products or applicable disease areas. All events must have clear objectives, be funded responsibly and aligned with Novartis' mission, in a way that meets societal expectations.

Events must have **clear purpose and be transparently conducted.** If the purpose of the event is non-promotional we must not use materials with brand colors and logos or any promotional content and avoid any perceptions of disguised promotion.

Common types of events organized or funded by Novartis are:

- Promotional **speaker programs** to educate HCPs on Novartis products or applicable disease areas.
- **Scientific meetings** to facilitate legitimate scientific debate, gain or provide scientific or medical educational information
- **Disease awareness programs** to increase knowledge and education about diseases and their management.
- **Investigator meetings** to initiate, update, or close-out Novartis sponsored or supported studies. Such meetings must be managed in accordance with the requirements of the relevant investigator study.
- Novartis **site visits** for customers or regulatory authorities. Such visits must be coordinated with the local site management
- **Third party congress or symposia** to provide medical education

Novartis Associates should organize events in accordance with the *P3 Guideline on Events and Professional Meetings.*

3.9 Venue, Travel, and Hospitality

All events, meetings, or activities must be held in a venue appropriate for scientific or educational exchange and in accordance with local laws, regulations, and industry codes. Novartis must avoid venues that may be perceived as extravagant or applying inappropriate influence. For Novartis-organized events refreshments and/or meals incidental to the main purpose of the event may be provided, however no entertainment or other leisure/social activities should be provided or paid for by Novartis. Interactions with public officials may be subject to additional laws, regulations and industry codes.

Where permitted locally, Novartis may fund HCPs to attend events in their country of practice (or home country). However, Novartis does not fund HCPs to attend international events with the exception of HCPs who are providing a service to Novartis. International travel may be funded only under certain circumstances where HCPs are engaged by Novartis to provide professional services. In all instances, we must ensure that event funding does not interfere with HCP independence.

3.10 Fees for Service

Novartis may engage with HCPs and HCOs for professional services, either directly or via a third party. Such services may include the engagement of HCPs as **speakers for promotional speaking programs, scientific standalones, or other events, consulting engagements, advisory boards** and/or **market research**. Irrespective of direct engagement or via a third party, Novartis is responsible for engaging **appropriately and without the intent**, perception or consequence of inappropriately influencing HCPs or HCOs for the use of our products.

All engagements must be based on a legitimate need for the service. Any HCP or HCO engaged by Novartis must have the necessary experience and/or capabilities to provide the services. The engagement must be confirmed in a written agreement signed by both parties before commencing any services. Compensation for services must be reasonable and at fair market value in relation to the services rendered. Engagement of HCPs who are public officials may be subject to additional laws, regulations and industry codes.

Cross-country engagements of HCPs must be approved by qualified Novartis Associates from the HCP's practicing country for compliance with local laws, regulations and industry codes. Compensation for services must be paid into the HCP's practicing country.

Novartis Associates must follow the *P3 Guideline on HCP and HCO Engagement.*

3.11 Interactions with Patients and Patient Organizations

Novartis may interact with patients, caregivers, and patient organizations to understand their perspective and provide knowledge regarding diseases, treatments, and its care. All interactions must be ethical, transparent, non-promotional, and consistent with Novartis' mission and **maintain the independence of the patient and patient organizations**.

Novartis must treat **patient information with respect and protect confidentiality.** We must not accept any patient or caregiver information from third parties unless the patient or caregiver has provided explicit consent for the provision of the information to Novartis.

In most markets, interactions with patients are non-promotional activities and must not be used for, or mixed with, promotional purposes. Promotion of prescription-only products to patients (direct-to-consumer promotion, "DTC") is not allowed in most countries. Where such promotion is allowed, it must strictly follow the applicable local laws, regulations and industry codes. Advertisements for patient recruitment in public media, where permitted, must not be misused for promotion of a product.

Novartis may engage with patients or patient organization for services, such as participation in **patient advisory boards**. All engagements must be based on a legitimate need for the service and confirmed in a written agreement signed by both parties before commencing any services. Compensation for services must be reasonable in relation to the services rendered.
Novartis may also provide financial and other support to patients and patient organizations. Such support may be in the form of **Patient Support Programs** ("PSPs"), **Patient Assistance Programs** (PAPs), funding to support/establish patient organizations, etc.

Novartis Associates must follow the *P3 Guideline on Interactions with Patients and Patient Organizations*.

3.12 External Funding

Novartis may provide funding or other support to external organizations. This includes **grants**, **donations**, funding for medical education such as **preceptorship programs**, and **sponsorships**. We must fund **responsibly**, in a manner that maintains our reputation, aligns with our mission to discover new ways to improve and extend people's lives, advance medical or scientific knowledge, and supports communities where Novartis Associates live and work.

External funding or support must only be given to legitimate organizations, never to individuals, and in accordance with the *P3 Guideline on External Funding*. It must have a clear and defined purpose. Funding must be reasonable and legitimate in light of the activity being funded and properly tracked, documented, reported, and accounted for, as required by local laws, regulations and industry codes. Where applicable, funding must follow the *Novartis Anti-Bribery Policy*.

4 Definitions

Adverse Event

An adverse event is any unfavorable medical occurrence or unintended sign (including an abnormal laboratory finding), symptom, disease or injury temporally associated with the use of a medical device, medicinal or investigational product, in patients, users, or other persons, whether or not it is considered to be related to or due to the product

Customer

Defined broadly as:

- Patients and patient organizations
- Healthcare partners, including but not limited to, healthcare professionals, healthcare organizations, payers, third party distributors/wholesalers, suppliers, intermediaries
- Non-HCP Retailers

Caregiver

Someone who participates in or makes medical decisions for a patient. Examples of caregivers include parents or legal guardians, spouses or partners, adult children, relatives, or other friends.

Disease Awareness Programs

A program intended to provide information, awareness, or education regarding health and diseases and their management to the general public, potential patients, or HCPs

Over the Counter (OTC) Product

A product marketed for use by consumer without the intervention of a HCP in order to obtain the product.

Cultural Acknowledgements

An inexpensive item, not related to the practice of medicine (also referred to as 'Courtesy Gift'), involving the HCP or their immediate family members to acknowledge significant national, cultural or religious holidays or events.

Donation

Benefit granted by Novartis to legitimate organizations for an altruistic and specified purpose, where Novartis does not expect to receive any benefit, consideration or service in return

Event

A conference, congress, symposium, or any other meeting of a scientific, educational, or professional nature organized or funded partially or fully by Novartis or a third party to disseminate knowledge enhancing information, increase knowledge of Novartis products, provide scientific, educational and/or professional information

Gifts

Benefits of any kind given to someone as a sign of appreciation or friendship without expectation of receiving anything in return.

Grant

Independently requested contribution conveyed to a legitimate organization for a specified purpose without agreement or intent to receive any tangible benefit (a measurable or quantifiable and objective benefit).

Healthcare Organizations (HCOs)

Any legal entity (such as a company, partnership, or healthcare institution), whether public or private, that offer/provide Medical Services to patients and may prescribe, order, dispense, recommend, purchase, supply, administer, lease, and use Novartis products, and all members of their office staff, and medical associations or organizations

Examples of HCOs include physician practices, hospitals (including university hospitals), ambulatory surgical centers, pharmacies, clinics, nursing facilities, managed care entities, group purchasing organizations (GPOs), specialty pharmacies, medical societies, and businesses owned by an individual or group of HCPs.

Healthcare Professional (HCP)

Any member, student, or researcher of the medical, dental, optometry, opticianry, pharmacy, or nursing profession or any other person, social workers, clinical psychologists, formulary committee members, and pharmacy & therapeutics (P&T) committee members who in the course of his or her professional activities provides medical services and may prescribe, order, dispense, recommend, purchase, supply, administer, lease, or use pharmaceutical products and/or medical technologies, and all members of their office staff.

Items of Medical Utility

Items given to HCPs that (1) are intended for the direct education of HCPs or patients, or are for use by patients to assist them in the administration of their treatment or management of their conditions, and (2) do not have value to HCPs outside of the scope of their practice and educational need

Medical Services

Performing or ordering any examination, test, or procedure to diagnose or treat any medical or health-related issue, or filling a prescription for a pharmaceutical or device product that is eligible for payment by someone (whether payor is public or private) other than a patient/consumer

Patient

Any person who may receive a prescription for, and/or are treated with a pharmaceutical product and/or medical technology for his or her individual needs.

Patient Organization

Independent organization which has the goal of providing direct support to people affected by an illness or advocating for, among other things, patients' rights, disease awareness and patient information in one or more therapeutic areas. Such organizations are often established by patients, their family members and caregivers but may also include Health Care Professionals (HCPs), volunteers and policy makers among their membership or leadership

Patient Support Program

A program that involves direct or indirect interactions with a patient or patient's caregiver implemented by Novartis or a third-party on behalf of Novartis. Examples include helping patients manage medication administration and adherence, provide disease management support or provide or arrange for financial assistance for patients who cannot afford medications.

Pharmaceutical Samples

Free pharmaceutical products supplied to HCPs authorized to prescribe that product in order to enable HCPs and their patients to gain experience in dealing with the product

Promotional Aid

Non-monetary items that are branded or include minimal information intended to promote Novartis or its products. Examples of Promotional Aids include pens, mousepads, and microfiber cloths.

Public Official

- Any elected or appointed officer or employee of a government or government department, government agency, or of a company owned or partially owned by a government. Medical and scientific personnel qualify as public officials when they work at a hospital, clinic, university or other similar facility owned or partially owned by a government.
- Any elected or appointed officers or employees of public international organizations, such as the United Nations

- Any person acting in an official capacity for or on behalf of a government or a government department, government agency, or of a public international organization
- Politicians and candidates for a political office
- Any other person who is considered to be a public official according to applicable laws, regulations and industry codes

Research and development activities

Activities conducted to obtain scientific and clinical knowledge in order to address unmet medical needs. These activities include clinical and non-clinical studies, exploratory early stage research, investigator meetings, studies in human subjects or involving human/patient data, and animals or biological materials.

Scientific Exchange

Collection, publication, distribution and communication of scientific knowledge (knowledge related to, derived from or used in science for sharing), which may include information concerning a Novartis product.

Sponsorship

Agreement by which Novartis, for the mutual benefit of Novartis and the sponsored party, provides funding to establish an association between the Novartis' image, brands, or services and a sponsored event, activity, or organization

5 References

- P3 Guideline on Items of Medical Utility and Cultural Acknowledgements
- P3 Guideline on Market Research
- P3 Guideline on Interactions with Patients and Patient Organizations
- P3 Guideline on External Funding
- P3 Guideline on Events and Professional Meetings
- P3 Guideline on HCP and HCO Engagements
- P3 Guideline on Promotional and Non-Promotional Materials
- Novartis Anti-Bribery Policy
- Novartis Position on Clinical Study Transparency
- Novartis Guideline for the Publication of Results from Novartis-Sponsored Research
- Novartis Quality Manual
- Novartis Global Adverse Event Reporting Standard
- Novartis Third Party Guideline

6 Implementation

Training

Associates must familiarize themselves with this Policy and the relevant Guidelines referred to in this Policy. Associates must be trained in line with the Novartis-wide compliance training curriculum. Additional training requirements for Associates and third parties conducting business on behalf of Novartis may be defined in local SOPs.

Third parties

Third parties involved in conducting activities covered by this Policy and on behalf of Novartis are expected to comply with this Policy, applicable laws and to adhere to ethical business practices. Novartis Associates contracting third parties are ultimately responsible for how third parties conduct these activities on behalf of Novartis.

Breach of this policy

Failure to comply with this Policy may lead to disciplinary and other actions, up to and including termination of employment.

Reporting potential misconduct/non-retaliation

Any Associate with knowledge of suspected misconduct must report his or her suspicion promptly in accordance with the Business Practices Office (BPO) process. Associates who report potential misconduct in good faith or who provide information or otherwise assist in any inquiry or investigation of potential misconduct will be protected against retaliatory action.

Exceptions

No exceptions can be granted from compliance with applicable laws, regulations and industry codes. The Compliance Leadership Team (CLT) will review exceptions related to this Policy.

Responsibilities

It is the responsibility of every Novartis Manager to adhere to this Policy within his or her area of functional responsibility, lead by example, and provide guidance to the Associates reporting to him or her. All Associates are responsible for adhering to this Policy.

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Anti-Bribery Third Party Guideline

Novartis Global Guideline for engaging Third Parties

Effective: May 1, 2017

Version GIC 100.16.V3.EN

[redacted]

Contents

Glossary

Associate – Directors, officers, managers, and employees of Novartis AG and its affiliates

Business Owner - The person from the business unit who requests or sponsors the engagement of a Third Party and who is responsible for the business impact of such engagement.

Compliance Confirmation – A Compliance Confirmation is an attestation requested from the Third Party to confirm their compliance with the Law and to confirm the validity of the information collected as part of the due diligence. A template for the Compliance Confirmation is attached to Annex 5 of this Guideline.

Due Diligence Checklist – The Due Diligence Checklist is a document that is designed to help the Due Diligence Coordinator to conduct and document the efforts related to the due diligence. This checklist (issued by Group I&C) is not an exhaustive list but ensures that the main sources of information will be collected.

Due Diligence Coordinator – The person who receives the request to perform the risk-based Due Diligence on the prospective Third Party

Executive Summary – The Executive Summary is a document that captures and summarizes the information collected during the due diligence process, the identified Red Flags, the proposed measures to address the risks identified with the proposed Third Party engagement, and the decision whether or not to engage the prospective Third Party.

Guideline – The term Guideline refers to this Anti-Bribery Third Party Guideline.

Material Change to the Structure of the Third Party – A material change to the structure of a Third Party covers the following two situations:

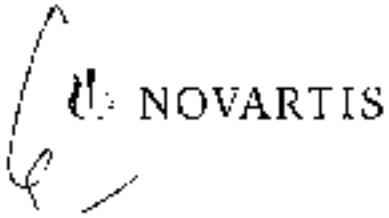
(a) **Change in ownership/control:** the Third Party or any person who Controls the Third Party has a change of Control. "Control" in this context means the direct or indirect ownership of more than 50% of the equity interest or voting rights in a corporation or business entity, or the ability in fact to control the management decisions of such corporation or business entity (e.g., by the appointment of a majority of the directors or management or otherwise); or

(b) **Change to membership of the executive body of the Third Party:** there is a change to the membership of the executive body of the Third Party. For example, a change to the executive management of the Third Party (e.g., CEO, N-1 to CEO)

Questionnaire for Third Parties – The Questionnaire is designed to assist the Due Diligence Coordinator to gather information from the Third Party amongst others about their business, their ownership and structure, government relations, compliance with laws and commercial references

Red Flag – A Red Flag is information that indicates an increased risk of corruption or another potential issue with a Third Party, such as any undesirable characteristic that pertain to a company's ownership, business structure or relationships and/or compliance with laws.

Third Party – The term Third Party is defined in Section 2.8 of the Anti-Bribery Policy as any natural person or legal entity with whom Novartis interacts and who poses, due to the nature of their business, a particular level of bribery risk. Section 1.4 of this Guideline sets out the specific types of services that pose a bribery risk.



List of Acronyms

DDC – Due Diligence Coordinator

Group I&C – Group Integrity & Compliance

LCO – Local Compliance Officer

PEP – Politically Exposed Person

RCO – Regional Compliance Officer

1 Introduction

1.1 Purpose

Our continued commitment to ethical business conduct is central to earning and maintaining the trust and support of our key stakeholder groups and realizing our aspiration to be a trusted leader in changing the practice of medicine.

To achieve this aspiration, it is essential that Novartis only engages Third Parties that are suitable from an anti-bribery perspective. We expect Third Parties with whom we work to comply with bribery and corruption laws and to observe our requirements concerning anti-bribery.

This Guideline elaborates on section 2.8 of the Novartis Anti-Bribery Policy, and gives Associates instructions as to the requirements for the management of Third Parties from an Anti-Bribery perspective.

1.2 Scope and Applicability

This Guideline applies to all Associates.

It enters into force as of May 1, 2017 and replaces the previous version of the Novartis Third Party Guideline dated March 1, 2012.

This Guideline is not intended to override or supersede more restrictive laws relating to bribery. In addition to this Guideline, other Novartis principles and practices or equivalent documents may apply to the engagement of Third Parties (e.g. professional practices and procurement rules).

1.3 Roles and Responsibilities

The **Business Owner** has ultimate responsibility for managing and mitigating the bribery risks associated with Third Parties and must:

- confirm the legitimate need for the goods and/or service provided by the Third Party
- identify whether a Third Party falls within the scope of this Guideline
- ensure that the Due Diligence Coordinator (DDC) is provided with all necessary information to fulfill the requirements outlined in this Guideline
- validate the information captured in the Executive Summary and decide on the engagement of the Third Party
- ensure that the Agreement covers the content of the clauses listed in Section 2.2.1
- monitor the Third Party in adherence to the contract and in accordance with the measures identified in the Executive Summary
- define an audit plan, if necessary, for the Third Party in consultation with LCC and Legal

Procurement shall appoint DDCs in the relevant market, where possible cross-divisionally, and shall communicate the appointment.

The DDC is responsible for:

- Performing the due diligence or ensuring that it is performed for all new Third Parties or existing Third Parties who fall within the scope of this Guideline by virtue of the provision of a new service (see sections 2.1.1 and 2.1.2)

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- Supporting the Business Owner in making an informed decision about the engagement of the Third Party (see section 2.1.3)
- Monitoring and performing any subsequent assessments after the Third Party has been engaged (see section 2.2.2)

If the Third Party is domiciled in a different country to the Novartis contracting entity, the DDC of the contracting entity may decide to request support from the DDC of the country in which the Third Party is domiciled. If such a request is made, the DDC in that country is obliged to provide support.

The **Local Compliance Officer** (LCO) is responsible for advising the Business Owner and the DDC. The LCO must approve any decision to pursue the engagement of any Third Party that is classified as medium or high risk.

Legal is responsible for supporting the Business Owner, as requested, when engaging the Third Party, including but not limited to the overall adequacy of the contract and inclusion of all necessary clauses.

The **Head Legal** of the local division or unit must approve any decision to pursue the engagement of any Third Party that is classified as high risk.

Group Integrity & Compliance (Group I&C) provides resources supporting the rollout of this Guideline (e.g., guidance, communication toolkits). They are responsible for keeping a central repository of these resources. A database of appointed DDCs is also maintained by Group I&C.

1.4 Third Parties Subject to this Guideline

A Third Party is subject to this Guideline if they engage in any of the activities specified below:

- Sell or resell or assist in selling or reselling Novartis products (through demand generation and/or active promotion of a Novartis product
- Act on behalf of Novartis or assist Novartis in dealing with government agencies to obtain permits, licenses, visas, regulatory approvals, pricing, reimbursement, participation in tenders, etc.
- Act on behalf of Novartis or assist Novartis in dealing or interacting with health care professionals
- Conduct clinical trials on behalf of Novartis

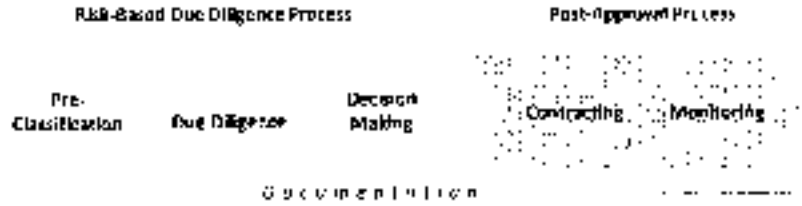
Further guidance to support the identification of Third Parties that fall within the scope of this Guideline can be found in Annex 6.

Due diligence on Third Parties that are selected as mandatory global providers for one or more of the activities listed above must be undertaken at the global level. Local organizations engaging such mandatory global providers for the activities that are subject to global due diligence are not required to perform a separate due diligence

2 Anti-Bribery Third Party Risk Management

The management of Third Parties requires the identification, assessment, mitigation and monitoring of the risk associated with the engagement of Third Parties.

The following risk based due diligence and post-approval processes must be implemented to ensure that the risk is adequately managed:



2.1 Risk Based Due Diligence Process

2.1.1 Pre-classification of Third Party

Before the commencement of the due diligence the Third Party must be pre-classified as "low", "medium" or "high" risk using the Novartis Risk Classification Methodology as per the Responsible Procurement Risk Assessment Process. This provides an indication of the risk-adjusted efforts required for each step of the management of the Third Party (e.g., due diligence, decision making, contracting and monitoring). Risk pre-classification is based on risk-related factors such as the geography, the type of services provided and background of Third Party.

2.1.2 Due Diligence

The purpose of the due diligence is to:

- Confirm the pre-classification through the collection and verification of due diligence process relevant information relating to the Third Party
- Identify and assess specific areas of elevated risk and seek to mitigate those risks

For all Third Parties, information on the Third Parties' business, ownership & management, government relations, compliance with laws, licenses, registrations, and certifications (such as licenses to trade) and commercial references must be collected. An essential component of this exercise is the full and accurate completion of the Novartis Anti-Bribery "Questionnaire for Third Parties" (Questionnaire) by the Third Party

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Depending on the Third Party risk pre-classification, the following due diligence activities must be completed.

Risk Classification	Minimum Activities Required
Low	Basic Due Diligence: • Verification of Questionnaire responses • Global screening of Third Party (sanctions and watch lists, etc.) • Conduct adverse internet & media search of Third Party in local language(s) and/or English
Medium	Mid-Level Due Diligence: • All low-risk due diligence activities plus: • Screening of key individuals (sanctions and watch lists, Politically Exposed Person list (PEP), etc.) • Conduct adverse internet and media searches of key individuals in the local language(s) and/or English
High	Enhanced Due Diligence: • All low and medium-risk due diligence activities plus: • Local public database searches focusing on in-country public records including litigation, regulatory, criminal, bankruptcy and directorship role of the Third Party • Verification of references collected in Questionnaire

Group I&C identifies external vendors that will provide the activities listed above.

Where the outcome of the due diligence is unclear due to conflicting or inadequate information, the DDC must conduct further investigation. This may require communication with the Third Party to clarify and validate the information collected, or to gather additional information. The DDC should discuss and align with Legal and/or the Local Compliance Officer as to whether further investigation by Global Security is needed.

Where Red Flags have been identified, mitigating and monitoring measures (if available) must be proposed to address the associated risks.

To conclude the due diligence, the DDC must prepare an Executive Summary of the information collected and verified during the due diligence. The Executive Summary must include:

- a final risk classification (i.e., low, medium or high risk)
- any Red Flags identified
- any proposed mitigating measures and monitoring activities

In order to support an informed decision, the DDC must send the Executive Summary to the Business Owner. In cases where the Third Party is classified as medium or high risk the Executive Summary shall also be sent to the LCO (for medium and high risk) and the Head Legal (for high risk only) of the local division or unit.

2.1.3 Decision Making

The Business Owner is responsible for deciding whether or not to engage the Third Party based on the results of the concluded due Diligence. For Third Parties that are classified as medium risk, the LCO has to approve the engagement. For Third Parties that are classified as high risk the LCO and the Head Legal of the local division or unit have to approve the engagement.

Depending on the risk classification of a Third Party, the following functions and roles must be involved:

Risk Classification	Decision	Consultation	Escalation in case of disagreement about	
			Risk Classification, Mitigation and/or Monitoring	**Third Party Engagement**
Low Risk	Business Owner	CDC	LCO	-
Medium Risk	Business Owner & LCO	CDC	*Regional Compliance Officer (RCO) & next level manager of the Business Owner*	-
High Risk	Business Owner LCO & Head Legal of the local division or unit	CDC	*Regional Compliance Officer (RCO, & Divisional Country Head*	

Legal, Finance, Integrity & Compliance, and other functions should be consulted by the Business Owner as appropriate

The decision concerning the engagement of a Third Party must be documented in the Executive Summary. The concluded Executive Summary must be signed by the representatives of the functions involved.

Where Red Flags have been identified during the due diligence that could not be fully resolved (e.g. due to incomplete information), the Business Owner can only proceed if the other functions involved in decision making approve the engagement, and specific monitoring measures are documented in the Executive Summary.

Any due diligence that has been concluded may later be used by other Business Owners (from the same or another Novartis division or unit), provided that (i) the nature of the service remains the same (ii) the due diligence is not older than 3 years, and (iii) there is no Material Change to the Structure of the Third Party and there are no grounds to believe that the risk classification of the Third Party has increased

A new due diligence may be conducted for any Third Party that failed to be approved after a prior Novartis due diligence if there are reasonable grounds to believe that the risk associated with the Third Party has decreased.

2.2 Post Approval Process

2.2.1 Contracting

Before a Third Party can be engaged by Novartis, or receive any payment from Novartis, a written contract or another written document with a similar legally binding effect (hereinafter referred to as 'Agreement') must be concluded and must have come into effect. The Agreement must clearly describe the subject matter (e.g. goods and/ or services to be performed), and the terms of remuneration.

Clauses that address the following concepts must be included in each Agreement with a Third Party:

- An unequivocal statement that they will not promise, offer, pay, cause to pay, accept payment or induce payment or take any action that could be considered a bribe and any such action will be grounds for immediate termination
- An unequivocal statement, agreeing to comply with the law including those related to bribery and corruption such as the US Foreign Corrupt Practices Act UK Bribery Act
- No sub-contracting of the services without Novartis prior written consent
- No assignment of the Agreement without Novartis prior written consent
- Obligation to inform Novartis of any Material Change in the Structure of the Third Party
- The right to terminate the Agreement upon occurrence of any of the following events (to the extent permitted under local law):
    - If the Third Party breaches the 'Compliance with Law' clause
    - In the event of any material omission or misrepresentation of information provided by the Third Party in the due diligence
    - In the event of a material delay (at least thirty days) or failure to provide a Compliance Confirmation (where applicable)

  The termination right should be immediate where permitted under local law.

For Third Parties that pose a medium or high risk, the following additional concepts should be included in the Agreement:

- Right to audit the Third Party
- Refusal by the Third Party to be audited may result (subject to local law) in immediate termination of the Agreement by Novartis
- Responsibility to deliver during the term of the Agreement a Compliance Confirmation for each calendar year. The Compliance Confirmation shall be delivered during the first quarter of the year following the end of the calendar year to which the Compliance Confirmation relates
- Responsibility to provide training to the personnel of the Third Party or assign responsibility for such training to Third Party personnel according to the *Compliance Training Guideline for Externals Part 2: Companies and External Service Providers*

Examples of clauses that capture the aforementioned concepts are included in Annex 4 of this Guideline. Legal counsel shall have the authority to draft their preferred contract language which still adequately addresses the above concepts. Furthermore, some of these concepts may be covered by appropriate language in the Novartis Supplier Code if the Novartis Supplier Code is referenced in the Agreement with the Third Party.

2.2.2 Monitoring

The Third Party must be monitored on an on-going basis by the Business Owner and the respective DDC. The monitoring must be appropriate to the risk classification.

(a.) Event Triggered Monitoring Activities:
In instances where there is a change in circumstances (e.g., a Material Change to the Structure of a Third Party or newly identified Red Flags), the impact on the decision to continue to engage the Third Party and any possible mitigating and monitoring measures must be assessed. The Executive Summary must be updated accordingly.

This requires that the DDC and Business Owner work closely to inform each other of any relevant information that they become aware of that may have a negative impact on the risk classification of the Third Party.

(b.) Renewal of the Due Diligence:
The due diligence process must be renewed in line with the Novartis contract life and in any case at least every three years.

(c.) Pre-Defined Monitoring Activities:
An annual "Compliance Confirmation" shall be provided to Novartis by all Third Parties classified as medium and high risk. An example of such confirmation is included in Annex 5 of this Guideline.

The Business Owner in consultation with the LCO and Legal must define, if necessary, an appropriate audit plan for the Third Party.

3 Sub-Contracting and Assignment of Rights and Obligations

Any subcontracting of the services contracted by Novartis is subject to prior written approval in line with the Decision Making process defined in section 2.1.3. The risk classification of the Third Party applies to its sub-contractor.

Clauses that are materially equivalent to those that have been inserted into the Agreement with the Third Party as a result of applying section 2.2.1 should be included in the contract between the Third Party and its sub-contractor.

The requirements relating to sub-contracting also apply to any assignment of rights or obligations by the Third Party.

4 Record Keeping

Documentation related to the engagement of the Third Party must be retained to demonstrate that Novartis has taken reasonable precautions to avoid involvement in corrupt activities or with corrupt actors by providing evidence of credible due diligence, decision making, contracting and monitoring. The relevant documents should at a minimum include:

Due Diligence Process Documentation:

- Completed "Questionnaire for Third Parties" including any documentation provided by the Third Party
- Results of the Basic, Mid-Level or Enhanced Due Diligence
- Results of investigations performed by Global Security, if requested
- Completed "Due Diligence Checklist"
- Executive Summary of due Diligence
- Decision by the Business Owner, by the LCO (for medium or high risk Third Parties), and by Head Legal of the local division or unit (for high risk Third Parties); this should be shared across business units / divisions through the DDC

Contract Related Documentation:

- Agreement (e.g., Contract, Purchase Order, and evidence of relevant documentation required by Procurement)
- Documentation to support the conclusion that services and goods are priced at no more than market value (e.g., a fair market value analysis or the results of a procurement bidding process)
- Evidence of the transfer of value and/or proof the services or products were delivered (e.g., invoices)

Monitoring Related Documentation (as applicable based on Guideline):

- Documentation of training as defined by the Compliance Training Guideline for Externals Part 2: Companies and External Service Providers
- Evidence of an annual "Compliance Confirmation" by any medium or high risk Third Party
- Evidence of the results of any Third Party Audit, where performed
- Evidence of any additional local monitoring, where performed

All relevant documents should be made available at country level.

5 Implementation

5.1 Training

Associates must familiarize themselves with this Guideline. They must be trained in line with the Novartis-wide compliance training curriculum and the *Integrity & Compliance Training for Novartis Internal Associates Framework Guideline*. Additional training requirements may be defined in local company procedures.

Group I&C and/or divisional I&C provide the respective training tools.

The local compliance organization performs training about this Guideline. Procurement provides training about the systems and tools used to execute this Guideline.

5.2 Breach of this Guideline

Breaches of this Guideline will not be tolerated and can lead to disciplinary and other actions up to and including termination of employment.

5.3 Responsibilities with regard to the implementation of this Guideline

Subject to local adaption, every Novartis manager must implement this Guideline within his or her area of functional responsibility, lead by example, and provide guidance to the Associates reporting to him or her.

All Associates are responsible for adhering to the principles and rules set out in this Guideline.

The owner of this Anti-Bribery Third Party Guideline is Group I&C. They will prepare a high-level plan for the rollout of this Guideline which shall also define roles and responsibilities.

Any questions should be addressed to a representative from Integrity & Compliance or Legal.

Annexes

1. Questionnaire for Third Parties
2. Due Diligence Checklist
3. Executive Summary
4. Sample Clauses
5. Sample Compliance Confirmation
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2 Anti-Bribery Third Party Risk Management

The management of Third Parties requires the identification, assessment, mitigation and monitoring of the risk associated with the engagement of Third Parties.

The following risk based due diligence and post-approval processes must be implemented to ensure that the risk is adequately managed:

2.1 Risk Based Due Diligence Process

2.1.1 Pre-classification of Third Party

Before the commencement of the due diligence, the Third Party must be pre-classified as "low", "medium" or "high" risk using the Novartis Risk Classification Methodology as per the Responsible Procurement Risk Assessment Process. This provides an indication of the risk-adjusted efforts required for each step of the management of the Third Party (e.g., due diligence, decision making, contracting and monitoring). Risk pre-classification is based on risk-related factors such as the geography, the type of services provided and background of Third Party.

2.1.2 Due Diligence

The purpose of the due diligence is to:

- Confirm the pre-classification through the collection and verification of due diligence process relevant information relating to the Third Party
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For all Third Parties, information on the Third Parties' business, ownership & management, government relations, compliance with laws, licenses, registrations, and certifications (such as licenses to trade) and commercial references must be collected. An essential component of this exercise is the full and accurate completion of the Novartis Anti-Bribery "Questionnaire for Third Parties" (Questionnaire) by the Third Party.

Depending on the Third Party risk pre-classification, the following due diligence activities must be completed.

Risk Classification	Minimum Activities Required
Low	Basic Due Diligence: • Verification of Questionnaire responses • Global screening of Third Party (sanctions and watch lists, etc.) • Conduct adverse internet & media search of Third Party in local language(s) and/or English
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Where the outcome of the due diligence is unclear due to conflicting or inadequate information, the DDC must conduct further investigation. This may require communication with the Third Party to clarify and validate the information collected, or to gather additional information. The DDC should discuss and align with Legal and/or the Local Compliance Officer as to whether further investigation by Global Security is needed.

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2.2.1 Contracting

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भारतीय गैर न्यायिक

भारत INDIA

रु. 500 FIVE HUNDRED RUPEES

पाँच सौ रुपये Rs. 500

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA ◑ 2021 ◑ 09 SEP 2021 BE 226663

Sub-Treasury Officer, Vasai.

27 AUG 2021

Sub-Treasury Officer, Vasai.

27/08/21

NOVARTIS HEALTHCARE PRIVATE LIMITED(First Part)

AND

King George's Medical University (Second Part)

AND

Dr. Suchanshu Kumar Dwivedi (Third Part)

3060

जोडपत्र - २/ Annexure - I

१ मुद्रांक विक्री नोंदवही अनु. क्रमांक -/दिनांक
(Serial No. / Date) ________

दस्ताचा प्रकार
(Nature of document) ________ 09|09|9

२ दस्त नोंदणी करणार आहेत का?
(Whether it is to be registered?) ________

४ मिळकतीचे थोडक्यात वर्णन
(Property Description in brief) ________

मुद्रांक विकत घेणाऱ्याचे नाव व सही ________
(Stamp Purchaser's Name & Signature)

हस्ते असल्यास त्याचे नाव, पत्ता व सही
(If through other person then ________
Name, Address & Signature)

दुसऱ्या पक्षकाराचे नाव
(Name of the other party) ________

मुद्रांक शुल्क रक्कम
(Stamp Duty Amount) ________

६. परवानाधारक मुद्रांक विक्रेत्याची सही ________
व परवाना क्रमांक ठिकाण श्री. [illegible]
मुद्रांक विक्रीचे ठिकाण/पत्ता [illegible]

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

Novartis Healthcare Pvt. Ltd.
Inspire BKC, "G" Block
8th & 7th Floor, BKC Main Road,
Bandra Kurla Complex,
Bandra (East),
Mumbai - 400 051.

FIRST AMENDMENT TO CLINICAL TRIAL AGREEMENT

This First Amendment is made at Mumbai and entered into on 8th day of OCT, 202[illegible] by and between;

NOVARTIS HEALTHCARE PRIVATE LIMITED, a company incorporated under the Indian Companies Act, 1956 and having its registered office at 7th floor, G Block, BKC Main Road, Bandra Kurla Complex, Bandra (East), Mumbai – 400051, Maharashtra, India (hereinafter referred to as "**Novartis**", which expression shall, unless repugnant to the context or meaning thereof be deemed to mean and include its successors and assigns) of the First Part;

AND

King George's Medical University, Erstwhile Chhatrapati Shahuji Maharaj Medical University, Chowk, Shah Mina Road, Lucknow-226003, Uttar Pradesh, India; represented by Dr. Shally Awasthi whose designation is **Faculty Incharge Research Cell** ; hereinafter referred to as "**the Institution**", (which expression shall unless repugnant to the context or meaning thereof be deemed to mean and include its successors and assigns) of the Second Part;

AND

Dr. Sudhanshu Kumar Dwivedi consulting at King George's Medical University (hereinafter referred to as "**the Investigator**", which expression shall, unless it be repugnant to the context or meaning thereof, be deemed to mean and include his/her heirs, executors, administrators and successors) and the Third Part;

(Novartis, Investigator and Institution may hereinafter be individually referred to as '**Party**' and are collective y referred as '**Parties**').

WHEREAS

A. By a Clinical Trial Agreement dated 17-July-2020 entered into between the Parties hereto ("**Agreement**"), the Investigator and the institution have agreed to provide certain services to Novartis on the terms and conditions contained in the Agreement.
B. Now by this First Amendment, the Parties are desirous of modifying and restating the sub-clause on 'Trial Staff Personal Data' under the Data Privacy clauseon the terms and conditions herein after appearing.

NOW THIS AMENDMENT WITNESSETH AND IT IS HERE BY AGREED BY AND BETWEEN THE PARTIES AS FOLLOWS:

1. Clause 15.3 (Trial Staff Personal Data) is modified by replacing the second sentence of this clause so that the revised clause 15.3 is as set forth below:

   15.3 Trial Staff Personal Data. Prior to and during the course of the Trial, the Principal Investigator and Trial Staff may be required to provide personal data which falls within the scope of the Applicable Laws and/or is needed for the implementation of the Agreement. The Institution and the Principal Investigator agree to inform Trial Staff that their personal data will be processed by Novartis and are responsible for sharing an appropriate privacy notice with such staff members following the framework attached as Annex .....

2. The Parties also hereby add Annex.....(Global Template - Privacy notice for clinical trial site personnel) to the Agreement pursuant to above clause 15.3.

3. This Amendment shall be effective from 5-April-2021 and shall be coterminous with the Agreement read with the Prior Addendums/Amendments for all intents and purposes.

4. Save and except to the extent aforesaid, all other terms and conditions of the Agreement shall continue to remain unaltered, valid and binding upon the Parties.

IN WITNESS WHEREOF, the Parties to this Amendment have caused their duly authorized representatives to enter into and execute this Amendment.

Novartis Healthcare Private Limited

By: _____

Name: **Saumya Mathew**

Title: **Country Trial Operations Lead**

Date: 8th OCT-2021

KING GEORGE'S MEDICAL UNIVERSITY

By: _____

Name: Dr. **Sudhanshu Kumar Dwivedi**

Title: Principal Investigator

Date: 20/10/21

By: _____

Name: **Dr. Shally Awasthi**

Title: Faculty Incharge Research Cell

Date: 01/10/21

Member Secretary
Institutional Ethics Committee
King George's Medical University U.P
Lucknow

Annex1: Payment (and Equipment) Schedule

Financial Break-up

STUDY NUMBER: CTQJ230A12301

STUDY NAME: A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein (a) lowering with TQJ230 on major cardiovascular events in patients with established cardiovascular disease

Investigator's Name: Dr. Sudhanshu Kumar Dwivedi

Institute Name: King George's Medical University

Payee Name: Vice Chancellor, KGMU

Pan Card Number: AAAAK4509K

GSTIN: 09AAAK4509K1ZJ

Committed Number of Study Subjects: 45

- CRC Fees of INR 20000 per month will be paid by sponsor from effective date of this addendum – 01 till close out visit.

ANNEX 2: PRINCIPAL INVESTIGATOR – PERSONAL DATA DISCLOSURE FORM

1. You understand that Novartis may wish to process your personal data for administrative and commercial purposes for example in a database to be used for the organization of future clinical trials. You further understand and agree that your personal data may if necessary for these purposes be transferred to third parties, including other companies related to Novartis in the form of a group and their advisors and third party service providers, as well as to regulatory authorities and tax authorities, as required by applicable law or relevant stock exchange rules.
You are not required to give your consent to the re-use of your personal data and your refusal may not impact the conduct of the current Trial, just further communications.
2. Novartis wants to ask your permission to include certain elements of your personal data in a database maintained by a third party. The GrantPlan 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.
You are not required to give consent to this disclosure in order to proceed with this clinical trial. However, by doing so, you are helping to collect information on fair costs in clinical trials.

General terms of consent
I accept and agree that my personal data may be transferred to and processed in countries outside India, including the United States of America, where the level of data protection may be lower than in my country of origin. I have noted that Novartis will protect my data in this instance by entering into specific data transfer agreements, as established by the applicable privacy regulations contracts.
I am aware of my rights to access, ask for a free copy and/or request modification or deletion of my data as applicable by contacting Novartis's Data Protection Officer at [generic email address]. I also acknowledge my rights to lodge a complaint in front of the relevant Data Protection Authorities as needed.

- ☐ Yes, I hereby agree that Novartis may use my personal data for the administrative and commercial purposes described in Section 1 above..
- ☐ No, I do not give permission for Novartis to use my personal data for the administrative and commercial purposes described in Section 1 above.
- ☐ Yes, I hereby agree that Novartis may disclose my personal data in connection with the GrantPlan database.
- ☐ No, I do not give my permission to disclose my personal data in connection with the GrantPlan database.

Place and Date: 20/04/21

Name: Dr. Sudhanshu Kumar Dwivedi
Principal Investigator

ANNEX 3
Applicable Anti-Corruption Legislation

The Institution, the Principal Investigator, the investigational staff and any other person contributing to the Trial (the ***Trial Parties***) shall at all times in the conduct of the Trial comply with the Bribery Act 2010 of the United Kingdom (***Bribery Act***), the Foreign Corrupt Practices Act 1977 of the United States of America (***FCPA***), the Prevention of Corruption Act 1988 and any other applicable anti-bribery and anti-corruption legislation (together the ***Applicable Anti-Corruption Legislation***).

It is the responsibility of the Trial Parties to ensure that they are familiar with, and comply with, the provisions of the Applicable Anti Corruption Legislation. Nevertheless, the following is intended as a summary of the key principles underlying the Bribery Act and the FCPA.

(A) The Trial Parties must at all times act with integrity and honesty and comply with the highest ethical standards.

(B) The Trial Parties must not make, give, or offer any payment, gift or other benefit or advantage to any person for the purposes of:

(i) securing any improper advantage; or

(ii) inducing the recipient or another person to do or omit to do any act in violation of their duties or responsibilities (or for the purposes of rewarding such conduct).

This restriction applies at all times and in all contexts. For the avoidance of any doubt, it applies both to dealings with "public officials" and to dealings with employees and agents of commercial enterprises.

(C) Nevertheless, particular care must be exercised with dealings with public officials. The Trial Parties must not make, give or offer any payment, gift or other benefit or advantage for the purposes of influencing any act or decision of a public official (or inducing such official to use their influence with another person, entity or government instrumentality) or to affect or influence any act or decision of such other person, entity or government instrumentality).

(D) The term "***Public Official***" includes any person acting on behalf of any government department, agency or instrumentality or any state owned or controlled enterprise. By way of example, this includes health care professionals employed by a state- or local municipality-run hospital or clinic, and representatives of public international organizations.

(E) The Trial Parties must not make, give or offer any payment, gift or other benefit or advantage to any person whilst knowing or suspecting that all or a portion of such money, gift, benefit or advantage will be used, whether directly or indirectly, in breach of (B) or (C) above.

(F) The Trial Parties shall make and keep books, records and accounts which, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the Trial Parties.

(G) The Trial Parties shall devise and maintain a system of internal accounting controls sufficient to provide reasonable assurances that:

(i) transactions are executed in accordance with management's general or specific authorization;

(ii) transactions are recorded as necessary

(I) to permit preparation of financial statements in conformity with generally accepted accounting principles or any other criteria applicable to such statements, and

(II) to maintain accountability for assets;

(iii) access to assets is permitted only in accordance with management's general or specific authorization; and

(iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

ANNEX 4: NOVARTIS PROFESSIONAL PRACTICES POLICY

ANNEX 5: Global Template - Privacy notice for clinical trial site personnel

[Month Year]

This privacy notice is addressed to:

- **Clinical investigators** (principal investigator, sub-investigator or co-investigator);
- **Other Site staff** such as nurses, pharmacists or technicians, whose Personal Data may be processed in the course of the clinical trial sponsored by Novartis.

You are receiving this Privacy Notice because Novartis Healthcare Pvt LTD ("Novartis") will process information about you, which constitutes "Personal Data".

This privacy notice is provided to you to ensure transparency in relation to collection, use and disclosure of your Personal Data by Novartis for purposes related to the conduct of clinical trials sponsored by Novartis Healthcare Pvt LTD ("**Novartis Clinical Trials**") which are being carried at your Clinical Trial Site ("the "**Site**"). For the purposes described in this Privacy Notice, **Novartis** is responsible for the processing of your Personal Data acting as a "Controller".

Collection of Personal Data

For the purposes described in this Privacy Notice, we may collect the following information about you including:

- name, identification number, address and other contact details,
- financial information (e.g. bank account number, financial interests in any of the Novartis group companies),
- qualifications, publications and information contained in the CV you provide to us where necessary,
- previous experience in clinical trials within or outside of Novartis and copy of the GCP training received,
- technical data related to your use of Novartis IT systems.

Purposes and legal basis for processing your Personal Data

Processing purpose	Legal basis
1. to conduct Novartis Clinical Trials in accordance with good clinical practice and applicable laws;	Novartis' legitimate interest to conduct clinical trials to test potential treatments as well as compliance with legal and regulatory obligations
2. to support applications for and to comply with the conditions of any marketing approval granted in respect of any medication studied under a Novartis Clinical Trial ("**Study Medication**")	compliance with legal and regulatory obligations
3. to support applications to vary the terms of any marketing approval granted in respect of a Study Medication;	Novartis' legitimate interest to conduct clinical trials to test potential treatments;
4. to carry out research related to the development of pharmaceutical products, diagnostics or medical aids and improve clinical trial practice;	Novartis' legitimate interest to conduct clinical trials to test potential treatments;
5. to comply with the US Financial Disclosure regulation which is intended to ensure that financial interests and arrangements of clinical investigators that could affect the reliability of data submitted to the Federal Drug Administration of the	Legitimate interest and compliance with legal and regulatory obligations;

	U.S.A. ("FDA") are identified and disclosed to the FDA[1]	
6	to ensure traceability and follow-up of drug safety notification.	compliance with legal and regulatory obligations.

If applicable to Novartis Clinical Trial, your Personal Data (name and contact information) may be incorporated in subject recruitment advertisements (print media or on Internet). Any such advertisement would be approved by the Ethics Committee before it is made public.

Sharing of Personal Data

In the course of our activities and for the purposes listed in this Privacy Notice, your Personal Data can be accessed by, or transferred to the following categories of recipients, on a need to know basis to achieve such purposes:

- the sponsor of the Clinical Trial,
- our personnel (including personnel, departments or other companies of the Novartis group),
- our independent agents or brokers (if any),
- our suppliers and service providers that provide services and products to us,
- our partners in the context of consortia or industry initiatives,
- our IT systems providers, cloud service providers, database providers and consultants,
- our business partners who offer products or services jointly with us or with our subsidiaries or affiliates,
- any third party to whom we assign or novate any of our rights or obligations, our advisors and external lawyers in the context of the sale or transfer of any part of our business or its assets,
- national and/or international regulatory bodies or Ethics Committees.

The above third parties are obliged to protect the confidentiality and security of your Personal Data, in compliance with applicable laws.

If we transfer your Personal Data to other jurisdictions, we will make sure to protect your Personal Data by (i) applying the level of protection required under the local data protection/privacy laws applicable in the country of destination, (ii) acting in accordance with our policies and standards and, (iii) for entities located in the European Economic Area (i.e. the EU Member States plus Iceland, Liechtenstein and Norway; the "EEA"), unless otherwise specified, by transferring your Personal Data on the basis of standard contractual clauses approved by the European Commission. You may request additional information in relation to international transfers of Personal Data and obtain a copy of the adequate safeguard put in place by exercising your rights as described below.

For intra-group transfers of Personal Data, the Novartis group has adopted Binding Corporate Rules, a system of principles, rules and tools, provided by European law, in an effort to ensure effective levels of data protection relating to transfers of Personal Data outside the EEA and Switzerland. Read more about the Novartis Binding Corporate Rules at novartis.com/privacy-policy.

Duration of storage

We will keep your Personal Data as long as needed for legal and regulatory requirements. Please note that we are required to retain Clinical Trial Documentation for a minimum of 25 years.

What are your rights and how can you exercise them?

Under conditions provided by the Law, you have a right to request a copy of the personal information we hold about you. You may also object to its use or ask for it to be updated, restricted, deleted, or transferred to another organisation. If you wish to contact us regarding our use of your Personal Data or you wish to exercise your data privacy rights, you may send an email to < PI email ID >.

[1] Clinical Investigators: principal investigator, sub-investigator or co-investigator who are directly involved in the treatment or evaluation of research subjects in Novartis Clinical Trials affected by this law, must disclose information to Novartis regarding their financial interests in companies belonging to the Novartis group as well as those of their spouse and each dependent child.

If you are not satisfied with how we process your Personal Data, please address your request to our Data Protection Officer at global.privacy_office@novartis.com, who will investigate your concern. In any case, you also have the right to file a complaint with a responsible supervisory authority, in addition to your rights above.