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INDIA NON JUDICIAL

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Purchased by	:	QUINTILES RESEARCH INDIA PVT LTD
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	QUINTILES RESEARCH INDIA PVT LTD
Second Party	:	K L E SOCIETYS DR PRABHAKAR KORE HOSPITAL
Stamp Duty Paid By	:	QUINTILES RESEARCH INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

AUTHORISED SIGNATORY
The Stamp Duty Paid
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Statutory Alert.

1. The authenticity of this Stamp Certificate should be verified at www.shcilestamp.com. Any discrepancy in the details on the Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
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Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

CLINICAL TRIAL AGREEMENT

Made between **Dr. Vardaraj Gokak**, having a place of business at KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590010, Karnataka, India (the "Investigator"), **KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre**, having a place of business at Nehru Nagar, Belagavi - 590010, Karnataka, India (the "Institution"), **GDD Experts India Pvt. Ltd.** having a place of businessat Ground Floor, Gulmohar Apartment, Opposite Hislop College, Nagpur- 440001, Maharashtra, India (the "Research Company"), F Hoffmann-La Roche Ltd, having a place of business at Grenzacherstrasse 124, 4070 Basel, Switzerland ("Sponsor") and **Quintiles Research (India) Private Limited**, having its office at B-101-106, Shapath IV, S G Road, Ahmedabad- 380 051, India ("Quintiles").

PROTOCOL NUMBER:	GA28951
PROTOCOL TITLE:	An Open-label extension and safety monitoring study of moderate to severe Ulcerative Colitis patients previously enrolled in Etrolizumab Phase II/III studies
PROTOCOL DATE:	22 October 2015
SPONSOR:	F. Hoffmann-La Roche Ltd
PRINCIPAL INVESTIGATOR:	**Dr. Vardaraj Gokak**
KEY ENROLLMENT DATE: (date by which site is to enroll at least one (1) subject)	100 Calendar Days after Site Initiation Visit

WHEREAS, the Investigator and Institution [or "and Research Company"], if any, (hereafter, jointly, the "Site") are willing to conduct a clinical trial (the "Study"), in accordance with the above-referenced protocol and any subsequent amendments thereto (the "Protocol") and Sponsor and Quintiles request the Site to undertake such Study;

WHEREAS, Quintiles has been duly authorized by the Sponsor to carry out certain obligations of the Sponsor in the conduct of the Study, consistent with the terms of this Agreement;

NOW THEREFORE, the following is agreed

1. Quintiles and Sponsor hereby appoint the Site to conduct the Study, and the Site agrees to ensure that the Site and the Site's employees, agents, and staff will conduct the Study in accordance with the Protocol (as may be amended from time to time by Sponsor), the terms of this agreement, including the Terms and Conditions attached as Attachment A, the Payment Schedule and Budget attached as Attachment B, and any other attachments hereto, which all are incorporated by reference herein (the "Agreement"), good clinical practices, and all applicable laws and regulations. The Site hereby confirms that it has enough time and resources to perform the Study according to the highest quality standards. The Site understands and agrees that if Site has not enrolled at least one (1) subject by the Key Enrollment Date then Sponsor may terminate this Agreement in accordance with Section 5 of Attachment A.

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Enrollment of Patients
The Effective Date of this Agreement is as listed in Section 3. Consequently, the Site will not be permitted to screen patients, randomize patients, receive Investigational Product or receive any payment until the validity date of this contract is reached.

In addition, Sponsor has a right to limit or increase unilaterally and at any time the number of subjects participating in the Study.

2. Payments shall be made in accordance with the provisions set forth in Attachment B, with the last payment being made after the Site completes all its obligations hereunder, and Quintiles has received all completed case report forms ("CRFs") and, if Quintiles requests, all other Confidential Information as defined in Attachment A, Section 2 (Confidential and Proprietary Information). The Site will act as an independent contractor, and shall not be considered the employee or agent of Quintiles or Sponsor. Neither Quintiles nor Sponsor shall be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Site. The Site acknowledges and agrees that Investigator's judgment with respect to Investigator's advice to and care of each subject is not affected by the compensation Site receives hereunder. The parties agree that the payee designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following payee (the "Payee"):

Institution and Investigator acknowledge and confirm that if Investigator is a named payee hereunder, such payment arrangement is in accordance with the modalities laid down by the Institution for receipt of funding for the Study and is not in violation of the MCI Regulations.

PAYEE NAME:	GDD EXPERTS INDIA PVT. LTD.
PAYEE ADDRESS:	Ground Floor, Gulmohar Apartment, Opposite Hislop College, Nagpur- 440001, Maharashtra, India
PAN OF PAYEE	AADCG0363Q

It should be noted that all the payments made to the Payee are subject to Tax Deducted at Source (TDS) in accordance with India tax laws, as amended from time to time. Quintiles 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.

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

The parties acknowledge that the designated Payee is authorized to receive all of the payments for the services performed under this Agreement. If the Investigator is not the Payee, then the Payee's obligation to reimburse the Investigator will be determined by a separate agreement between Investigator and Payee, which may involve different payment amounts and different payment intervals than the payments made by Quintiles to the Payee. **Investigator acknowledges that if Investigator is not the Payee, neither Quintiles nor Sponsor will pay Investigator, even if the Payee fails to reimburse Investigator**

3. This Agreement will become effective on the date of approval of the Study by Drugs Controller General India or on the date on which it is last signed by the parties, whichever date is later, (the "Effective Date") and shall continue until completion or until terminated in accordance with the provision in Attachment A. Quintiles shall attach a copy of the letter

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from the Drugs Controller ,General India approving the Study to this Agreement as Attachment C, and the parties agree that such letter shall be incorporated by reference herein. If such approval letter has not been received as of the date the parties sign this Agreement, Quintiles shall keep the original signed Agreements until receipt of such approval letter, and upon receipt of such letter, Quintiles shall attach a copy of the letter to each original Agreement as Attachment C and forward an original Agreement to each other party, while retaining one original Agreement its files. If such approval letter already has been received prior to the signatures of the parties, Quintiles shall immediately attach a copy of the letter hereto as Attachment C, and upon signature of all parties, each party shall receive an original of the Agreement, which shall include such letter as Attachment C In the event of a conflict between the Protocol and this Agreement, the terms of this Agreement will govern.

4. The date of execution of this Agreement is as listed in Section 3 above. Consequently, the Site will not be permitted to screen patients, randomize patients, receive Investigational Product or receive any start up payment until the validity date of this contract is reached.

5. Prior to and during the course of the Study, Quintiles or Study Sponsor may request to collect personal data which may be subject to data privacy laws or regulations (collectively "Data Privacy Legislation") relating to the Study from the Site, including from its investigators, sub-investigators, other Site staff or personnel involved in the conduct of the Study. The Investigator hereby consents to the processing of Investigator's personal data collected by Quintiles or Sponsor, and Investigator and Institution agree to obtain any consents, as may be necessary in accordance with applicable Data Privacy Legislation, for the processing of any personal data collected by Quintiles or the Sponsor from its investigators, sub-investigators, staff and personnel involved in the conduct of the Study. Such consent shall authorize the transfer of personal data, to countries other than the Site's own country, including without limitation the United States, even though data protection may not exist or be as developed in those countries as in the Site's own country, for the following purposes: a) the conduct and interpretation of the Study; b) review by governmental or regulatory agencies, Sponsor, Quintiles, and their agents, and affiliates and collaborators; c) satisfying legal or regulatory requirements; d) publication on www.clinicaltrials.gov and websites and databases that serve a comparable purpose; and e) storage in databases for use in selecting sites in future clinical trials. In the event any Site personnel participating in the Study are not willing to provide such consent, Site acknowledges that such personnel will not be able to participate in the Study.

6. Institution and Principal Investigator agree that the compensation they receive from this Agreement does not exceed the fair market value of the services they are providing, and that no payments are being provided to them for the purpose of inducing them to purchase or prescribe any drugs, devices or products. Site agrees that it will not bill any patient, insurer, or governmental agency for any items, visits, services or expenses provided or paid for by Quintiles or Sponsor.

   Institution and Principal Investigator and GDD Experts India Pvt. Ltd. represent and warrant that neither they nor any individual or entity acting on their behalf, nor any payee under this Agreement, will, directly or indirectly, offer or pay, or authorize an offer or payment of, any money or anything of value to any Public Official (defined below) or public entity, with the knowledge or intent that the payment, promise or gift, in whole or in part, will be made in order to influence an official act or decision that will assist Quintiles, Sponsor or the Site in securing an improper advantage or in obtaining or retaining business or in directing business to any person or entity.

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In addition to other rights or remedies under this Agreement or at law, Sponsor and/or Quintiles may terminate this Agreement if Site and GDD Experts India Pvt. Ltd. breaches any of the representations or warranties contained in this Section or if Quintiles or Sponsor learns that improper payments are being or have been made to Public Officials by Site or any individual or entity acting on its behalf.

For the purposes of this Agreement, "Public Official" means any officer or employee of a government, a public international organization or any department or agency thereof, or any person acting in an official capacity, including, for a public agency or enterprise; and any political party or party official, or any candidate for public office.

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

By: Subashri Shivkumar

Name: Subashri Shivkumar

Title: Head Clinical Development Services

Date: 29/Sept/2016

ACKNOWLEDGED AND AGREED BY SPONSOR (Quintiles executing on Sponsor's behalf):

By: Subashri Shivkumar

Name: Subashri Shivkumar

Title: Head Clinical Development Services

Date: 29/Sept/2016

ACKNOWLEDGED AND AGREED BY THE PRINCIPAL INVESTIGATOR:

By: _____

Name: Dr. Vardaraj Gokak

Title: Principal Investigator

Date: 15/10/16

ACKNOWLEDGED AND AGREED BY KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre:

By: _____

Name: Dr. M. V. Jali

Title: Medical Director

Medical Director & Chief Executive
KLES Dr Prabhakar Kore Hospital &
Medical Research Centre, BELAGAVI.

Date: 21/10/2016

ACKNOWLEDGED AND AGREED BY GDD EXPERTS INDIA PVT. LTD.:

By: _____

Name: Vinod Gyanchandani

Title: Head- Clinical Operations

Date: 30/SEP/2016

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ATTACHMENT A
TERMS AND CONDITIONS

Capitalized terms not defined herein shall have the meanings assigned to them in the attached Agreement.

1) **Conduct of the Study.** The parties to the Agreement agree that the Study will be performed in strict accordance with the Protocol, all applicable laws, regulations and guidelines, and good clinical practices ("GCPs"), and Indian Medical Council (Professional Conduct, Etiquette and Ethics)(Amendment) Regulations, 2009 – Part-I ("MCI Regulations"). The Investigator shall review all case report forms ("CRFs") to ensure their accuracy and completeness, shall review and understand the information in the investigator's brochure, shall ensure that all informed consent requirements are met (including any needed authorizations for the use, storage and transfer of personal data), shall ensure that all required reviews and approvals (or favorable opinions) by applicable regulatory authorities and Institutional Review Boards ("IRBs") or Independent Ethics Committees ("IECs") are obtained and shall provide a copy of such approval to Quintiles prior to enrollment of any subjects. A sample informed consent form has been provided by the Sponsor for use in the Study; any modifications to this form must be approved by Quintiles or Sponsor prior to its use, such approval not to be unreasonably withheld. The Site agrees to ensure that all clinical data are accurate, complete, and legible. The Site shall promptly and fully produce all data, records and information relating to the Study to Quintiles and Sponsor and their representatives during normal business hours, and shall assist them in promptly resolving any questions and in performing audits or reviews of original subject records, reports, or data sources. The Site agrees to cooperate with the representatives of Quintiles and Sponsor who visit the Site, and the Site agrees to ensure that the employees, agents and representatives of the Site do not harass, or otherwise create a hostile working environment for, such representatives. The Site warrants that it has the legal authority to share the clinical data and Study-related records and information with Quintiles and Sponsor. The Site shall use the product being tested (the "Investigational Product"), and any comparator products provided in connection with the Study, solely for the purpose of properly completing the Study and shall maintain all Investigational Product and any comparator products in a locked, secured area at all times. Upon completion or termination of the Study, the Site shall return all unused Investigational Product, comparator products, equipment, and materials and all Confidential Information (as defined below).

2) **Confidential and Proprietary Information.** All information (including, but not limited to, documents, descriptions, data, CRFs, photographs, videos and instructions), and materials (including, but not limited to, the Investigational Product and comparator products), provided to the Site by Quintiles, Sponsor, or their agents, (whether verbal, written or electronic), and all data, reports and information, relating to the Study or its progress (hereinafter, the "Confidential Information") shall be the property of Sponsor. The Site shall keep the Confidential Information strictly confidential and shall disclose it only to its employees involved in conducting the Study, who are subject to confidentiality obligations that are consistent with this Agreement, on a need-to-know basis. These confidentiality obligations shall continue until ten (10) years after completion of the Study, but shall not apply to Confidential Information to the extent that it: a) is or becomes publicly available through no fault of the Site; b) is disclosed to the Site by a third party not subject to any obligation of confidence; c) must be disclosed to IRBs, IECs, or applicable regulatory authorities; d) must be included in any subject's informed consent form, e) is published in accordance with Article 3 herein; or, f) is required to be disclosed by applicable law, provided that the Site shall give Sponsor and Quintiles prompt, advance written notice to permit Quintiles, Sponsor or their agents to object to or otherwise limit such disclosure. The existing inventions and technologies of Sponsor, Quintiles, or the Site are their separate property and are not affected by this Agreement. Sponsor shall have exclusive ownership of any inventions or discoveries arising in whole or in part from Confidential Information or arising from the conduct of the Study. The Site will promptly notify Sponsor in writing if it or Investigator conceives or makes any such inventions or discoveries and,

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at Sponsor's expense, execute any documents and give any testimony necessary for Sponsor to obtain patents in any country or to otherwise protect Sponsor's interests in such inventions or discoveries. The Site agrees to comply with any applicable data privacy or data protection legislation of the country in which the data originated.

3) **Publication.** Site understands that this Study is being conducted at multiple research sites. Site is free to publish or present the Study results obtained at the Site, but only after the first publication or presentation that involves the multi-center data or eighteen (18) months after the completion of the multi-center Study, whichever is first. At least sixty (60) days prior to submitting or presenting a manuscript or other materials relating to the Study to a publisher, reviewer, or other outside persons, the Site shall provide to Sponsor a copy of all such manuscripts and materials, and allow Sponsor sixty (60) days to review and comment on them. If the Sponsor requests, the Site shall remove any Confidential Information (other than Study results) prior to submitting or presenting the materials. In addition, at Sponsor's request, the Site shall delay publication for an additional ninety (90) days to allow Sponsor the opportunity to file for patent protection. No party hereto shall use any other party's name in connection with any advertising, publication or promotion without prior written permission.

4) **Inspection and Debarment.** When given reasonable notice, the Site agrees to allow authorized Quintiles, Sponsor and regulatory authority personnel direct access to the Site's records relating to the Study, including subject medical records, for monitoring, auditing, and inspection purposes. If any source data are kept on computer files only, the site shall make print-outs of all patients' data relevant to the Study for the purpose of source data verification, signed, dated and retained as source documents. The Site shall immediately notify Quintiles of, and provide Quintiles copies of, any inquiries, correspondence or communications to or from any governmental or regulatory authority relating to the Study, including, but not limited to, requests for inspection of the Site's facilities, and the Site shall permit Quintiles and Sponsor to attend any such inspections. The Site will make reasonable efforts to separate, and not disclose, all confidential materials that are not required to be disclosed during such inspections. Site and Investigator each represents and warrants that there are no pending for-cause regulatory audits, investigations or proceedings involving Site, Investigator, or any of their employees or agents performing Study activities which relate to compliance with laws regarding the conduct of any clinical research. The Investigator and the Institution shall be jointly responsible for maintaining essential Study documents in the manner specified by current good clinical practice ("GCP") guidelines and applicable laws for fifteen (15) years after the completion of the Study or such longer period as specified by current GCP guidelines and applicable laws. In addition, Site shall take measures to prevent accidental or premature destruction of these documents. If the Investigator leaves an institution, then responsibility for maintaining Study records shall be determined in accordance with applicable regulations. During the Study and for 15 years thereafter, if an investigator or sub-investigator leaves an institution or otherwise changes addresses, he or she shall promptly notify Sponsor and Quintiles of his or her new address. The Site represents and warrants that neither it, nor any of its employees, agents or other persons performing the Study under its direction, has been debarred, disqualified or banned from conducting clinical trials or is under investigation by any regulatory authority for debarment or any similar regulatory action in any country, and the Site shall notify Quintiles immediately if any such investigation, disqualification, debarment, or ban occurs.

5) **Termination.** Sponsor may suspend enrollment or terminate this Agreement effective immediately upon written notice. The Site may terminate this Agreement upon written notice if circumstances beyond the Site's reasonable control prevent the Site from completing the Study, or if the Site reasonably determines that it is unsafe to continue the Study. Upon receipt of notice of termination, the Site shall immediately cease any subject recruitment, follow the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs, and Quintiles shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in the

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Attachment B; provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all subject CRF pages and all data clarifications issued and satisfaction of all other applicable conditions set forth in the Agreement. Neither Quintiles nor Sponsor shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages

6) **Claims and Disclaimers.** The Site shall promptly notify Quintiles and Sponsor in writing of any claim of illness, injury or death or damage actually or allegedly arising from the conduct of the Study Sponsor agrees to indemnify and hold harmless the Site and Investigator from any third party claims of illness, injury or damage directly arising out of the conduct of the Study in accordance with the Protocol, except to the extent any such illness, injury or damage is caused by the Site or Investigator's negligence misconduct, failure to follow the Protocol or breach of applicable law or regulation. Sponsor shall have the right to control the defense of any such claims and the Site shall cooperate fully with Sponsor in handling such claims. Quintiles expressly disclaims any liability in connection with the Investigational Product, including any liability for any product claim arising out of a condition caused by or allegedly caused by the administration of such product except to the extent that such liability is caused by the negligence, willful misconduct or breach of this Agreement by Quintiles Neither Quintiles nor Sponsor will be responsible for, and the Site agrees, to the extent allowed by law, to indemnify and hold them harmless from, any third party claims of illness, injury or damage resulting from the Site's negligence, failure to adhere to the Protocol, failure to obtain informed consent, unauthorized warranties, breach of this Agreement, breach of applicable law or regulation or willful misconduct.

7) **Financial Disclosure.** In order to allow Sponsor to comply with its U.S. regulatory requirements, the Site agrees that, for each listed or identified investigator or sub investigator who is directly involved in the treatment or evaluation of research subjects, it shall promptly return to Quintiles a financial disclosure form that has been completed and signed by such investigator or sub investigator, which shall disclose any applicable interests held by those investigators or sub investigators or their spouses or dependent children. Quintiles may withhold payments if it does not receive a completed form from each such investigator and sub investigator The Site shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one (1) year after its completion. The Site agrees that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, Quintiles, and their agents, and the Site consents to such review. The Site further consents to the transfer of its financial disclosure data to the Sponsor's country of origin, and to the U.S. if the Site is outside of the U.S., even though data protection may not exist or be as developed in those countries as in the Site's own country.

8) **Shipping of Dangerous Goods and Infectious Materials.** The shipment of dangerous goods and infectious materials (including infectious subject specimens) is subject to local, national, and international laws and regulations. The Site is responsible for ensuring that each individual who packages or handles any dangerous goods or infectious materials for shipping from the Site complies with all applicable laws and regulations

9) **Adverse Event Reporting.** Investigator agrees to report any serious adverse events (SAEs) as required by law, regulation and the Protocol. Within 24 hours (or such other time as specified in the Protocol) of first knowledge of any SAE or any event that could affect the safety of the Study participants, Investigator will notify
Investigator will notify Quintiles and the Sponsor via the electronic data capture system (eDC). In the case of the eDC being offline, the responsible Site staff will fax the paper SAE form to Quintiles Lifecycle Safety using the toll free fax number (+353 1 809950) and enter the SAE into the eDC system as soon as it is back online

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10) **Additional Contractual Provisions.** This Agreement, including these Terms and Conditions, constitutes the sole and complete agreement between the parties and replaces all other written and oral agreements relating to the Study. No amendments or modifications to this Agreement shall be valid unless in writing and signed by all the parties. Failure to enforce any term of this Agreement shall not constitute a waiver of such term. If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect. This Agreement shall be binding upon the parties and their successors and assigns. The Site shall not assign or transfer any rights or obligations under this Agreement without the written consent of Sponsor. Sponsor may, and/or Quintiles may upon Sponsor's request, assign this Agreement to a third party, (and Quintiles may upon Sponsor's request assign its rights and obligations under this Agreement to Sponsor), and Sponsor and/or Quintiles (as the case may be) shall not be responsible for any obligations or liabilities under this Agreement that arise after the date of the assignment, and the Site hereby consents to such an assignment. Site will be given prompt notice of such assignment by the assignee. The terms of this Agreement that contain obligations or rights that extend beyond the completion of the Study shall survive termination or completion of this Agreement, including without limitation Sections 2, 3, 4, 6 , 7 and 10 of this Attachment A.

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ATTACHMENT B

BUDGET AND PAYMENT SCHEDULE

A. PAYMENT TERMS

Quintiles will reimburse the Payee every month, on a completed visit per subject basis in accordance with the attached budget. Ninety percent (90%) of each payment due, including any Screening Failure (see Article C below), will be made based upon prior enrollment data confirmed by subject Case Report Forms ("CRFs") received from the Site supporting subject visitation. The balance of monies earned, up to ten percent (10%), will be pro-rated upon verification of actual subject visits, and will be paid by Quintiles to the Payee upon final acceptance by Sponsor of all CRFs pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by Quintiles and/or Sponsor, the return of all unused supplies to Quintiles, as well as confirmation that all electronic patient diaries have been returned and upon satisfaction of all other applicable conditions set forth in the Agreement Site shall have thirty (30) days from the receipt of the final payment to dispute any discrepancies relating to payments made pursuant to this section. Site understands that at some point following such period, Quintiles will close its books relating to the Study and any disputes received after such period may be forwarded to Sponsor for resolution.

Site represents that the services it provides under this Agreement are taxable services under the laws governing service tax in India, and that it is required to charge service tax for the services rendered to Quintiles at the prevailing rate. Site represents that it is entitled to require such payment of the service tax under the laws of India. Site undertakes to provide Quintiles with an invoice, to be sent to Quintiles at the address mentioned in Section E of this attachment, in respect of such taxable services and such invoice shall be in accordance with the terms of the Service Tax Rules of 1994 as may be amended from time to time or any successor legislation

It should be noted that all the payments made to the Payee are subject to Tax Deducted at Source (TDS) in accordance with India tax laws, as amended from time to time. Quintiles 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.

Major, disqualifying Protocol violations are not payable under this Agreement

B. DISCONTINUED OR EARLY TERMINATION PAYMENTS:

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

C. ORIGINAL INVOICES:

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

Quintiles Research India Private Ltd., Bangalore
Attention: Finance PSC – Accounts Payable (Investigator Payments)
III Floor, Etamin Block,
Prestige Technology Park,
Sarjapur - Marathahalli Outer Ring Road
Bangalore – 560103, India

Please note that invoices will not be processed unless they reference the Sponsor name, Protocol number and Investigator and will be included with the regular payments After receipt and

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verification, reimbursement for invoices will be included with the next regularly scheduled payment for subject activity.

- **Institution Review Boards ("IRBs") or Independent Ethics Committees ("IECs") Payments**

IRB/IEC costs will be reimbursed on a pass-through basis and are not included in the attached Budget. Any subsequent re-submissions or renewals, upon approval by Quintiles and Sponsor, will be reimbursed upon receipt of appropriate documentation.

- **Study Start-Up Fee**

A one time, non-refundable payment of **Sixty Thousand Rupees (INR 60,000)** to cover Study Start-Up activities [which includes institutional overhead], will be made upon completion and receipt by Quintiles of all original contractual and regulatory documentation and receipt of original invoice.

- **Record Storage Fee/Archiving Fee**

A record storage payment of **One Lakh, Twenty Thousand Rupees (INR 1, 20,000),** [which includes institutional overhead], will be made upon receipt of original supporting invoices from a third party vendor and are not included in the attached Budget. In accordance with Sponsor's Protocol requirements, Institution shall maintain all site study records in a safe and secure location to allow easy and timely retrieval, when needed.

- **Patient Travel Expenses**

Patient travel expenses will be reimbursed upon receipt of original supporting invoices from third party vendors at a flat rate of **Five Hundred Rupees (INR 500) or up to (INR 1000)** per visit per patient per round trip) and are not included in the attached Budget. Invoices must contain the following information in order for a payment to be issued- Subject number or initials, amount paid, visit number in which patient travel is being requested.

- PREGNANCY TEST, ALCOHOL AND GAUZE:

Quintiles will provide the Site with pregnancy tests, alcohol pad and gauze during the course of the Study, in reasonable and needed amounts. Site will provide such materials to patients (study subjects) to take home for the purposes of Study protocol procedures.

- ADVERSE EVENT REPORTING:

Investigator will report any serious adverse events (SAEs) as required by law, regulation and the Protocol. Within 24 hours (or such other time as specified in the Protocol) of first knowledge of any SAE or any event that could affect the safety of the Study participants, Investigator will notify Quintiles and the Sponsor via the electronic data capture system (eDC). In the case of the eDC being offline, the responsible Site staff will fax the paper SAE form to Quintiles Lifecycle Safety using the toll free fax number (+353 1 809950) and enter the SAE into the eDC system as soon as it is back online.

F. INFRASTRUCTURE / EQUIPMENT:

1. <u>e-Diaries and Tablet Return</u>.

   <u>Section 1</u>. The final payment will be made after Sponsor has received copies of all completed Case Report Forms ("CRFs") for each of the Subjects participating in the Study with all queries resolved as well as confirmation that all electronic patient diaries have been returned. Site shall have thirty (30) days from the receipt of the final payment to dispute any discrepancies relating to payments made pursuant to this section 1. Site understands that at some point following such period, QUINTILES will close its books relating to the

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Study and any disputes received after such period may be forwarded to Sponsor for resolution.

Section 2: Subject to the conditions set forth below, Sponsor or QUINTILES will provide HTC-HD2 T8585 Handheld Computer (eDiary) and Acer Iconia W510P (eQuestionnaires), which is required for use in the Study and that Site does not otherwise own or have access to (the "Equipment") to Site for use in the Study.

(i) Equipment Use; Maintenance. Site agrees to house the Equipment on site and to use the Equipment solely in connection with the Study during the term of the Agreement. Site agrees to maintain the Equipment in good working condition, reasonable wear and tear excepted. In the event that the Equipment malfunctions or ceases to operate during the conduct of the Study through no fault of Site, Sponsor or QUINTILES will arrange for appropriate maintenance or replacement of the Equipment including, at Sponsor's option, reimbursing Site for reasonable maintenance or replacement expenses.

(ii) Return or Purchase of Equipment. Upon completion or any earlier termination of the Study at Site, Site shall, at its option, either: (A) return the Equipment to Sponsor/Sponsor at Sponsor's/Sponsor's expense; or (B) reimburse Sponsor/Sponsor for the residual fair market value of the Equipment as of the date of termination. Sponsor/Sponsor or QUINTILES may, at its option, either withhold the final payment to Site until the Equipment is returned, or until Site reimburses Sponsor/Sponsor for the residual fair market value of the Equipment as of the date of completion or termination of the Study. IN THE EVENT OF TRANSFER OR ASSIGNMENT UNDER THIS PARAGRAPH, THE EQUIPMENT SHALL BE TRANSFERRED AND ASSIGNED "AS IS," AND SPONSOR/SPONSOR MAKES NO WARRANTY OR REPRESENTATION, EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO FITNESS, MERCHANTABILITY, QUALITY, DESIGN, CONDITION, SUITABILITY OR PERFORMANCE OF THE EQUIPMENT.

1. Bioclinica Devices:

Subject to the conditions set forth below, Sponsor or QUINTILES will provide Lenovo Thinkpad E450 Laptop Includes Power Supply and Ethernet Cable-, Dazzle Video Creator Platinum HD- Video Input Adapter and Transcend 8GB USB Memory Stick which is required for use in the Study and that Site does not otherwise own or have access to (the "Bioclinica Devices") to Site for use in the Study.

(i) Bioclinica Devices Use; Maintenance. Site agrees to house the Bioclinica Devices on site and to use the Bioclinica Devices solely in connection with the Study during the term of the Agreement. Site agrees to maintain the Bioclinica Devices in good working condition, reasonable wear and tear excepted. In the event that the Bioclinica Devices malfunctions or ceases to operate during the conduct of the Study through no fault of Site, Sponsor or QUINTILES will arrange for appropriate maintenance or replacement of the Bioclinica Devices, including, at Sponsor's option, reimbursing Site for reasonable maintenance or replacement expenses.

(ii) Return or Purchase of Bioclinica Devices. Upon completion or any earlier termination of the Study at Site, Site shall, return the Bioclinica Devices to Sponsor/Quintiles at Sponsor's/Quintiles' expense. Sponsor or QUINTILES may withhold the final payment to Site until the Bioclinica Devices is returned.

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G BUDGET DETAILS:

The Budget is as follows:

It is agreed that the Site will receive INR Five Lakh Ninety Eight Thousand One Hundred and Eighty Four only (INR 598,184) per completed patient for the Study according to the schedule indicated below. This per patient amount is intended to cover the following study- related costs incurred by the Site:

- costs related to the patients visits (day care cost, stay)
- costs for study related communications
- salaries of study staff and Investigator
- Institute service charges and overheads

Budget Table:

Visit No.		Per Patient Amount Including 20% Overhead (INR)
In-Clinic Etrolizumab Administration Every 4 Weeks	Visit 0	11,485
	Visit 4	13,138
	Visit 8	9,920
	Visit 12	16,817
At-Home Etrolizumab Administration Every 4 Weeks	Clinic Visit at Every 12-Week Interval	363,048
	Clinic Visit at Every 48 Week Interval	123,831
	Clinic Visit at Week 108	16,988
12- Week Safety Follow Up	Week 6	5,348
	Week 12/ Early Termination	16,294
92-week Extended PML Monitoring Period	24, 48, 68, and 92 Weeks after Patient Discontinuation from Study OR Symptom-Driven Unscheduled Telephone call OR Early Termination	21,314
TOTAL Amount Per Completed Patient Including 20% Overhead (INR)		598,184

Unscheduled Visit*	10,897
Early withdrawal from Treatment Visit*	17,857
12- Week Safety Follow Up - Unscheduled Visit*	10,897

*Unscheduled Visit Fee and Early Withdrawal from Treatment Fee will be paid upon receipt of completed eCRFs, not included in the total cost per subject.

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Additional Invoiced Items:

INVOICED ITEMS:	Unit Cost (including OH) (INR)
Serum pregnancy test	300
Urine pregnancy test	200
Informed consent for patients enrolling only in Part 2 (SM)	1,133
Etrolizumab administration, per occurrence	622
In clinic Etrolizumab administration on 4th and 8th week of every 12 weeks	4,474
ECG	300
Concomitant medications	302
Adverse events	688
Limited/Symptom driven physical examination, including GI (includes Vital signs (BP, pulse rate))	2,926
Flexible sigmoidoscopy, with colonic biopsies	6,100
PML neurologic examination	2,000
Colonoscopy, with colonic biopsies	6,500
Biopsy; Staining and preparation of the slides including shipping and handling	600
Central Labs (JCV antibody, storage for JCV, Anti-therapeutic antibody) includes Collection, Preparation and Processing	402
Partial Mayo Clinic Score (pMCS)	284
Mayo Clinic Score (MCS)	440
Central Labs (Hematology, Chemistry (including LFTs), Hepatitis B DNA, CRP)	191
PK sampling (serum)	200
Neurologist - Per Hour	1,000
Brain MRI with contrast, includes interpretation and report	11,000
Brain MRI without contrast, includes interpretation and report	6,000
Lumbar puncture	2,600
Cerebrospinal fluid (CSF) analysis for JCV by PCR; includes lab handling for shipment to central lab	500
Reconsenting Fee	932

Note:

- This Budget includes all study costs related to the Protocol (including but not limited to laboratory costs, patient travel expenses and site overheads), except for any other payments contained within this Attachment.
- All questions regarding study payments or the financial arrangements should be directed to Quintiles at the address noted above during normal business hours (IST).

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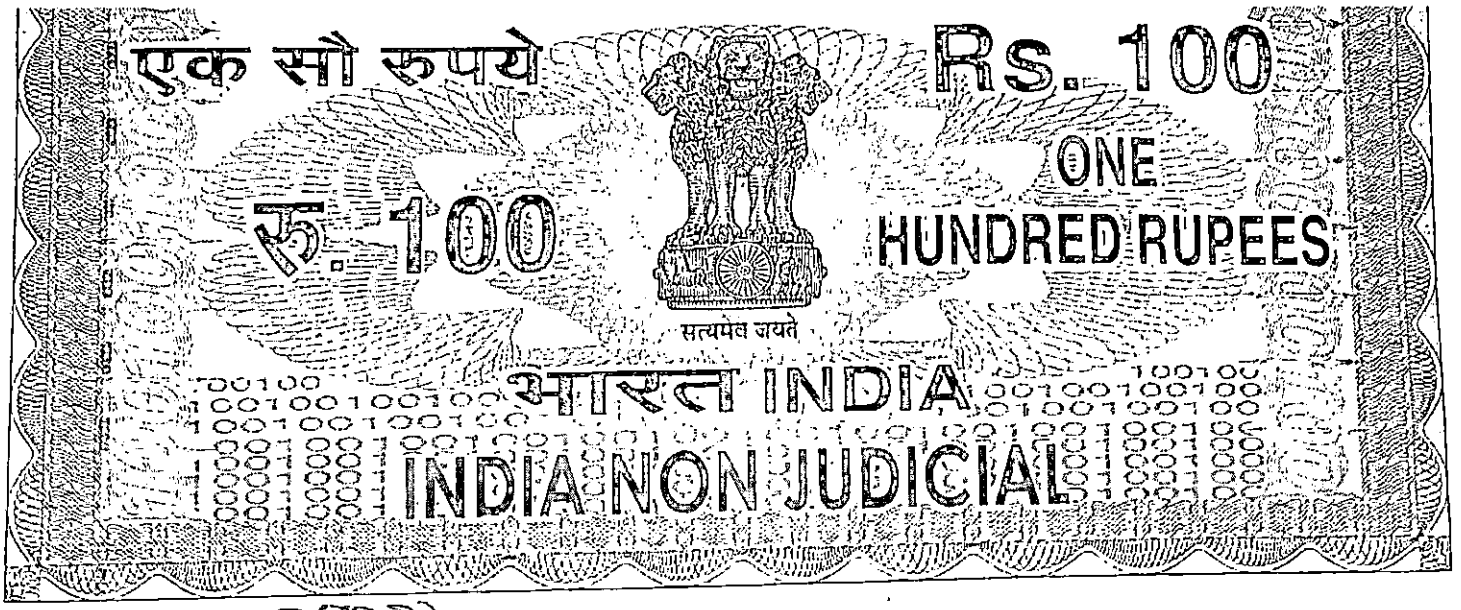

गुजरात ગુજરાત GUJARAT

BB 174606

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નામ:

સરનામું:

12 JAN 2017

શૈલેષકુમાર વાસુદેવભાઈ ત્રિવેદી

લા. નં.:- એસ. બી.- ૬૩/૧૯૯૬

અમદાવાદ-સીટી સીવીલ કોર્ટના રાણાંદી

લેનાર ની સહીઃ

Cliantha Research Limited
Opp. Pushparaj Towers,
Nr. Judges Bunglows,
Bodakdev, Ahmedabad-380054.
Ph. : +91-79-26853088-92
Fax : +91-79-26853093

CLINICAL TRIAL AGREEMENT

PROTOCOL MYL-1402O-3001

This Clinical Trial Agreement (the "**Agreement**") is effective on the date fully executed by the parties (the "**Effective Date**") and entered into by and between

CLIANTHA RESEARCH LIMITED, a company incorporated under the Companies Act, 1956 having its Registered Office at Opp. Pushparaj Towers, Nr. Judges Bunglows, Bodakdev, Ahmedabad – 380 054, India (hereinafter referred to as "**CRO**" which expression, unless repugnant to the context or meaning thereof shall mean and include its affiliates, employees, assignees, subsidiaries, nominees, agents and successors-in-interest)

AND

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findings that could adversely affect the Subject's safety, could have an impact on the conduct the Study, or could alter the ECs / IRB's approval to continue the Study.

CRO will be responsible to notify on time the health authorities in India.

15. MISCELLANEOUS

A. Use of Names; Publicity. Except as otherwise required by applicable law, regulation or co order, no Party to this Agreement will use the name or other identifying marks of any other Pa or its affiliates or its staff/employees, agents in any advertisement or sales promotional material in any publication, press release, or other public statement without prior written approval of t other Party; provided however that Sponsor may identify the Institution as a participating clini site and the Principal Investigator as an investigator in a Study. The Institution and the Princi Investigator shall have the right to acknowledge the Sponsor's support of the research perform under this Agreement in scientific publications and other scientific communications (any su publications or communications shall be made in accordance with Section 7 herein). Each of Parties hereto shall not disclose to any third party the terms of this Agreement even existence this Agreement without the prior written consent of the other Party, except to advisors, investo and others on a need-to-know basis under circumstances and ensure the confidentiality there or to the extent required by law, regulation or court order.

B. Independent Contractors. The Parties acknowledge that the relationship between the Spons CRO, Institution and Principal Investigator created by this Agreement is that of independ contractors and shall not to be considered as partner, agent, employee, or representative of Cl or the Sponsor. That neither the Principal Investigator nor Institution or CRO may create assume any obligation on behalf of the Sponsor.

C. Limitation of Liability. In no event shall the Parties be liable to each other for any spec incidental, or consequential damages arising out of or relating to this Agreement, or the subj matter hereof, however caused and whether such claim is based in contract, tort (includ negligence), or otherwise, even if an authorized representative of the Sponsor is advised of possibility of such damages.

D. Notices. Any notices required or permitted to be given hereunder shall be in writing, shall addressed to the Party to whom such notice is intended as follows, or such other address and, number as such Party may substitute by written notice hereunder, and shall be effective receipt.

Any notice to Sponsor shall be addressed as follows:

Address : **MYLAN LABORATORIES LIMITED INDIA,**
Clinical Research Centre, Saradhi Chambers, Plot No. 4-A, Beside Poulomi Hospital, Rukminipuri, Dr. A. S. Rao Nagar, Hyderabad 500062

Attn : **Dr. Sanjeev Honade**

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Dr. Mahesh Kalloli, the Principal Investigator presently employed at KLE's Dr. Prabhakar Kore Hospital & MRC, Belagavi-590010, Karnataka, India(hereinafter referred to as the **"Principal Investigator"** which expression, unless repugnant to the subject or context therein, shall mean and include his legal heirs, administrators, executors and assigns)

AND

KLE's Dr. Prabhakar Kore Hospital & MRC, Belagavi-590010, Karnataka, India hereinafter referred to as the **"Institution"** which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administrators, executors, assigns & successors-in-interest).

Dr. Ravi C, CMS Clinical Research Pvt.Ltd., (hereinafter referred to as the "SMO" which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administrators, executors, assigns & successors-in-interest).

CRO, Principal Investigator and Institute is referred to herein individually as a "Party" and collectively as "Parties".

Whereas, **Mylan GmbH** (hereinafter referred to as the **"Sponsor"**) through its Agent CRO desires the Institution to study (add study drug in comparison with reference and/or placebo) and the Institution is willing to perform a clinical study of the Study Drug (defined herein below); and

WHEREAS, the Study (defined below) is of mutual interest and benefit to the Sponsor, CRO, Institution and Principal Investigator and will further the investigational and research objectives of the Institution and Principal Investigator;

WHEREAS, the Principal Investigator and the Institution have the **qualified personnel and the facilities** equipped according to Good Clinical Practices (GCP) to undertake the Study with the responsibility for the proper conduct of the Study (defined herein below);

NOW, THEREFORE, in consideration of the promises and mutual covenants herein contained, the Parties agree as follows:

1. THE STUDY AND THE PROTOCOL

A. The MYL-1402O-3001(the **"Study Drug"**) shall be conducted, under the direction of the Principal Investigator, in the treatment of patients (**"Subjects"**) in accordance with this Agreement and the protocol identified as Protocol ID No MYL-1402O-3001 and entitled " **Multicenter, Double- Blind, Randomised, Parallel-Group Study to Assess the Efficacy and Safety of MYL-1402O Compared With Avastin ®, in the First –line Treatment of Patients with Stage IV Non Squamous Non –Small Cell Lung Cancer"** a copy of which is attached hereto as Exhibit A (the **"Protocol"**), including any subsequent duly authorized amendments, and which is hereby incorporated by reference (the **"Study"**). The Study will be monitored by the CRO as per the Protocol.

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D. Claims. The indemnifying Party, at its own expense, shall have the exclusive right to ... claims, control investigation and litigation, and select counsel, including the right to compro... or settle any claims, actions, suits, demands, or judgments, provided that it shall not compromis... or settle any such action with an admission of liability or wrongdoing by the indemnified Party without such Party's written consent.

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

F. Subject Injury. Subject shall be entitled to financial compensation as well as reimbursement of reasonable and necessary medical expenses from the CRO in case of Subject injury or death during clinical trial in accordance with Rule 122DAB of Drugs and Cosmetics Rules, 1945 as may be amended from time to time.

12. INSURANCE

A. Parties represent and warrant that they possess and shall maintain, for the duration of the Agreement and thereafter, at its own expenses, insurance coverage for their respective services in the performance of the Study. Each Party shall provide the other Party with proof of insurance upon request.

B. Institution Insurance. Institution and Principal Investigator shall maintain during the term of this Agreement, general liability insurance and professional liability insurance coverage sufficient to meet its indemnification obligations on appropriate conditions and will provide to Sponsor and CRO thirty (30) days prior written notice of cancellation of its coverage.

This Clause 12 shall survive termination of this Agreement.

13. TERM AND TERMINATION

A. Term. This Agreement shall begin on the Effective Date and shall remain in full force and effect until the completion of the Study and the submission of the Final Report pursuant to Clause 4(F) (*iv*), above, unless earlier terminated in accordance with this Agreement.

B. Termination.

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Study prior to termination. Within ninety (90) days ... any termination, the Institution and the Principal Investigator shall provide to the Sponsor data collected in connection with the Study, including, without limitation, Study reports and the Final Report described in Clause 4(F), above, and, except as otherwise provided herein, shall return to the Sponsor any and all materials and Confidential Information provided by the Sponsor for the conduct of the Study, at the Sponsor's expense, provided, however, that the Institution may retain one (1) copy of the Confidential Information for record keeping purposes and shall make no further use of, all Sponsor Confidential Information, and any other records, data, materials and information that are the property of Sponsor. The CRO shall remain liable for payment for any CRFs submitted prior to the effective date of termination, or within ninety (90) days thereafter, in compliance with the terms of this Agreement. Notwithstanding any termination or expiration of the Study or this Agreement, Institution shall remain responsible for compliance with all obligations under Applicable Laws and other requirements as per this Agreement with regards to disposition of the Study Materials.

viii. Survival. Termination of this Agreement by either Party shall not affect the rights and obligations of the Parties accrued prior to termination. All provisions in this Agreement which, by their nature, extend beyond termination of the Agreement, together with the provisions of Clauses 4(F), 5, 6, 7, 9, 10, 11, and 12 shall survive any termination of this Agreement for any reason.

14. Drug Safety and Reporting. The recording of adverse events (AEs) is an important aspect of the Study documentation. It is the Principal Investigator's responsibility to document all AEs according to the detailed guidelines of the Protocol. The Principal Investigator agrees to answer any questions of Sponsor and/or CRO's Medical Monitor concerning any AEs. According to the Protocol, the Principal Investigator will assess at each visit whether any adverse event (AE) including abnormal laboratory values has occurred. The details of all AEs, whether reported by the Subject or observed by the Principal Investigator / Study personnel during the entire Study, will be recorded onto the appropriate source document. Each adverse event must be recorded in the AE section of the case report form (CRF), regardless of the causal relationship.

The Principal Investigator must immediately report all serious adverse events (as defined in Protocol), which occur during the course of the Study and up to the date of the Subject's last visit, to the addressee given below. The SAE Report form will be used for documentation and reporting.
Initial and follow up SAE reports are to be faxed / Mail the Medical Affairs Department of CRO for onward transmission to SPONSOR

If the event is unexpected and fatal or life threatening and is considered by the Principal Investigator possibly related to the Study medication, the Drug Safety Department of CRO shall be informed immediately by telephone and followed immediately by fax/ Mail.

CRO undertakes to notify the Principal Investigator and SPONSOR of all serious unexpected adverse events, which occur during the course of the Study in any other location and are reported in an expedited manner to health authorities. The Principal Investigator will inform the local

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INSTITUTE

By: 18/1/2017

(Signature & Date)

Dr. M.V.Jali

BY EXECUTING THIS DOCUMENT IN THE SPACE PROVIDED BELOW, THE PRINCIPAL INVESTIGATOR HEREBY ACKNOWLEDGES AND AGREES TO COMPLY WITH THE TERMS OF THIS AGREEMENT AND THE APPLICABLE PROTOCOL, AS AMENDED FROM TIME TO TIME

PRINCIPAL INVESTIGATOR

By: 16/01/2017

(Signature & Date)

Dr. Mahesh Kalloli

CLIANTHA RESEARCH LIMITED

By: 12 Jan 17

(Signature & Date)

Dr. Dharmesh Domadia, Associate Vice President- Global Clinical Operations

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H. Severability. In the event that any provision of this Agreement is determined to be illegal, invalid or unenforceable by a court of competent jurisdiction, the remainder of this Agreement shall remain in full force and effect without said provision. The Parties shall negotiate in good faith a substitute clause for any provision declared illegal, invalid or unenforceable, which shall most nearly approximate the original intent of the Parties in entering this Agreement.

I. Execution. The Institution's IRB/IEC shall be the authorized representative of the Institution to approve the Protocol and any amendments thereto. This Agreement may be executed in one or more counterparts, all of which together shall constitute one and the same agreement. This Agreement may be executed by facsimile or other electronic signature.

J. Changes to the Protocol. If at a future date changes in the Protocol appear desirable, such changes may be made through prior written agreement between Sponsor and Institution. If such changes affect the cost of the Study, Institution will submit to Sponsor a written estimate for approval. If in the course of performing this Agreement, however, generally accepted standards of clinical research and medical practice relating to the safety of Subjects require a deviation from the Protocol, such standards will be followed. In such case, the Party aware of the need for a deviation will immediately inform the other of the facts causing such deviation as soon as the facts are known to the Party.

K. Covenant Not to Hire. Sponsor shall not, and shall not permit any of its affiliates to, employ or offer to employ any Key Personnel (as defined in this Section) until one year following termination or expiration of this Agreement, unless Institution, or Institution's affiliate, as the case may be, gives its written consent thereto. "Key Personnel" shall mean those individuals employed by Institution, who perform research related services for Institution or any of its affiliates, including, but not limited to, persons serving as research coordinators and grant account managers.

IN WITNESS WHEREOF, the undersigned have entered into this Agreement as of the date first set forth above.

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The further details for the payments should be provided as

1. **Cheque in the favor of: CMS CLINICAL RESEARCH PVT. LTD.**
2. **PAN Number: AAFCC8457M**
3. **Name of Bank: HDFC Bank**
4. **Branch: Hyderabad**
5. **Account No: 50200007478582**
6. **Branch Code: 000368**
7. **IFS CODE : HDFC0000368**

E. Reimbursement. Upon completion of the Study or earlier termination of this Agreement as provided herein, the Institution shall reimburse the CRO for any amounts that were paid by the CRO to the Institution which exceed the amounts to which the Principal Investigator was entitled for completed Subject visits under the Budget and Payment Schedule of this Agreement.

F. Payments for Screen Failure: CRO shall pay only per Subject charges for screen failure. The maximum ratio for screen failure Subjects shall be 3:1 i.e. maximum one screen failure per three randomized Subjects.

G. Payment for Study Coordinator: PI will make sure payment to study coordinator / involved study team to ensure that the Quality and deliverables of the Project are not affected at any phase of the study.

H. All payments payable by CRO are subject to deduction of taxes at source ('TDS') as per applicable law unless relevant exemption certificate is produced by the Site. Service tax will be paid, if applicable, on generation of valid invoice showing the amount of service tax to be charged before any payment is made under this Agreement

4. OBLIGATIONS OF THE INSTITUTION AND THE PRINCIPAL INVESTIGATOR

A. IEC/IRB Approval. The Principal Investigator shall be responsible, with the cooperation of the Institution and CRO/Sponsor, for obtaining approval from the IEC / IRB of the Protocol and the Subject's Informed Consent Form. The Principal Investigator shall provide the CRO or Sponsor's designee with written confirmation of the IEC / IRB's approval prior to the treatment of Subjects. If the IEC/IRB withdraws approval of the Study, at any time, the Principal Investigator shall be immediately notified by the Sponsor or CRO, providing a written explanation of the circumstances leading to such withdrawal of approval, and the Principal Investigator shall cease the treatment of all Subjects under the Study.

B. Performance of the Study. The Principal Investigator shall conduct the Study solely at the Institution. Principal Investigator will personally conduct or supervise the investigation of the Study. Principal Investigator will ensure that all persons assisting in the performance of the Study are informed of their obligations with regard to the Study. Principal Investigator agrees to report promptly, in writing, any non-compliance of the Protocol. The Principal Investigator shall exercise due care in the conduct of the Study, and represent and warrant that it will be conducted

EXHIBIT B/ [illegible]

BUDGET:

Principal Investigator : Dr. Mahesh Kalloli

Site Address : KLE's Dr. Prabhakar Kore Hospital & MRC, Belagavi-590010, Karnataka, India

PAYMENT SCHEDULE

Payment Schedule for the total study Grant for first X patients is as follows:

Overall Per Patient Budget

Amount in Indian rupees per patient	Reimbursement
313200/-	Includes the following ● PI and site team payment including Co- Investigator (s), Site coordinator(s), Nurse(s), Dietician as applicable ● Patient hospital charges like room charges and meal charges ● Institutional overhead ● Stationary and Miscellaneous
11,000/-	Patient compensation INR 500 per visit x 22 visits
324200/-	**Total Amount**

Budget Bifurcation

Patient Visits	*Hospital / Day Care Charges	PI charges	PI Grant (INR) Visitwise
Screening	0	10000	10000
Randomization	0	2000	2000
Period 1			
Cycle 1	3500	8000	11500
Cycle 2	3500	10000	13500
Cycle 3	3500	8000	11500
Cycle 4	3500	10000	13500
Cycle 5	3500	8000	11500
Cycle 6	3500	10000	13500
Period 2			
Cycle 701	2500	6000	8500
Cycle 702	2500	6000	8500
Cycle 703	2500	6000	8500
Cycle 704	2500	7000	9500
Cycle 705	2500	6000	8500
Cycle 706	2500	6000	8500

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i. Either Party may terminate this Agreement immediately upon written notice to the other if:

b. the authorization and approval to perform the Study in India is withdrawn by the DCGI and/or other applicable regulatory authority in India;

c. animal, human and/or toxicological test results, in the opinion of either Sponsor or Institution, support termination of the Study; or

d. the circumstances require termination of Study in order to protect the safety, rights, or welfare of Subjects enrolled in the Study. In the alternative, either Party may immediately dis-enroll any Subject to protect that Subject's safety, rights or welfare without terminating this Agreement, but shall promptly give the other Party written notice of the dis-enrollment.

ii. This Agreement may be terminated by either party, upon thirty (30) days prior written notice, if either of the following conditions occurs:

a. if either Party fails to comply with the terms of this Agreement within thirty (30) days of receipt of written notice, with opportunity to cure, from the other Party; or

b. if the Principal Investigator is unwilling or unable (for whatever reason) to act as Principal Investigator and no mutually acceptable replacement has been found in accordance with Clause 4C of this Agreement..

iii. This Agreement may be terminated by either Party for any reason other than those listed in Clause 12(B) upon thirty (30) days prior written notice.

iv. Upon the effective date of termination, there shall be an accounting conducted by Institution, subject to verification by Sponsor. Within thirty (30) days after receipt of adequate documentation therefrom, CRO will make payment to Institution for.

a. all services properly rendered and monies properly expended by the Institution until the date of termination not yet paid for; and

b. Reasonable non-cancelable obligations (as evidenced in writing) properly incurred for the Study by Institution prior to the effective date of termination.

v. Immediately upon receipt of a notice of termination, the Principal Investigator shall stop enrolling Subjects into the Study and shall cease conducting procedures on Subjects already enrolled in the Study as directed by CRO, to the extent medically permissible.

vi. Immediate Termination by the CRO/Sponsor. The CRO/Sponsor may terminate this Agreement, in whole or in part, effective immediately, upon written notice to the Principal Investigator; a) if the Sponsor, in its sole discretion, deems that the safety of the Subjects will be compromised by a delay in termination; or b) for any violation of the Study Schedule set forth in Clause 2) prior to the shipment of the Study Drug to the Institution.

vii. <u>Effect of Termination</u>. In the event this Agreement is expired or terminated prior to completion of the Study, for any reason, the Principal Investigator shall a) notify the IRB/IEC that the Study has been terminated; b) cease enrolling Subjects in the Study; c) cease treating Subjects under the Protocol as directed by the CRO to the extent medically permissible and appropriate, and d) terminate, as soon as practicable, but in no event more than thirty (30) days after the effective date of termination, all other Study activities; provided, however, upon the CRO's request, the Institution and the Principal Investigator shall continue to collect data and prepare and complete CRFs for Subjects treated in the

A. Budget and Payment Schedule: In consideration of the services performed, CRO shall reimburse the Institution all undisputed direct and indirect costs reasonably incurred by the Institution in accordance with the Budget and Payment Schedule, attached hereto as Exhibit B and incorporated herein by reference (the "**Budget and Payment Schedule**"). Payment shall be made by cheque. Payment shall be made within thirty (30) days after CRO has received invoice from the Principal Investigator. In addition, CRO shall reimburse directly the IEC / IRB for all costs associated with the Study. Notwithstanding the Payment Schedule mentioned in Exhibit B, the payment made by CRO shall be deemed to be as full and final payment payable by CRO as consideration for the services provided by Site including Principal Investigator, Institution and SMO.

B. Payment of Costs Outside Budget and Payment Schedule. Payment for any costs not specifically described in the Budget and Payment Schedule must be approved in advance in writing by the CRO's Project Manager.

C. Payment Terms. CRO shall have no obligation to make payments for any subject who is not qualified to participate in the Protocol based on the inclusion and exclusion criteria described in the Protocol. Queries pertaining to a subject's eligibility shall be addressed to and resolved by the CRO and sponsor's clinical and/or medical monitor identified in the Protocol prior to entry of any such subject into the study.

The foregoing notwithstanding:

Upon submission of such documentation as may be requested, to the extent not already paid by CRO, CRO will pay the actual cost of completed visits in accordance with the Budget and Payment Schedule for the Subjects who are dropped from the Study or withdraw from the Study; provided, however, such costs were incurred at a time when, in the good faith judgment of CRO, none of the Institution, its employees or agents, or the Principal Investigator knew or could have reasonably determined that such Subject was not or would not be an Eligible and Evaluable Subject. **"Eligible and Evaluable Subjects"** are defined as Subjects who have satisfied all the Protocol requirements, including compliance with dosing regimen and visit schedule, and are eligible to be included in the statistical analysis for the Study; and Institution and Principal Investigator agree that all payments made under this Section are made solely for the performance of activities relating to the Study and for no other purpose.

D. Payment Recipient and Mailing Address. All cheques shall be made payable to the entity / person mentioned in the Clause 3A.

The mailing address for checks shall be:

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respect to its debarment or a Notice of Intent to Disqualify, the CRO shall have the right to terminate this Agreement immediately without further cost or liability. The Principal Investigator represents and warrants on his own behalf that he has not used, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred, and neither shall use, in any capacity, the services of any individual, corporation, partnership, or association which has been debarred. In the event that the Principal Investigator becomes aware of the debarment or threatened debarment of any individual, corporation, partnership, or association providing services to the Principal Investigator which directly or indirectly relate to Principal Investigator's activities under this Agreement, the Principal Investigator shall notify the CRO immediately and the CRO shall have the right to terminate this Agreement immediately without further cost or liability.

B. Of the CRO. The CRO represents and warrants that (i) it has the legal authority and right to enter into this Agreement, (ii) it has no obligation to any other party that is in conflict with the CRO's obligations under this Agreement, and (iii) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms.

CRO represents and warrants to Institution and Principal Investigator the following: (i) any Study Drug or device administered or used in carrying out the Protocol has been approved by the DCGI or FDA or by the other regulatory agencies if applicable for investigational use; and (ii) CRO has at all times complied with and will continue to comply with all DCGI or FDA and comparable foreign rules, regulations, requirements, and guidelines regarding administration, manufacture, and production of drugs and devices under regulatory control of the DCGI or FDA and/or comparable foreign agencies in connection with any drug or device administered or used pursuant to the Protocol. In particular, CRO shall comply with all DCGI or FDA reporting rules that require it to inform Institution and/or Principal Investigator of any serious and unexpected adverse experience associated with the Study Drug or device.

C. No Other Representations or Warranties. Except for the limited representations and warranties given in this Clause 8, none of the Sponsor, the CRO, the Institution, or the Principal Investigator makes or receives any representations or warranties, express or implied, statutory or otherwise, and each expressly disclaims any implied warranties of merchantability, fitness for a particular purpose, or non-infringement.

D. Of the Institution: Institution will ensure that the Principal Investigator remits to the Sponsor all clinical data, including without limitation, case record forms, medical reports and the information generated during the performance of the Study. Institution will notify the CRO and Sponsor immediately if the Principal Investigator ceases to be employed by or associated with the Institution.

10. GOVERNING LAW

This Agreement shall be governed by and construed in accordance to the Laws of India. Disputes, if any, shall be arbitrated upon under the Arbitration and Conciliation Act, 1996 in English language and the venue shall be Hyderabad, India. It is expressly agreed that the arbitral award

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without limitation all source documents and data, and correspondence involving the IEC/IRB and applicable regulatory agencies); (iii) inspect and copy, at Sponsor's expense, any or all written and electronic data and work product relating to the Study; and (iv) collect financial billing and economic outcomes (including expense reports) provided that collection of such information is clearly described in the Informed Consent Form and appropriately authorized by the Subject and the IEC/IRB. The Principal Investigator and the Institution shall cooperate with the Sponsor and use reasonable efforts to promptly provide all of the information requested by the Sponsor.

The Institution and the Principal Investigator shall also cooperate with the Sponsor and with any regulatory agencies in the event of announced or unannounced monitoring, audit or inspection by such regulatory agencies. The Institution and the Principal Investigator shall notify the Sponsor by telephone of the intended or possible inspection within **twenty four (24) hours** of becoming aware of it; in addition, notice of the intended or possible inspection shall be sent to Sponsor within **forty eight (48) hours** of the telephonic notification. If a written response is required, the Institution and Principal Investigator shall permit representatives of the Sponsor to review and comment on such response prior to its being sent to the regulatory agencies. The Institution and Principal Investigator shall provide Sponsor with a copy of any report received in connection with, or as a result of such inspection within **three (3) days** of its receipt.

F. Supplies.

a. The CRO or Sponsor's designee shall supply to the Principal Investigator, at no charge, sufficient quantity of the Study Drug to conduct the Study, as well as the materials, equipment and information which the Protocol specifies. The Principal Investigator acknowledges that the Study Drug is experimental in nature, and therefore shall use prudence and reasonable care in the use, handling, storage, transportation, disposition and containment of the Study Drug and any of its derivatives. Within **thirty (30) days** following the completion or termination of the Study, all unused Study Drugs, devices and other materials that were furnished to the Institution by or on behalf of Sponsor shall, at Sponsor's expense, be returned to Sponsor, or if Sponsor so directs destroyed in accordance with instructions provided by the Sponsor. The Sponsor shall solely own all rights, title and interest in the Study Drug, including any materials derived therefrom and all intellectual property rights therein. The transfer of physical possession of the Study Drug here under, and/or the possession or use of the Study Drug by the Principal Investigator, shall neither constitute nor be construed as a sale, lease, or offer to sell or lease the Study Drug or other transfer of title in or to the Study Drug. Further, the Principal Investigator shall use the Study Drug solely for the conduct of the Study and in accordance with the Protocol unless they obtain the prior written authorization of the Sponsor.

b. Any instruments, materials or other equipment supplied/provided by the CRO to the Principal Investigator shall be used solely for the purpose of conducting the Study and as per the Protocol/ Study requirements/ Study manuals under the Agreement. Also, any damage caused to the equipment supplied/provided by the CRO under the said Agreement or any repairing cost incurred in order to maintain the said equipment or repair the damage done while conducting the Study shall be borne solely by the Principal Investigator and no liability of the same shall be placed upon the CRO.

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without limitation all source documents and data, and correspondence involving the IEC/IRB and applicable regulatory agencies); (iii) inspect and copy, at Sponsor's expense, any or all written and electronic data and work product relating to the Study; and (iv) collect financial billing and economic outcomes (including expense reports) provided that collection of such information is clearly described in the Informed Consent Form and appropriately authorized by the Subject and the IEC/IRB. The Principal Investigator and the Institution shall cooperate with the Sponsor and use reasonable efforts to promptly provide all of the information requested by the Sponsor.

The Institution and the Principal Investigator shall also cooperate with the Sponsor and with any regulatory agencies in the event of announced or unannounced monitoring, audit or inspection by such regulatory agencies. The Institution and the Principal Investigator shall notify the Sponsor by telephone of the intended or possible inspection within **twenty four (24) hours** of becoming aware of it; in addition, notice of the intended or possible inspection shall be sent to Sponsor within **forty eight (48) hours** of the telephonic notification. If a written response is required, the Institution and Principal Investigator shall permit representatives of the Sponsor to review and comment on such response prior to its being sent to the regulatory agencies. The Institution and Principal Investigator shall provide Sponsor with a copy of any report received in connection with, or as a result of such inspection within **three (3) days** of its receipt.

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a. The CRO or Sponsor's designee shall supply to the Principal Investigator, at no charge, sufficient quantity of the Study Drug to conduct the Study, as well as the materials, equipment and information which the Protocol specifies. The Principal Investigator acknowledges that the Study Drug is experimental in nature, and therefore shall use prudence and reasonable care in the use, handling, storage, transportation, disposition and containment of the Study Drug and any of its derivatives. Within **thirty (30)** days following the completion or termination of the Study, all unused Study Drugs, devices and other materials that were furnished to the Institution by or on behalf of Sponsor shall, at Sponsor's expense, be returned to Sponsor, or if Sponsor so directs destroyed in accordance with instructions provided by the Sponsor. The Sponsor shall solely own all rights, title and interest in the Study Drug, including any materials derived therefrom and all intellectual property rights therein. The transfer of physical possession of the Study Drug here under, and/or the possession or use of the Study Drug by the Principal Investigator, shall neither constitute nor be construed as a sale, lease, or offer to sell or lease the Study Drug or other transfer of title in or to the Study Drug. Further, the Principal Investigator shall use the Study Drug solely for the conduct of the Study and in accordance with the Protocol unless they obtain the prior written authorization of the Sponsor.

b. Any instruments, materials or other equipment supplied/provided by the CRO to the Principal Investigator shall be used solely for the purpose of conducting the Study and as per the Protocol/ Study requirements/ Study manuals under the Agreement. Also, any damage caused to the equipment supplied/provided by the CRO under the said Agreement or any repairing cost incurred in order to maintain the said equipment or repair the damage done while conducting the Study shall be borne solely by the Principal Investigator and no liability of the same shall be placed upon the CRO.

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Disclosing Party: The term "Disclosing Party" shall mean the Party disclosing Confidential Information to other Party.

Receiving Party: The term "Receiving Party" shall mean the Party receiving Confidential Information from the other Party.

All Confidential information shared hereunder for purpose of completion of Study and who are legally bound by confidentiality and non-use obligations, no less restrictive than those contained in this Agreement and any other confidentiality agreement executed. In addition, Institution, Principal Investigator and Site shall not use any Confidential Information for any purpose other than the conduct of the Study and shall ensure that the co-investigator who has access to Confidential Information is informed of its confidential nature and agrees to comply with the obligations of confidentiality and non-use, as set out in this Agreement and any other confidentiality agreement executed.

In addition to any other rights and obligations contained herein or elsewhere in the Agreement, Sponsor, or CRO on Sponsor's behalf, shall be entitled to seek an injunction from a court of competent jurisdiction for the purpose of stopping or preventing any existing or anticipated breach of the terms Confidentiality and of this Agreement.

B. Notwithstanding anything to the contrary in this Agreement, nothing herein shall (i) prevent the Institution from disclosing to the DCGI or any other appropriate regulatory agency Confidential Information (including Study results) that indicates that the administration or use of the Study Drug or device is associated with a serious risk of harm to the Subjects, provided that Institution furnishes at least fourteen (14) days advance written notice to the Sponsor and Sponsor fails during such time to either make the disclosure requested by Institution or to adequately demonstrate to the Institution that it has complied with all applicable disclosure requirements, or (ii) prevent Institution and/or Principal Investigator from informing the Subjects or potential Subjects of any adverse experiences or risks associated with the Study Drug or device.

C. Non-Disclosure and Non-Use. Except as otherwise expressly provided herein, for the term of this Agreement, and for a period of ten (10) years thereafter, the Parties shall not disclose to any third party Confidential Information and shall not use for any purpose other than as expressly provided for herein any such Confidential Information, without the express written consent of the Disclosing Party. Without limiting the foregoing, the Parties shall disclose Confidential Information only to those employees of the respective Party who require such Confidential Information for the purposes of this Agreement and who are bound by an obligation of confidentiality and non-use no less stringent than set forth herein. Upon disclosing Confidential Information to any employee, the employing Party shall advise them of the confidential nature of the information, and shall require them to take all necessary and reasonable precautions to prevent the unauthorized disclosure thereof. In the event that the Parties are required to disclose Confidential Information pursuant to an order or requirement of a court, administrative agency, or other governmental body, the Parties, as the case may be, may disclose the Confidential Information provided that the Receiving Party provides the Disclosing Party with reasonable advance notice thereof to enable the Disclosing Party to seek an appropriate protective order or

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to prevent the disclosure. In such a situation, the Receiving Party shall provide reasonable assistance to the other Party to obtain a protective order or to prevent disclosure.

D. Medical Confidentiality. Notwithstanding any of the foregoing, Sponsor and CRO shall maintain the confidentiality of all medical records, case history, test reports, fitness data and charts to which it may have access in accordance with all applicable federal, state and local confidentiality laws and regulations and its corresponding regulations issued under DCGI or other applicable regulations. Sponsor shall not use, disclose, maintain, store, or transmit any individually identifiable Subject information except as permitted by such laws.

E. The PI and Institution hereby acknowledge and agree that in accordance with the applicable laws and codes, and in particular with any transparency obligations contained therein, certain value transfers between pharmaceutical companies and healthcare professionals and/or healthcare or academic institutions or hospitals, are subject to mandatory publication. The Parties acknowledge that, in accordance with said obligations the Sponsor is responsible for the publication of the relevant information in the appropriate format and within the applicable timeframe. Such information shall at least include the amount, purpose and recipient of the value transfers. The PI and Institution hereby explicitly agrees with such publication by Sponsor, provided the publication is in accordance and strictly limited to the requirements of the said laws and codes, and does not go beyond the requirements of the applicable privacy laws.

6. Protection. Without limiting the foregoing, the Parties shall maintain reasonable procedures to prevent accidental or other loss of any Confidential Information of the Disclosing Party, and shall use at least the same procedures and degree of care which each uses to protect its own confidential information, but in no case less than reasonable care. In the event of loss, disclosure or use of any Confidential Information in violation of this Agreement, the Receiving Party shall immediately notify the Disclosing Party. The Parties shall prevent the disclosure of medical records and private or personal information, whether confidential or not, to the extent required by applicable laws or regulations.

7. PUBLICATION

Subject to governing law, the Sponsor shall have the sole right to review, use, publish, and disclose any data, information, or results developed or arising out of the Study as the Sponsor, in its discretion, deems appropriate, including, without limitation, in submissions to the FDA and other governmental agencies. If Principal Investigator wants to publish information arising from his/her participation in the Study, the prior written approval from Sponsor is required.

8. OWNERSHIP OF MATERIALS, DATA, INVENTIONS, AND DISCOVERIES

A. Materials and Data. The Sponsor shall solely own all right, title and interest in and to the Study Drug and any and all information, data or other materials delivered to the Institution or the Principal Investigator by or on behalf of the Sponsor as well as any derivatives, progeny, or improvements developed therefrom, and all intellectual property rights therein. Further, all data and work product arising out of or relating to the Study, including, without limitation, the Study Records, CRFs, reports, and specimens, and all intellectual property rights therein, shall be the

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be free to dispose of its interest in accordance with its technology transfer policies. If Sponsor and Institution fail to reach agreement on the terms for an exclusive license of a particular Institution Invention within four (4) months after Sponsor provides notice that it wishes to exercise its option, then for a period of one (1) year thereafter, the Institution shall not offer to license the Institution Invention to any third party on materially better terms than those last offered to the Sponsor without first offering such terms to Sponsor, in which case Sponsor shall have a period of thirty (30) days to accept the offer.

C. No Other Rights. Except as expressly set forth herein, none of the Sponsor, the Principal Investigator, or the Institution transfers to any other Party hereto, by operation of this Agreement or otherwise, rights to any patent, copyright, trademark or other intellectual property right of any kind.

9. REPRESENTATIONS, WARRANTIES AND COVENANTS

A. Of the Principal Investigator. The Principal Investigator represents and warrants that (i) he has the legal authority and right to enter into this Agreement; (ii) he has no obligation to any third party that is in conflict with, or has the potential to conflict with, its obligations under this Agreement; (iii) he has and will maintain throughout the conduct of the Study, all training, information, licenses, approvals and certifications necessary for safely, adequately, and lawfully performing the Study; (iv) he will not enter into any agreement with any third party to directly or indirectly fund or support the Study without the express written consent of the CRO (excluding laboratory investigations, radiological investigations or any other requirement to fulfill Protocol criteria), and (v) this Agreement has been duly executed and delivered by it and constitutes a valid, binding obligation enforceable against it in accordance with its terms.

The Principal Investigator represents and warrants that no clinical study or trial in which he was involved was terminated for any reason prior to completion that was due, in whole or in part, to the Principal Investigator's non-compliance with the applicable protocol and/or safety requirements of the study or any applicable local, state or federal law. The Principal Investigator further represents and warrants that he has not received any written notice from the DCGI/FDA or NIH of any violation of any applicable law relating to clinical studies that has not been disclosed to the CRO and attached to this Agreement as an Exhibit hereto. For the purposes of the prior sentence, "written notice" shall include, but not be limited to, DCGI or FDA lists of Inspectional Observations (FDA Form 483), Notices of Adverse Findings, regulatory letters, warning letters, notices of intent to initiate clinical investigator disqualification proceedings under national regulations or under 21 C.F.R. 312.70 or 21 C.F.R. 812.119 or any similar regulation ("**Notice of Intent to Disqualify**"). The Principal Investigator further represents and warrants that he has never been disqualified from receiving investigational drugs or medical devices by the DCGI or FDA or NIH or any other federal governmental body. In the event that any of the foregoing events in this paragraph occur during the course of this Study, the Principal Investigator shall provide the CRO with a full written explanation of the circumstances of such an incident within ten (10) days of the occurrence of such an incident. If the Institution or the Principal Investigator becomes debarred as per the national or local regulations, this Agreement will

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Certificate No.	:	IN-KA11899844806922O
Certificate Issued Date	:	19-Sep-2016 02:49 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ JAYANAGAR4/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKACRSFL08738079176422620
Purchased by	:	QUINTILES RESEARCH INDIA PVT LTD
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	QUINTILES RESEARCH INDIA PVT LTD
Second Party	:	K L E SOCIETYS DR PRABHAKAR KORE HOSPITAL
Stamp Duty Paid By	:	QUINTILES RESEARCH INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

AUTHORISED SIGNATORY

Please write or type below this line

Statutory Alert

1. The authenticity of this Stamp Certificate should be verified at www.shcilestamp.com. Any discrepancy in the details on this Certificate and as available on the website renders it invalid.
2. The onus of checking the legitimacy is on the users of the certificate.
3. In case of any discrepancy please inform the Competent Authority.

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CLINICAL TRIAL AGREEMENT

Made between **Dr. Vardaraj Gokak**, having a place of business at KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehru Nagar, Belagavi - 590010, Karnataka, India (the "Investigator"), **KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre**, having a place of business at Nehru Nagar, Belagavi - 590010, Karnataka, India (the "Institution"), **GDD Experts India Pvt. Ltd.** having a place of business at Ground Floor, Gulmohar Apartment, Opposite Hislop College, Nagpur- 440001, Maharashtra, India (the "Research Company"), **F. Hoffmann-La Roche Ltd**, having a place of business at Grenzacherstrasse 124, 4070 Basel, Switzerland ("Sponsor") and **Quintiles Research (India) Private Limited**, having its office at B-101-106, Shapath IV, S G Road, Ahmedabad- 380 051, India ("Quintiles").

PROTOCOL NUMBER:	GA29102
PROTOCOL TITLE:	Phase III, randomized, double-blind, placebo controlled, multicenter study to evaluate the efficacy (maintenance of remission) and safety of Etrolizumab compared with placebo in patients with moderate to severe active Ulcerative Colitis who are naive to TNF Inhibitors
PROTOCOL DATE:	28 August 2015
SPONSOR:	F. Hoffmann-La Roche Ltd
PRINCIPAL INVESTIGATOR:	Dr. Vardaraj Gokak
KEY ENROLLMENT DATE: (date by which site is to enroll at least one (1) subject)	100 Calendar Days after Site Initiation Visit

WHEREAS, the Investigator and Institution [or "and Research Company"], if any, (hereafter, jointly, the "Site") are willing to conduct a clinical trial (the "Study"), in accordance with the above-referenced protocol and any subsequent amendments thereto (the "Protocol") and Sponsor and Quintiles request the Site to undertake such Study;

WHEREAS, Quintiles has been duly authorized by the Sponsor to carry out certain obligations of the Sponsor in the conduct of the Study, consistent with the terms of this Agreement;

NOW THEREFORE, the following is agreed:

1. Quintiles and Sponsor hereby appoint the Site to conduct the Study, and the Site agrees to ensure that the Site and the Site's employees, agents, and staff will conduct the Study in accordance with the Protocol (as may be amended from time to time by Sponsor), the terms of this agreement, including the Terms and Conditions attached as Attachment A, the Payment Schedule and Budget attached as Attachment B, and any other attachments hereto, which all are incorporated by reference herein (the "Agreement"), good clinical practices, and all applicable laws and regulations. The Site hereby confirms that it has enough time and resources to perform the Study according to the highest quality standards. The Site understands and agrees that if Site has not enrolled at least one (1) subject by the Key Enrollment Date then Sponsor may terminate this Agreement in accordance with Section 5 of Attachment A.

   Enrollment of Patients
   The Effective Date of this Agreement is as listed in Section 3. Consequently, the Site will not be permitted to screen patients, randomize patients, receive Investigational Product or receive any payment until the validity date of this contract is reached.

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In addition, Sponsor has a right to limit or increase unilaterally and at any time the number of subjects participating in the Study

1. Payments shall be made in accordance with the provisions set forth in Attachment B, with the last payment being made after the Site completes all its obligations hereunder, and Quintiles has received all completed case report forms ("CRFs") and, if Quintiles requests, all other Confidential Information as defined in Attachment A, Section 2 (Confidential and Proprietary Information). The Site will act as an independent contractor, and shall not be considered the employee or agent of Quintiles or Sponsor. Neither Quintiles nor Sponsor shall be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Site. The Site acknowledges and agrees that Investigator's judgment with respect to Investigator's advice to and care of each subject is not affected by the compensation Site receives hereunder.

   Institution and Investigator acknowledge and confirm that if Investigator is a named payee hereunder, such payment arrangement is in accordance with the modalities laid down by the Institution for receipt of funding for the Study and is not in violation of the MCI Regulations.

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

PAYEE NAME:	GDD EXPERTS INDIA PVT LTD.
PAYEE ADDRESS:	Ground Floor, Gulmohar Apartment, Opposite Hislop College. Nagpur- 440001, Maharashtra, India
PAN OF PAYEE	AADCG0363Q

   It should be noted that all the payments made to the Payee are subject to Tax Deducted at Source (TDS) in accordance with India tax laws, as amended from time to time. Quintiles 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.

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

   The parties acknowledge that the designated Payee is authorized to receive all of the payments for the services performed under this Agreement. If the Investigator is not the Payee, then the Payee's obligation to reimburse the Investigator will be determined by a separate agreement between Investigator and Payee, which may involve different payment amounts and different payment intervals than the payments made by Quintiles to the Payee. **Investigator acknowledges that if Investigator is not the Payee, neither Quintiles nor Sponsor will pay Investigator, even if the Payee fails to reimburse Investigator.**

3. This Agreement will become effective on the date of approval of the Study by Drugs Controller General India or on the date on which it is last signed by the parties, whichever date is later, (the "Effective Date") and shall continue until completion or until terminated in accordance with the provision in Attachment A. Quintiles shall attach a copy of the letter from the Drugs Controller General India approving the Study to this Agreement as Attachment C, and the parties agree that such letter shall be incorporated by reference herein. If such approval letter has not been received as of the date the parties sign this Agreement, Quintiles shall keep the original signed Agreements until receipt of such

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approval letter, and upon receipt of such letter, Quintiles shall attach a copy of the letter to each original Agreement as Attachment C and forward an original Agreement to each other party, while retaining one original Agreement its files. If such approval letter already has been received prior to the signatures of the parties, Quintiles shall immediately attach a copy of the letter hereto as Attachment C, and upon signature of all parties, each party shall receive an original of the Agreement, which shall include such letter as Attachment C. In the event of a conflict between the Protocol and this Agreement, the terms of this Agreement will govern.

4. The date of execution of this Agreement is as listed in Section 3 above. Consequently, the Site will not be permitted to screen patients, randomize patients, receive Investigational Product or receive any start up payment until the validity date of this contract is reached.

5. Prior to and during the course of the Study, Quintiles or Study Sponsor may request to collect personal data which may be subject to data privacy laws or regulations (collectively "Data Privacy Legislation") relating to the Study from the Site, including from its investigators, sub-investigators, other Site staff or personnel involved in the conduct of the Study. The Investigator hereby consents to the processing of Investigator's personal data collected by Quintiles or Sponsor, and Investigator and Institution agree to obtain any consents, as may be necessary in accordance with applicable Data Privacy Legislation, for the processing of any personal data collected by Quintiles or the Sponsor from its investigators, sub-investigators, staff and personnel involved in the conduct of the Study. Such consent shall authorize the transfer of personal data, to countries other than the Site's own country, including without limitation the United States, even though data protection may not exist or be as developed in those countries as in the Site's own country, for the following purposes: a) the conduct and interpretation of the Study; b) review by governmental or regulatory agencies, Sponsor, Quintiles, and their agents, and affiliates and collaborators; c) satisfying legal or regulatory requirements; d) publication on www.clinicaltrials.gov and websites and databases that serve a comparable purpose; and e) storage in databases for use in selecting sites in future clinical trials. In the event any Site personnel participating in the Study are not willing to provide such consent, Site acknowledges that such personnel will not be able to participate in the Study.

6. Institution and Principal Investigator agree that the compensation they receive from this Agreement does not exceed the fair market value of the services they are providing, and that no payments are being provided to them for the purpose of inducing them to purchase or prescribe any drugs, devices or products. Site agrees that it will not bill any patient, insurer, or governmental agency for any items, visits, services or expenses provided or paid for by Quintiles or Sponsor.

   Institution and Principal Investigator and GDD Experts India Pvt. Ltd. represent and warrant that neither they nor any individual or entity acting on their behalf, nor any payee under this Agreement, will, directly or indirectly, offer or pay, or authorize an offer or payment of, any money or anything of value to any Public Official (defined below) or public entity, with the knowledge or intent that the payment, promise or gift, in whole or in part, will be made in order to influence an official act or decision that will assist Quintiles, Sponsor or the Site in securing an improper advantage or in obtaining or retaining business or in directing business to any person or entity.

   In addition to other rights or remedies under this Agreement or at law, Sponsor and/or Quintiles may terminate this Agreement if Site and GDD Experts India Pvt. Ltd breaches any of the representations or warranties contained in this Section or if Quintiles or Sponsor learns that improper payments are being or have been made to Public Officials by Site or any individual or entity acting or its behalf.

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KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

For the purposes of this Agreement "Public Official" means any officer or employee of a government, a public international organization or any department or agency thereof, or any person acting in an official capacity, including, for a public agency or enterprise, and any political party or party official, or any candidate for public office.

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

By: Subashri Shivkumar

Name: Subashri Shivkumar

Title: Head Clinical Development Services

Date: 29/Sept/2016

ACKNOWLEDGED AND AGREED BY SPONSOR (Quintiles executing on Sponsor's behalf):

By: Subashri Shivkumar

Name: Subashri Shivkumar

Title: Head Clinical Development Services

Date: 29/Sept/2016

ACKNOWLEDGED AND AGREED BY THE PRINCIPAL INVESTIGATOR:

By:

Name: Dr. Vardaraj Gokak

Title: Principal Investigator

Date: 15/10/16

ACKNOWLEDGED AND AGREED BY KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre :

By:

Medical Director & Chief Executive
KLES Dr. Prabhakar Kore Hospital &
Medical Research Centre, BELAGAVI

Name: Dr. M. V. Jali

Title: Medical Director

Date: 21/10/2016

ACKNOWLEDGED AND AGREED BY GDD EXPERTS INDIA PVT. LTD.:

By:

Name: Vinod Gyanchandani

Title: Head- Clinical Operations

Date: 30/sep/2016.

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ATTACHMENT A
TERMS AND CONDITIONS

Capitalized terms not defined herein shall have the meanings assigned to them in the attached Agreement.

1) Conduct of the Study. The parties to the Agreement agree that the Study will be performed in strict accordance with the Protocol, all applicable laws, regulations and guidelines, and good clinical practices ("GCPs"), and Indian Medical Council (Professional Conduct, Etiquette and Ethics)(Amendment) Regulations, 2009 – Part-I ("MCI Regulations") The Investigator shall review all case report forms ("CRFs") to ensure their accuracy and completeness, shall review and understand the information in the investigator's brochure, shall ensure that all informed consent requirements are met (including any needed authorizations for the use, storage and transfer of personal data), shall ensure that all required reviews and approvals (or favorable opinions) by applicable regulatory authorities and Institutional Review Boards ("IRBs") or Independent Ethics Committees ("IECs") are obtained and shall provide a copy of such approval to Quintiles prior to enrollment of any subjects. A sample informed consent form has been provided by the Sponsor for use in the Study; any modifications to this form must be approved by Quintiles or Sponsor prior to its use, such approval not to be unreasonably withheld The Site agrees to ensure that all clinical data are accurate, complete, and legible. The Site shall promptly and fully produce all data, records and information relating to the Study to Quintiles and Sponsor and their representatives during normal business hours, and shall assist them in promptly resolving any questions and in performing audits or reviews of original subject records, reports, or data sources. The Site agrees to cooperate with the representatives of Quintiles and Sponsor who visit the Site, and the Site agrees to ensure that the employees, agents and representatives of the Site do not harass, or otherwise create a hostile working environment for, such representatives. The Site warrants that it has the legal authority to share the clinical data and Study-related records and information with Quintiles and Sponsor. The Site shall use the product being tested (the "Investigational Product"), and any comparator products provided in connection with the Study, solely for the purpose of properly completing the Study and shall maintain all Investigational Product and any comparator products in a locked, secured area at all times Upon completion or termination of the Study, the Site shall return all unused Investigational Product, comparator products, equipment, and materials and all Confidential Information (as defined below).

2) Confidential and Proprietary Information. All information (including, but not limited to, documents, descriptions, data, CRFs, photographs, videos and instructions), and materials (including, but not limited to, the Investigational Product and comparator products), provided to the Site by Quintiles, Sponsor, or their agents, (whether verbal, written or electronic), and all data, reports and information, relating to the Study or its progress (hereinafter, the "Confidential Information") shall be the property of Sponsor. The Site shall keep the Confidential Information strictly confidential and shall disclose it only to its employees involved in conducting the Study, who are subject to confidentiality obligations that are consistent with this Agreement, on a need-to-know basis. These confidentiality obligations shall continue until ten (10) years after completion of the Study, but shall not apply to Confidential Information to the extent that it: a) is or becomes publicly available through no fault of the Site; b) is disclosed to the Site by a third party not subject to any obligation of confidence; c) must be disclosed to IRBs, IECs, or applicable regulatory authorities; d) must be included in any subject's informed consent form; e) is published in accordance with Article 3 herein; or, f) is required to be disclosed by applicable law, provided that the Site shall give Sponsor and Quintiles prompt, advance written notice to permit Quintiles, Sponsor or their agents to object to or otherwise limit such disclosure. The existing inventions and technologies of Sponsor, Quintiles, or the Site are their separate property and are not affected by this Agreement. Sponsor shall have exclusive ownership of any inventions or discoveries arising in whole or in part from Confidential Information or arising from the conduct of the Study. The Site will promptly notify Sponsor in writing if it or Investigator conceives or makes any such inventions or discoveries and, at Sponsor's expense, execute any documents and give any testimony necessary for Sponsor to obtain patents in any country or to otherwise protect Sponsor's interests in such inventions or

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discoveries. The Site agrees to comply with any applicable data privacy or data protection legislation of the country in which the data originated

3) Publication. Site understands that this Study is being conducted at multiple research sites. Site is free to publish or present the Study results obtained at the Site, but only after the first publication or presentation that involves the multi-center data or eighteen (18) months after the completion of the multi-center Study, whichever is first. At least sixty (60) days prior to submitting or presenting a manuscript or other materials relating to the Study to a publisher, reviewer, or other outside persons, the Site shall provide to Sponsor a copy of all such manuscripts and materials, and allow Sponsor sixty (60) days to review and comment on them. If the Sponsor requests, the Site shall remove any Confidential Information (other than Study results) prior to submitting or presenting the materials. In addition, at Sponsor's request, the Site shall delay publication for an additional ninety (90) days to allow Sponsor the opportunity to file for patent protection. No party hereto shall use any other party's name in connection with any advertising, publication or promotion without prior written permission.

4) Inspection and Debarment. When given reasonable notice, the Site agrees to allow authorized Quintiles, Sponsor and regulatory authority personnel direct access to the Site's records relating to the Study, including subject medical records, for monitoring, auditing, and inspection purposes. If any source data are kept on computer files only, the site shall make print-outs of all patients' data relevant to the Study for the purpose of source data verification, signed, dated and retained as source documents. The Site shall immediately notify Quintiles of, and provide Quintiles copies of, any inquiries, correspondence or communications to or from any governmental or regulatory authority relating to the Study, including, but not limited to, requests for inspection of the Site's facilities, and the Site shall permit Quintiles and Sponsor to attend any such inspections. The Site will make reasonable efforts to separate, and not disclose, all confidential materials that are not required to be disclosed during such inspections. Site and Investigator each represents and warrants that there are no pending for-cause regulatory audits, investigations or proceedings involving Site, Investigator, or any of their employees or agents performing Study activities which relate to compliance with laws regarding the conduct of any clinical research. The Investigator and the Institution shall be jointly responsible for maintaining essential Study documents in the manner specified by current good clinical practice ("GCP") guidelines and applicable laws for fifteen (15) years after the completion of the Study or such longer period as specified by current GCP guidelines and applicable laws. In addition, Site shall take measures to prevent accidental or premature destruction of these documents. If the Investigator leaves an institution, then responsibility for maintaining Study records shall be determined in accordance with applicable regulations. During the Study and for 15 years thereafter, if an investigator or sub-investigator leaves an institution or otherwise changes addresses, he or she shall promptly notify Sponsor and Quintiles of his or her new address. The Site represents and warrants that neither it, nor any of its employees, agents or other persons performing the Study under its direction, has been debarred, disqualified or banned from conducting clinical trials or is under investigation by any regulatory authority for debarment or any similar regulatory action in any country, and the Site shall notify Quintiles immediately if any such investigation, disqualification, debarment, or ban occurs.

5) Termination. Sponsor may suspend enrollment or terminate this Agreement effective immediately upon written notice. The Site may terminate this Agreement upon written notice if circumstances beyond the Site's reasonable control prevent the Site from completing the Study, or if the Site reasonably determines that it is unsafe to continue the Study. Upon receipt of notice of termination, the Site shall immediately cease any subject recruitment, follow the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs, and Quintiles shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in the Attachment B; provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all subject CRF pages and all data clarifications issued and satisfaction of all other applicable conditions set forth in the Agreement. Neither Quintiles nor Sponsor shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages.

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6) Claims and Disclaimers. The Site shall promptly notify Quintiles and Sponsor in writing of any claim of illness, injury or death or damage actually or allegedly arising from the conduct of the Study. Sponsor agrees to indemnify and hold harmless the Site and Investigator from any third party claims of illness, injury or damage directly arising out of the conduct of the Study in accordance with the Protocol, except to the extent any such illness, injury or damage is caused by the Site or Investigator's negligence, misconduct, failure to follow the Protocol or breach of applicable law or regulation. Sponsor shall have the right to control the defense of any such claims and the Site shall cooperate fully with Sponsor in handling such claims. Quintiles expressly disclaims any liability in connection with the Investigational Product, including any liability for any product claim arising out of a condition caused by or allegedly caused by the administration of such product except to the extent that such liability is caused by the negligence, willful misconduct or breach of this Agreement by Quintiles. Neither Quintiles nor Sponsor will be responsible for, and the Site agrees, to the extent allowed by law, to indemnify and hold them harmless from, any third party claims of illness, injury or damage resulting from the Site's negligence, failure to adhere to the Protocol, failure to obtain informed consent, unauthorized warranties, breach of this Agreement, breach of applicable law or regulation or willful misconduct.

7) Financial Disclosure. In order to allow Sponsor to comply with its U.S. regulatory requirements, the Site agrees that, for each listed or identified investigator or sub investigator who is directly involved in the treatment or evaluation of research subjects, it shall promptly return to Quintiles a financial disclosure form that has been completed and signed by such investigator or sub investigator, which shall disclose any applicable interests held by those investigators or sub investigators or their spouses or dependent children. Quintiles may withhold payments if it does not receive a completed form from each such investigator and sub investigator. The Site shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one (1) year after its completion. The Site agrees that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, Quintiles, and their agents, and the Site consents to such review. The Site further consents to the transfer of its financial disclosure data to the Sponsor's country of origin, and to the U.S. if the Site is outside of the U.S., even though data protection may not exist or be as developed in those countries as in the Site's own country.

8) Shipping of Dangerous Goods and Infectious Materials. The shipment of dangerous goods and infectious materials (including infectious subject specimens) is subject to local, national, and international laws and regulations. The Site is responsible for ensuring that each individual who packages or handles any dangerous goods or infectious materials for shipping from the Site complies with all applicable laws and regulations.

9) Adverse Event Reporting. Investigator agrees to report any serious adverse events (SAEs) as required by law, regulation and the Protocol. Within 24 hours (or such other time as specified in the Protocol) of first knowledge of any SAE or any event that could affect the safety of the Study participants, Investigator will notify Quintiles and the Sponsor via the electronic data capture system (eDC). In the case of the eDC being offline, the responsible Site staff will fax the paper SAE form to Quintiles Lifecycle Safety using the toll free fax number (+353 1 809950) and enter the SAE into the eDC system as soon as it is back online.

10) Additional Contractual Provisions. This Agreement, including these Terms and Conditions, constitutes the sole and complete agreement between the parties and replaces all other written and oral agreements relating to the Study. No amendments or modifications to this Agreement shall be valid unless in writing and signed by all the parties. Failure to enforce any term of this Agreement shall not constitute a waiver of such term. If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect. This Agreement shall be binding upon the parties and their successors and assigns. The Site shall not assign or transfer any rights or obligations under this Agreement without the written consent of Sponsor. Sponsor may, and/or Quintiles may upon Sponsor's request, assign this Agreement to a third party, (and Quintiles may upon Sponsor's request assign its rights and obligations under this Agreement to Sponsor), and Sponsor and/or Quintiles (as the case may be) shall not be responsible for any obligations or

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liabilities under this Agreement that arise after the date of the assignment, and the Site hereby consents to such an assignment. Site will be given prompt notice of such assignment by the assignee. The terms of this Agreement that contain obligations or rights that extend beyond the completion of the Study shall survive termination or completion of this Agreement, including without limitation Sections 2, 3, 4, 6 , 7 and 10 of this Attachment A

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ATTACHMENT B
BUDGET AND PAYMENT SCHEDULE

A. PAYMENT TERMS

Quintiles will reimburse the Payee every month, on a completed visit per subject basis in accordance with the attached budget. Ninety percent (90%) of each payment due, including any Screening Failure (see Article C below), will be made based upon prior enrollment data confirmed by subject Case Report Forms ("CRFs") received from the Site supporting subject visitation. The balance of monies earned, up to ten percent (10%), will be pro-rated upon verification of actual subject visits, and will be paid by Quintiles to the Payee upon final acceptance by Sponsor of all CRFs pages, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by Quintiles and/or Sponsor, the return of all unused supplies to Quintiles, as well as confirmation that all electronic patient diaries have been returned and upon satisfaction of all other applicable conditions set forth in the Agreement. Site shall have thirty (30) days from the receipt of the final payment to dispute any discrepancies relating to payments made pursuant to this section. Site understands that at some point following such period, Quintiles will close its books relating to the Study and any disputes received after such period may be forwarded to Sponsor for resolution.

Site represents that the services it provides under this Agreement are taxable services under the laws governing service tax in India, and that it is required to charge service tax for the services rendered to Quintiles at the prevailing rate. Site represents that it is entitled to require such payment of the service tax under the laws of India. Site undertakes to provide Quintiles with an invoice, to be sent to Quintiles at the address mentioned in Section E of this attachment in respect of such taxable services and such invoice shall be in accordance with the terms of the Service Tax Rules of 1994 as may be amended from time to time or any successor legislation.
It should be noted that all the payments made to the Payee are subject to Tax Deducted at Source (TDS) in accordance with India tax laws, as amended from time to time. Quintiles 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

Major, disqualifying Protocol violations are not payable under this Agreement

B. SCREENING FAILURE PAYMENTS:

Quintiles will pay the Site up to 5 screening failure patients, at a rate of Twenty Thousand Two Hundred and Forty Rupees (INR 20,240) per Screen Failure. If the site reaches the cap of 5 screen failure, it should be discussed with relevant CPM before more patients can be screened

C. DISCONTINUED OR EARLY TERMINATION PAYMENTS:

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

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D. ORIGINAL INVOICES:

Original invoices pertaining to this Study for the following items must be submitted to Quintiles for reimbursement at the following address.

Quintiles Research India Private Ltd., Bangalore
Attention: Finance PSC – Accounts Payable (Investigator Payments)
III Floor, Etamin Block,
Prestige Technology Park,
Sarjapur - Marathahalli Outer Ring Road
Bangalore – 560103, India

Please note that invoices will not be processed unless they reference the Sponsor name, Protocol number and Investigator and will be included with the regular payments. After receipt and verification, reimbursement for invoices will be included with the next regularly scheduled payment for subject activity.

- **Institution Review Boards ("IRBs") or Independent Ethics Committees ("IECs") Payments**

IRB/IEC costs will be reimbursed on a pass-through basis and are not included in the attached Budget. Any subsequent re-submissions or renewals, upon approval by Quintiles and Sponsor, will be reimbursed upon receipt of appropriate documentation

- **Study Start-Up Fee**

A one time, non-refundable payment of **Sixty Thousand Rupees (INR 60,000)** to cover Study Start-Up activities [which includes institutional overhead], will be made upon completion and receipt by Quintiles of all original contractual and regulatory documentation and receipt of original invoice.

- **Record Storage Fee/Archiving Fee**

A record storage payment of **One Lakh, Twenty Thousand Rupees (INR 1, 20,000),** [which includes institutional overhead], will be made upon receipt of original supporting invoices from a third party vendor and are not included in the attached Budget. In accordance with Sponsor's Protocol requirements, Institution shall maintain all site study records in a safe and secure location to allow easy and timely retrieval, when needed

- **Patient Travel Expenses**

Patient travel expenses will be reimbursed upon receipt of original supporting invoices from third party vendors at a flat rate of **Five Hundred Rupees (INR 500) or up to (INR 1000)** per visit per patient per round trip) and are not included in the attached Budget. Invoices must contain the following information in order for a payment to be issued- Subject number or initials, amount paid, visit number in which patient travel is being requested.

- PRESCREENING ACTIVITIES:

To recognize Site's efforts in the Study prescreening procedures, Quintiles will compensate Site **Six Thousand Eight Hundred and Thirty Rupees (INR 6,830)** for each subject screened and randomized who was entered in the prescreening log at least 1 month before screening (the "Prescreening Payment"). To be eligible for the Prescreening Payment, Site must document that prescreening occurred at least 1 month prior to screening by submitting the prescreening log to Quintiles once per week. Site agrees that it will submit to Quintiles the prescreening log, completed screening documents, randomization CRF pages, and any additional information requested by Quintiles to appropriately document the subject prescreening, screening, and randomization activities. To receive the Prescreening Payment, Site shall issue an invoice to Quintiles containing the Patient Randomization Number of the qualifying subject.

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- PREGNANCY TEST, ALCOHOL AND GAUZE:

Quintiles will provide the Site with pregnancy tests, alcohol pad and gauze during the course of the Study, in reasonable and needed amounts. Site will provide such materials to patients (study subjects) to take home for the purposes of Study protocol procedures.

- ADVERSE EVENT REPORTING:

Investigator will report any serious adverse events (SAEs) as required by law, regulation and the Protocol. Within 24 hours (or such other time as specified in the Protocol) of first knowledge of any SAE or any event that could affect the safety of the Study participants, Investigator will notify Quintiles and the Sponsor via the electronic data capture system (eDC). In the case of the eDC being offline, the responsible Site staff will fax the paper SAE form to Quintiles Lifecycle Safety using the toll free fax number (+353 1 809950) and enter the SAE into the eDC system as soon as it is back online.

F. INFRASTRUCTURE / EQUIPMENT:

1. eDiaries and Tablet Return

Section 1: The final payment will be made after Sponsor has received copies of all completed Case Report Forms ("CRFs") for each of the Subjects participating in the Study with all queries resolved as well as confirmation that all electronic patient diaries have been returned. Site shall have thirty (30) days from the receipt of the final payment to dispute any discrepancies relating to payments made pursuant to this section 1. Site understands that at some point following such period, QUINTILES will close its books relating to the Study and any disputes received after such period may be forwarded to Sponsor for resolution.

Section 2: Subject to the conditions set forth below, Sponsor or QUINTILES will provide HTC-HD2 T8585 Handheld Computer (eDiary) and Acer Iconia W510P (eQuestionnaires), which is required for use in the Study and that Site does not otherwise own or have access to (the "Equipment") to Site for use in the Study.

(i) Equipment Use; Maintenance. Site agrees to house the Equipment on site and to use the Equipment solely in connection with the Study during the term of the Agreement. Site agrees to maintain the Equipment in good working condition, reasonable wear and tear excepted. In the event that the Equipment malfunctions or ceases to operate during the conduct of the Study through no fault of Site, Sponsor or QUINTILES will arrange for appropriate maintenance or replacement of the Equipment, including, at Sponsor's option, reimbursing Site for reasonable maintenance or replacement expenses.

(ii) Return or Purchase of Equipment. Upon completion or any earlier termination of the Study at Site, Site shall, at its option, either: (A) return the Equipment to Sponsor/Sponsor at Sponsor's/Sponsor's expense, or (B) reimburse Sponsor/Sponsor for the residual fair market value of the Equipment as of the date of termination. Sponsor/Sponsor or QUINTILES may, at its option, either withhold the final payment to Site until the Equipment is returned, or until Site reimburses Sponsor/Sponsor for the residual fair market value of the Equipment as of the date of completion or termination of the Study. IN THE EVENT OF TRANSFER OR ASSIGNMENT UNDER THIS PARAGRAPH, THE EQUIPMENT SHALL BE TRANSFERRED AND ASSIGNED "AS IS," AND SPONSOR/SPONSOR MAKES NO WARRANTY OR REPRESENTATION, EXPRESSED OR IMPLIED, INCLUDING BUT NOT LIMITED TO FITNESS, MERCHANTABILITY, QUALITY, DESIGN, CONDITION, SUITABILITY OR PERFORMANCE OF THE EQUIPMENT.

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2. Bioclinica Devices:

Subject to the conditions set forth below, Sponsor or Quintiles will provide Lenovo Thinkpad E450 Laptop- Includes Power Supply and Ethernet Cable- , Dazzle Video Creator Platinum HD- Video Input Adapter and Transcend 8GB USB Memory Stick, which is required for use in the Study and that Site does not otherwise own or have access to (the "Bioclinica Devices") to Site for use in the Study.

(i) Bioclinica Devices Use, Maintenance. Site agrees to house the Bioclinica Devices on site and to use the Bioclinica Devices solely in connection with the Study during the term of the Agreement. Site agrees to maintain the Bioclinica Devices in good working condition, reasonable wear and tear excepted. In the event that the Bioclinica Devices malfunctions or ceases to operate during the conduct of the Study through no fault of Site, Sponsor or Quintiles will arrange for appropriate maintenance or replacement of the Bioclinica Devices, including, at Sponsor's option, reimbursing Site for reasonable maintenance or replacement expenses.

(i) Return or Purchase of Bioclinica Devices. Upon completion or any earlier termination of the Study at Site, Site shall, return the Bioclinica Devices to Sponsor/Quintiles at Sponsor's/Quintiles' expense. Sponsor or Quintiles may withhold the final payment to Site until the Bioclinica Devices is returned.

G. BUDGET DETAILS:

The Budget is as follows:

It is agreed that the Site will receive INR Two Lakh Eighty Two Thousand One Hundred and Seven only (INR 282,107) per completed patient for the Study according to the schedule indicated below. This per patient amount is intended to cover the following study- related costs incurred by the Site

- costs related to the patients visits (day care cost, stay)
- costs for study related communications
- salaries of study staff and Investigator
- Institute service charges and overheads

Budget Table:

Visit No.	Per Patient Amount Including 20% Overhead (INR)
Screening Visit	26,717
Visit 0	15,762
Visit 4	14,824
Visit 8	10,985
Visit 10	21,910
Visit 12	16,980
Visit 16	10,985
Visit 20	16,433
Visit 24	11,741
Visit 32	16,790
Visit 44	17,189
Visit 56	16,223
Visit 62	29,827

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Phone call Visit 28, 36, 40, 48, 52, 60**		34,327
12- Week Safety Follow Up-	26,717	7,467
	15,762	13,950
TOTAL Amount Per Completed Patient Including 20% Overhead (INR)		282,107

Unscheduled Visit*	10,897
Early Withdrawal from Treatment*	17,857
12- Week Safety Follow Up - Unscheduled Visit*	10,897

***Unscheduled Visit Fee and Early Withdrawal from Treatment Fee will be paid upon receipt of completed eCRFs, not included in the total cost per subject.**

****If Phone call does not occur, clinic visit to be paid upon receipt of detailed invoice for weeks 28, 36, 40, 48, 52 and 60.**

Additional Invoice Details

INVOICED ITEMS:	Unit Cost (including OH) (INR)
Serum pregnancy test	300
Urine pregnancy test	200
Chest X-ray, includes interpretation and report	500
TB screen (QuantiFeron - TB Gold Test)	1,084
TB screen (Skin Test)	514
Colonoscopy, with biopsy	6,500
Sigmoidoscopy, with biopsy (Colonic biopsies (formalin, RNA later))	6,100
Etrolizumab / etrolizumab placebo	622
Clinic Visits for weeks 28, 36, 40, 48, 52, 60 if Phone Visit did not occur	5,823
PML Neurologic Examination	2,000
PK sampling (serum)	200
Central Labs (Hematology, Chemistry, Hepatitis B DNA)	191
Stool sample collection	300
Colonic biopsy (CMV)	6,500
Urinalysis	200
Central Labs (Anti-therapeutic antibody, CRP) includes Collection, Preparation and Processing	402
MCS	440
Partial MCS	284
Colonic biopsy (histopathological confirmation of UC)	6,500
Biopsy; Staining and preparation of the slides including shipping and handling	600
Neurologist - Per Hour	1,000
Brain MRI with contrast, includes interpretation and report	11,000
Brain MRI without contrast, includes interpretation and report	6,000
Lumbar puncture	2,600
Cerebrospinal fluid (CSF) analysis for JCV by PCR, includes lab handling for shipment to central lab	1,687
Reconsenting Fee	932
Investigator prescreening activities (per randomized patient from prescreening log)	6,830

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Note:

- This Budget includes all study costs related to the Protocol (including but not limited to laboratory costs, patient travel expenses and site overheads), except for any other payments contained within this Attachment.
- All questions regarding study payments or the Financial arrangements should be directed to Quintiles at the address noted above during normal business hours (IST).

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ATTACHMENT C

APPROVAL LETTER

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PACE

THE ADVANTAGE OF FOCUS

CLINICAL STUDY AGREEMENT

PROTOCOL: CS2514-2017-0004

SITE: //356-005//

// DR. JAYAPRAKASH APPAJIGOL //

ENTASIS THERAPEUTICS, INC.//30-APR-2019//

VERSION: //VERSION #1//

COUNTRY : INDIA

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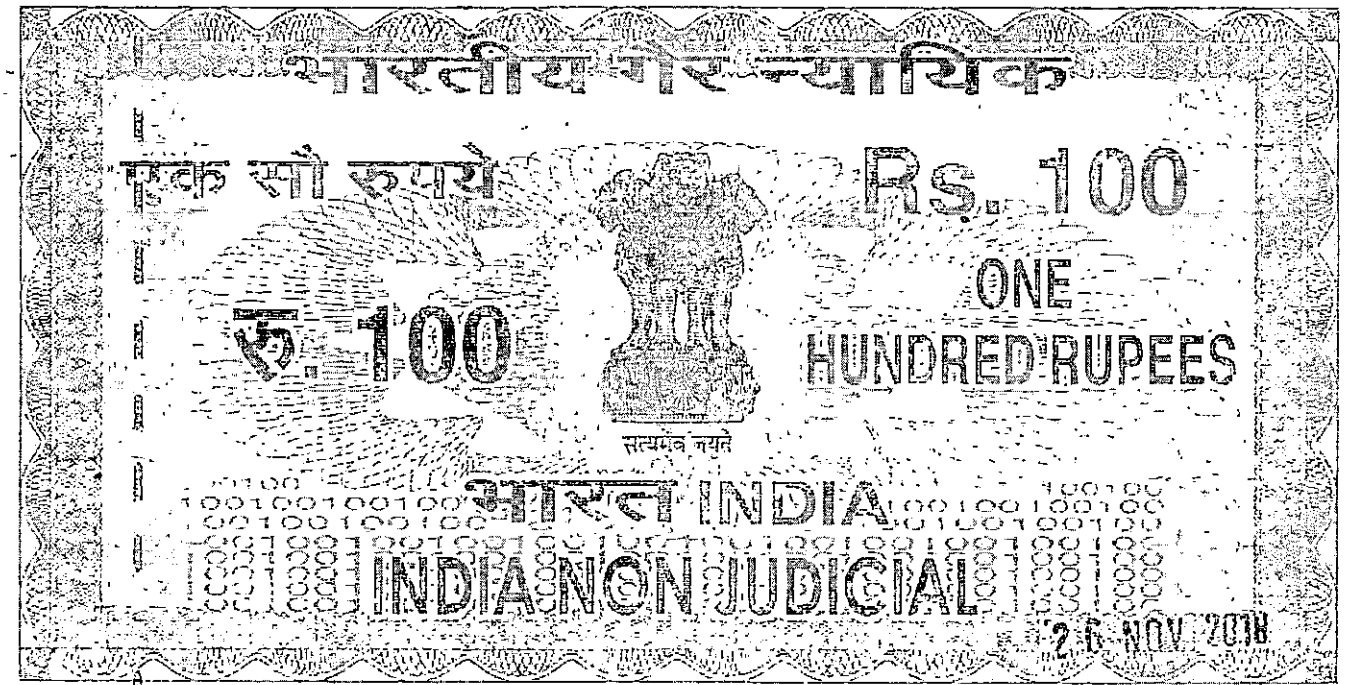

प्रतिज्ञापत्र/प्रतिज्ञापत्रा व्यतिरिक्त	
दस्ताचा प्रकार/अनुच्छेद क्रि	AGREEMENT
दस्त नोंदणी करणार आहेत का?	
नोंदणी करणार असल्यास दुय्यम निबंधक कार्यालयाचे नांव	
मिळकतीचे वर्णन	
मोबदला रक्कम	
मुद्रांक विक्रत घेणाराचे नांव	
दस्तऐवज करून देणाराचे नांव	
दस्त हाताळणारा त्याचे नांव व पत्ता	
मुद्रांक शुल्क रक्कम	26 NOV 2018
मुद्रांक बक्री नोंदवही अनु. क्रमांक/दिनांक	5404
मुद्रांक विक्रत घेणाराची सही	

ठाणे
19 NOV 2018

CLINICAL STUDY AGREEMENT

This clinical study agreement (together with Schedules and Appendices hereto, the "**Agreement**"), effective as of 30-APR-2019 (the "**Effective Date**"), is entered into by and among **Entasis Therapeutics, Inc.**, a United States Delaware corporation with an office at 35 Gatehouse Drive, Suite E0, Waltham, MA 02451 USA ("**Sponsor**"), acting through its authorized representative **Medpace Clinical Research LLC** with an office at Medpace Clinical Research LLC with an office at Office No. 817, 8th Floor, Rupa Solitaire, Building No. A-1, Sector-1, Millenium Business Park, Next to DAKC, Mahape, Navi Mumbai 400710, India ("**CRO**") and, **K.L.E.S Dr. Prabhakar Kore Hospital and Medical Research Centre**, a clinical research site with its principal office and place of business at NH Service Rd, Nehru Nagar, Belgaum, Karnataka 590010, India, ("**Institution**") and **Dr. Jayaprakash Appajigol**, with an address at K.L.E.S Dr. Prabhakar Kore Hospital and Medical Research Centre, NH Service Rd, Nehru Nagar, Belgaum, Karnataka 590010, India ("**Investigator**") and GDD Experts India Pvt. Ltd, a clinical research site with its principal office and place of business at GDD Experts India Pvt. Ltd, Ground Floor, Gulmohar Complex, Opposite Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India ("**SMO**"). Sponsor, Institution, Investigator and SMO are each sometimes referred to herein as a "**Party**" and collectively as the "**Parties**".

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WHEREAS, Sponsor is the sponsor of a multi-center clinical study of Sulbactam-ETX2514 (the "**Study Drug**"), under Protocol No. CS2514-2017-0004, titled "A Randomized, Active-Controlled Study to Evaluate the Efficacy and Safety of Intravenous Sulbactam-ETX2514 in the Treatment of Patients With Infections Caused by Acinetobacter baumannii-calcoaceticus Complex" (as it may be amended from time to time by the Sponsor, the "**Protocol**" and the performance of the Protocol at all sites shall be referred to herein as the "**Multi-Center Clinical Study**"); and

WHEREAS, Institution, Investigator and SMO possess expertise in the conduct and performance of clinical studies; and

WHEREAS, Sponsor has entered into a separate agreement with Medpace, Inc., together with its affiliate Medpace Clinical Research, LLC. CRO may, acting as an independent contractor on behalf of Sponsor, manage, monitor and coordinate the conduct of the Multi-Center Clinical Study on Sponsor's behalf; and

WHEREAS, Sponsor desires that Institution, Investigator and SMO participate in the conduct of the Multi-Center Clinical Study in accordance with the Protocol and the terms and conditions of this Agreement, and Institution and Investigator desire to participate in the conduct of the Multi-Center Clinical Study in accordance with the Protocol and the terms and conditions of this Agreement (such conduct at Institution shall be referred to herein as the "**Study**").

NOW THEREFORE, in consideration of the foregoing and the mutual covenants and promises set forth herein and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, the Parties agree as follows:

1 SCOPE OF WORK

1.1 Investigator, who is employed by or under contract with Institution, will be responsible for the conduct of the Study at Institution in strict compliance with the terms and conditions of this Agreement, any written instructions from Sponsor and/or its designee, all generally accepted standards of Good Clinical Practice, the Protocol, and with all applicable local laws and regulations governing the performance of clinical investigations. Institution represents and warrants that (a) it has consented to the conduct of the Study by Investigator at the Institution facilities located at the address set forth above; and (b) conduct of the Study at Institution does not conflict with any other obligation of Institution. Investigator and SMO will comply with the policies and procedures of Institution, including any applicable financial policies. Investigator and SMO will notify Sponsor and its designee promptly of any conflict between the terms of this Agreement and any such policy or procedure, and the parties will attempt to reach an appropriate accommodation. A copy of the Protocol has been provided to Institution and Investigator and is hereby incorporated by reference, together with any and all amendments thereto, into this Agreement.

1.2 Before the Study is initiated, Institution, Investigator and SMO will ensure that the Study is approved by the responsible ethics committee, which must be constituted in accordance with the requirements prescribed under the relevant statues and guidelines applicable in India (the "**EC**"). Institution Investigator and SMO will further ensure that the Study is subject to continuing oversight by the EC throughout the conduct of the Study. Changes or supplements to the Protocol may be made by Sponsor from time to time, upon written notice to Institution and Investigator. Institution, Investigator and SMO shall not alter or amend, and shall not permit any member of the Study Personnel to alter or amend, the Protocol in any way without the prior written consent of Sponsor. If required by applicable law, changes to the Protocol must be approved by the EC and the applicable Regulatory Authority.

1.3 Sponsor or its designee will provide the Study Drug to Institution at no cost to Institution, Investigator or SMO in amounts sufficient for the conduct of the Study as specified in the Protocol, as well as certain other Study medications, Equipment (as defined in Schedule B) and materials to be determined by Sponsor at its sole discretion (collectively, the "**Study Supplies**"). All Study Supplies are and will

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remain the sole property of Sponsor. Institution, Investigator and SMO will maintain control of the Study Supplies in accordance with applicable law, and in the manner outlined in the Protocol, this Agreement and any additional documents or written instructions provided or otherwise made available by Sponsor or its designee related to the receipt, handling, maintenance, storage, use and/or distribution of the Study Supplies. Institution Investigator and SMO will use Study Supplies solely to conduct the Study in accordance with the Protocol and that the Study Supplies are not transferred to any third parties. Institution, Investigator and SMO will be responsible to Sponsor for the Study Supplies entrusted to them and will notify Sponsor or its designee immediately if any Study Supplies are lost, damaged or destroyed.

1.4 Institution, Investigator and SMO will report adverse events experienced by subjects enrolled in the Study ("**Study Subjects**") (a) to Sponsor within twenty-four (24) hours of learning of such an event; (b) in accordance with instructions in the Protocol; and (c) pursuant to applicable law.

1.5 Institution, Investigator and SMO will enroll Study Subjects in the Study in accordance with the Protocol. Sponsor may require Institution and Investigator to discontinue subject enrollment at Institution if the total enrollment needed for the Multi-Center Clinical Study is achieved.

1.6 Investigator and SMO will be responsible for obtaining informed consent from each of the Study Subjects prior to the commencement of any Study-related procedure in accordance applicable law. The informed consent documents must be in a form approved by Sponsor and the EC ("**Consent Documents**"). Investigator and SMO will ensure that a copy of the Consent Documents signed by the Study Subject is provided to the Study Subject.

1.7 In accordance with applicable law, Sponsor plans to engage Medpace Clinical Research India Pvt., Ltd., an Indian corporation with a business address at c/o SKP Group, B-376, 3rd Floor, Nirman Vihar, New Delhi, Delhi 110092, India and place of business at Office No. 817, 8th Floor, Rupa Solitaire and Building No. A-1, Sector-1, Millenium Business Park, Mahape, Navi Mumbai 400710, Maharashtra, and an affiliate of CRO, to serve as the legal representative of Sponsor and as the legal representative of Sponsor, assist Sponsor in connection with certain obligations as required under applicable law.

2 INVESTIGATOR

2.1 Investigator will be responsible for the conduct of the Study in accordance with the terms of this Agreement and the Protocol. If, for any reason, he/she is unable to continue to serve as Investigator, Institution shall provide prompt written notice to Sponsor. If Institution and Sponsor cannot agree on a successor Investigator within thirty (30) days of receipt of such notice by Sponsor, then, Sponsor will have the right to immediately terminate the Study upon written notice to Institution, subject to Sections 8.4, 8.5 and 8.6. Institution and Investigator warrant and represent that Investigator is fully qualified to conduct the Study and to serve in the capacity of Investigator. Any sub-investigator and research staff who perform any portion of the Study ("**Study Personnel**") shall be employees of or under contract with Institution or SMO and appropriately trained and qualified to assist in the conduct of the Study. Institution, Investigator and SMO shall be responsible for Study Personnel's compliance with the terms of this Agreement and shall be jointly and severally liable for the acts of Study Personnel. Institution and Investigator represent that neither Institution nor Investigator is a U.S. citizen or resident or U.S. corporation or U.S. partnership, and that all payments Institution receives under this Agreement will be for services rendered outside the United States.

2.2 Investigator will complete and return to Sponsor or its designee (i) United States Food and Drug Administration Form 1572 Statement of Investigator or equivalent; and (ii) the financial disclosure document provided by Sponsor or its designee, which document discloses the amounts payable to Investigator and any financial interests which Investigator and/or his/her family members may have in Sponsor and/or the Study Drug. Investigator will be responsible for having all sub-investigator(s) complete and provide Sponsor or its designee with such financial disclosure forms. Such financial

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disclosure forms will be kept updated by Investigator and any sub-investigators during the Study and the updates will be provided to Sponsor or its designee, for a period of one (1) year after Study completion.

3 COMPLIANCE WITH APPLICABLE LAWS.

Institution, Investigator and SMO will assume all those responsibilities assigned under all applicable laws, rules, regulations, guidelines and standards including, without limitation, Indian Medical Council (Professional conduct, Etiquette and Ethics) Regulations, 2002, Drugs and Cosmetics Act (1940) and Drugs and Cosmetics Rules (1945), governing clinical trials, all relevant International Conference on Harmonization Good Clinical Practice ("**ICH GCP**") guidelines, Ethical Guidelines of the Indian Council of Medical Research, Indian GCP, standards and the World Medical Association Declaration of Helsinki "Ethical Principles for Medical Research Involving Human Subjects", and any other applicable laws and guidance relating to clinical trials of medicines, human rights, supply of medicines, collection and handling of human tissue and biological samples, and all applicable laws relating to the confidentiality, privacy and security of patient information.

4 CONFIDENTIAL INFORMATION

4.1 "**Confidential Information**" means all information that is (a) provided by or on behalf of Sponsor to Institution or Investigator, SMO or Study Personnel in connection with this Agreement or the Study, or (b) developed, obtained, or generated by Institution, Investigator, SMO or Study Personnel as a result of performing the Study under this Agreement (except for a Study subject's medical records). Confidential Information includes, but is not limited to, the Protocol, Study Data, results, reports from sites conducting the Multi-Center Clinical Study, all approvals and correspondence with or from the EC or other entities with oversight responsibilities for the Study, all Study correspondence, all Study Drug and other Study medication accountability forms and all CRFs: *provided, however*, that Institution and Investigator may use and/or publish Study Data solely in accordance with the Publications and Publicity Section of this Agreement. Confidential Information is the sole property of Sponsor.

4.2 Institution, Investigator and SMO shall not and shall ensure Study Personnel do not, use Confidential Information for any purposes other than to conduct the Study. Institution, Investigator and SMO will not disclose Confidential Information to any third parties other than Study Personnel and the responsible EC, who are under an agreement to be bound by the obligations of this Section 3 with respect to all Confidential Information. Institution, Investigator and SMO shall safeguard Confidential Information with the same standard of care that is used with Institution's confidential information, but in no event with less than reasonable care.

4.3 The obligations of non-disclosure and non-use under this Agreement will not apply to any portion of Confidential Information that Institution or Investigator or SMO can demonstrate by competent proof:

4.3.1 Is at the time of disclosure or later becomes publicly available through no fault or omission on the part of Institution or Investigator or SMO;

4.3.2 Is already known to Institution or Investigator or SMO at the time of disclosure and is free of any obligations of confidentiality;

4.3.3 Was obtained by Institution or Investigator or SMO from a third party which is not legally prohibited from disclosing such information; or

4.3.4 Is independently developed by Institution or Investigator or SMO without the aid, application or use of Confidential Information, as evidenced by contemporaneous written records.

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4.4 If disclosure of Confidential Information beyond that expressly authorized in this Agreement is required by applicable law, that disclosure does not constitute a breach of this Agreement so long as Institution or Investigator or SMO, as applicable, (a) notifies Sponsor in writing sufficiently prior to making such disclosure in order to permit Sponsor adequate time to seek confidential treatment of such information, (b) discloses only that Confidential Information required to comply with the legal requirement, and (c) continues to maintain the confidentiality of such Confidential Information with respect to all other third parties; *provided that*, Institution and Investigator and SMO will not be required to notify Sponsor in writing prior to making such disclosure to the extent such prior notification is prohibited by applicable law.

4.5 Both prior to and during the conduct of the Study, Investigator, SMO and Study Personnel may provide Sponsor and its designee with their personal data (as defined under applicable law) (the "**Personal Data**"). Investigator consents to the processing (including use, disclosure or transfer) of his/her Personal Data by Sponsor and its designee, and Investigator and SMO consent for the same on behalf of their respective agents and affiliates and national and foreign governmental or regulatory agencies for the following purposes (the "**Purposes**") (a) the conduct of clinical trials; (b) review by governmental or regulatory agencies, Sponsor and its designees and its and their respective agents, and affiliates; (c) satisfying legal or regulatory requirements; and (d) storage in databases for use in selecting investigators and institutions for future clinical trials. Investigator also agrees to the transfer of his/her Personal Data abroad, including to countries not having an equivalent level of protection as the country where the Study is taking place. Institution, Investigator and SMO represent and warrant that all Study Personnel have consented in writing to the processing of their Personal Data for the Purposes, including the transfer to other countries not having an equivalent level of protection as the country where the Study is taking place, and will notify Sponsor or its designee immediately in writing if such consent is withdrawn.

5 RECORDKEEPING

5.1 Institution and Investigator will collect and submit to Sponsor or its designee all data generated in the conduct of the Study including completed case report forms in the form and/or electronic medium supplied or specified by Sponsor or its designee ("**CRFs**"), X-rays, MRIs or other types of medical images, ECGs, EEGs or other types of tracings or printouts, and data summaries and other data as may be required under the Protocol (collectively, the "**Study Data**"). Institution and Investigator will ensure accurate and timely collection, recording, and submission of Study Data. Sponsor is the exclusive owner of all Study Data. Institution and Investigator will maintain complete and accurate medical records with respect to Study Subjects. All Study Subjects' medical records will be the property of Institution.

5.2 "**Biological Samples**" means blood, fluid and/or tissue samples collected from Study Subjects as may be set forth in the Protocol, and tangible materials directly or indirectly derived from such samples. Institution and Investigator will collect, retain and/or use Biological Samples solely as set forth in the Protocol and in accordance with Applicable Law. Institution and/or Investigator will provide Sponsor with quantities of Biological Samples as required by the Protocol. Sponsor may use such Biological Samples as specified in the Protocol, and as permitted in the Consent Documents and under applicable law. For the avoidance of doubt, nothing in this Section 4 limits the Institution, Investigator or Study Personnel from collecting biological samples independent of the Protocol from Study Subjects ("**Separate Samples**") as required for such Study Subjects' care or Institution's research purposes: *provided, however*, that Institution, Investigator and Study Personnel shall not (a) annotate or link Separate Samples with any information related to Sponsor, the Protocol, or the administration of, response to, or adverse events associated with, the Study Drug ("**Study Drug Information**"), except to the extent such information is necessary for Study Subject care purposes; (b) conduct any research on or using the Study Drug or the Study Drug Information, other than for the Study, without the Sponsor's prior written consent; or (c) disclose any Study Drug Information to any third party other

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than as expressly permitted in this Agreement. In no event will Sponsor be liable for any claims, losses or damages arising from or related to the collection or use of Separate Samples by Institution, Investigator or Study Personnel. Institution and Investigator individually and jointly represent that any Separate Samples shall be collected under and according to an informed consent form separate from the Consent Documents used in the Study.

5.3 Institution and Investigator shall maintain all records, data, documents or information related to the performance of the Study until the later of:

5.3.1 twenty-five (25) years following completion or early termination of the Study; and

5.3.2 the period required by Applicable Law and regulations.

5.4 At the end of such required retention period, Institution or Investigator shall not destroy any such records without first giving Sponsor sixty (60) days' prior written notice of its intent to do so and an opportunity to transfer the records to Sponsor or its designee, at Sponsor's reasonable expense. Institution will ensure that such records remain available to Sponsor and/or its designees at all times, regardless of whether the individual named as Investigator ceases to be affiliated with Institution.

5.5 Subject to the requirements of the Confidential Information section, following the end of the required retention period, Institution may retain in its possession an archival copy of Confidential Information that consists of any and all data, documents or information related to the performance of this Agreement solely to monitor its surviving obligations under this Agreement.

6 ACCESS TO RECORDS AND AUDITS

6.1 Institution will permit Sponsor and its designees to, at Institution's premises and at reasonable times, inspect progress of the Study, Study records and compliance with this Agreement. Sponsor will notify Institution prior to any inspection of the date and time of the inspection. Sponsor and its designees may review and/or request copies of data derived from the Study, and Institution or Investigator shall promptly provide such data. Study Subjects' medical records, including those maintained in electronic format, will be made available where appropriate for the purpose of source document verification and/or audit procedures. Institution and Investigator will be and will ensure that appropriate Study Personnel will be available during normal business hours and at mutually agreeable times to discuss or review Study Data and to resolve any questions relating to such data. Institution and/or Investigator will notify Sponsor and/or its designee by telephone and subsequently in written form, of any significant changes, including, but not limited to, changes in Study Personnel, Investigator, or physical location, that occur during the Study.

6.1.1. Within twenty-four (24) hours of receiving from the Drug Controller General of India or any other any governmental or regulatory body (a "**Regulatory Authority**"), a request to inspect Institution or Investigator in connection with the Study, Institution and/or Investigator shall provide written notification to Sponsor and any Sponsor designees of such inspection and shall also provide Sponsor and/or its designee with copies of any communications with a Regulatory Authority during and after such inspection. Sponsor and/or its designee(s) shall have the right to be present at any such inspections and shall have the opportunity to provide, review, and comment on any responses that may be required. Further, Institution and/or Investigator will provide Sponsor and/or its designee with copies of all materials, correspondence, statements, forms and records which Institution prepares, receives or obtains pursuant to this inspection.

7 COSTS AND PAYMENT SCHEDULE

In consideration of the proper performance of the Study by the Institution, Investigator, SMO and Study Personnel under the terms of this Agreement, Sponsor, either directly or through its designee, will pay the

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payee designated in Schedule A ("Payee") the amounts specified in Schedule A appended hereto and incorporated herein by reference. The amounts specified in Schedule A represent Institution's, Investigator's and SMO's costs of conducting the Study. Institution, Investigator and SMO accept such payment to the Payee as full consideration for services rendered and Payee will be solely responsible for making any and all payments due to Institution, Investigator, SMO and Study Personnel for their conduct of the Study. Neither Sponsor nor CRO shall have any obligation or liability whatsoever to make payments under this Agreement to any party other than Payee. All costs outlined on Schedule A shall remain firm for the duration of the Study, unless otherwise agreed to in writing by the Institution, Investigator. SMO and Sponsor. It is understood and agreed that no reimbursement will be provided by Sponsor for subjects who are randomized into the Study in violation of the Protocol, or who do not conform to the Protocol's inclusion and exclusion criteria or for whom serious deviations from the Protocol are made. The budget contained in Schedule A is inclusive of all applicable taxes. Should any tax laws require withholding, the Party legally responsible shall be liable for withholdings. Notwithstanding the foregoing, Sponsor may issue a written amendment, signed only by Sponsor, for the purpose of increasing the Study costs as described in the Schedule A. SMO provides clinical trials related services to the Institution. SMO works in compliance with the all applicable laws, rules and regulations. SMO's responsibilities under this Agreement shall include receiving and allocating payments made by the Sponsor or CRO on behalf of the Sponsor, to Institution, Investigator and/or Study Personnel, in accordance with the terms and conditions stipulated under this Agreement. CRO / Sponsor shall not be held liable for any disputes, including but not limited to financial, which may raise during the Study conduct between the Institution, Investigator and/or the SMO.

8 TERM AND TERMINATION

8.1 This Agreement shall commence as of the Effective Date and, unless terminated earlier as provided for in this section, shall continue until the completion of the Study.

8.2 Either Sponsor, Institution, Investigator or SMO (the "**Non-Breaching Party**") may terminate this Agreement for a material breach of a provision of this Agreement by another Party (the "**Breaching Party**") if the Breaching Party fails to cure the breach within thirty (30) days after receipt of written notice from the Non-Breaching Party specifying in detail the nature of the breach.

8.3 Sponsor may terminate the Study at any time upon giving thirty (30) days' advance written notice to Institution and Investigator. Further, Sponsor may terminate the Study immediately upon written notice to Institution, Investigator and SMO for the following reasons:

8.3.1 if Sponsor and Investigator mutually agree such termination is necessary to protect the safety, health or welfare of Study Subjects:

8.3.2 if a suitable replacement for the Investigator is not found, as set forth under Section 2.1;

8.3.3 if the regulatory authorization to perform the Multi-Center Clinical Study is withdrawn; or

8.3.4 if the Investigator fails to screen, recruit or a sufficient number of subjects to participate in the Study.

8.4 Sponsor, or CRO on behalf of Sponsor, will be obligated to pay Payee solely for those items set forth in the Schedule A that have been incurred prior to the date of notice of termination. Institution and Investigator shall promptly refund to Sponsor or shall cause Payee to promptly refund all unearned advance payments made by Sponsor or its designee under the Schedule A.

8.5 Upon completion or early termination of the Study:

8.5.1 this Agreement will terminate;

8.5.2 Investigator will immediately stop enrolling subjects into the Study and cease administering Study Drug and other Study medications to Study Subjects and conducting Study procedures

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on Study Subjects, to the extent consistent with the safety and welfare of the affected Study Subjects;

8.5.3 Sponsor, either directly or through its designee, will pay Payee for all reasonable costs accrued by Institution, Investigator and SMO in the performance of the Study as of the date of notice of termination, in accordance with Schedule A, including non-cancelable obligations incurred prior to the date of notice of termination;

8.5.4 in no event shall Sponsor be obligated to pay any invoices submitted after the time period for submitting final invoices set forth in Schedule A has expired;

8.5.5 Institution, Investigator and SMO will furnish to Sponsor, within thirty (30) days of the effective date of termination, all Study Data, including completed or partially completed CRFs and, if applicable, any Biological Samples;

8.5.6 In accordance with Sponsor's instructions, Institution, Investigator and SMO will return to Sponsor or, at Sponsor's option, destroy all documents, Confidential Information, and Study Supplies provided by Sponsor or its designees for the conduct of the Study, to Sponsor or its designee within thirty (30) days. If Sponsor requests that such documents, Confidential Information or supplies be destroyed, Institution, Investigator and SMO will destroy same and provide Sponsor with written certification of such destruction;

8.5.7 If applicable, Investigator and SMO will promptly submit final written reports to Sponsor as specified in the Protocol.

8.6 Upon completion of the Study, the terms of Sections 8.5.1, 8.5.2, 8.5.4 through 8.5.6 will apply as of the Study completion date.

8.7 The Sections titled Investigator, Confidential Information, Recordkeeping, Access to Records, Costs and Payment Schedule, Term and Termination, Intellectual Property, Publications and Publicity, Notices, Indemnification, Debarment, Anti-Bribery/Anti-Corruption, Independent Contractor and Miscellaneous shall each survive the termination or expiration of this Agreement.

9 INTELLECTUAL PROPERTY

Institution, Investigator and SMO jointly and severally acknowledge and agree that all inventions, discoveries, know-how, and improvements (including new uses and improvements of the Study Drug), whether or not protectable under patent, copyright or other intellectual property law, resulting from the performance of the Study, or the use of the Study Drug or the Confidential Information, made by Institution or Investigator or SMO, alone or jointly with others (collectively, with all associated intellectual property rights, the "**Inventions**") will be the sole and exclusive property of Sponsor. Institution, Investigator and SMO will and will ensure all Study Personnel will, promptly disclose to Sponsor in writing all Inventions and will assign and does assign to Sponsor all right, title and interest throughout the world to Inventions without any obligation of Sponsor to pay any royalties or other consideration to Institution or Investigator or SMO. Institution, Investigator and SMO will, and will cause Study Personnel to (a) cooperate fully in obtaining patent and other proprietary protection for any patentable or protectable Inventions all in the name of Sponsor and at Sponsor's cost and expense; and (b) execute and deliver all requested applications, assignments, and other documents and take such other measures as Sponsor or its designee reasonably requests, in order to perfect and enforce Sponsor's rights in the Inventions. Institution, Investigator and SMO represent and warrant that all Study Personnel have an obligation to assign and otherwise effectively vest in Institution and/or Investigator and/or SMO any and all rights that such Study Personnel might otherwise have in the results of their work without any obligation of Sponsor to pay any royalties or other consideration to such Study Personnel and as necessary to permit the Institution, Investigator and SMO to comply with their obligations under this Section 9.

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10 PUBLICATIONS AND PUBLICITY

10.1 It is understood that the Study is part of the Multi-Center Clinical Study. After (a) publication of the Multi-Center Clinical Study results; (b) notification by Sponsor that the Multi-Center Clinical Study submission is no longer planned; or (c) the eighteen (18) month anniversary of the completion or early termination of the Multi-Center Clinical Study, whichever occurs first. Institution and Investigator may publish the Study Data in accordance with the provisions of Section 10.1.1 below:

10.1.1 Institution and Investigator shall provide Sponsor with an advance copy of any proposed publication or oral presentation at least sixty (60) days prior to the planned date of submission or presentation (the "**Review Period**"). During the Review Period Sponsor may request in writing and Institution and Investigator agree to, (a) the deletion of any Confidential Information other than Study Data, (b) any reasonable changes requested by Sponsor, and (c) a delay of such proposed submission for an additional period, not to exceed ninety (90) days after the Review Period, in order to protect the potential patentability of any Invention described therein. Sponsor, at its election, shall be entitled to receive in any such publication an acknowledgement of its sponsorship of the Study. Institution and Investigator shall ensure that the publications acknowledge Sponsor's sponsorship of the Study and that Institution and Investigator were paid by Sponsor for the conduct of the Study.

10.2 Except to the extent required by applicable law, no Party will use the name of another Party in any form of advertising, promotion or publicity or in any press release, without the prior written consent of that Party. Institution, Investigator and SMO expressly consent to Sponsor's listing of information about the Study on publicly accessible internet sites (for example, ClinicalTrials.gov, patient recruitment sites, etc.), including the name and contact information for Institution and/or Investigator and/or SMO.

10.3 SMO shall have no rights to publish or present to any third party any information related to the Study.

11 NOTICES

All notices required under this Agreement will be in writing and be deemed to have been given when delivered by hand; sent by certified mail; or delivered by internationally recognized bonded courier as follows, *provided that* all urgent matters, such as safety reports, will be promptly communicated as specified in the Protocol, and confirmed in writing:

IF TO SPONSOR:

Entasis Therapeutics
Attention: Emily Stone
35 Gatehouse Drive, Suite EO, Waltham, MA 02451
Clinical Operations Department
With a copy to: Chief Business Officer
(at Sponsor's address above)
and
Medpace Clinical Research, LLC
Attention General Counsel
5375 Medpace Way
Cincinnati, OH 45227
and
Medpace Clinical Research India Pvt. Ltd.

CONFIDENTIAL

Dr. V.A.Kothiwale
Registrar
KLE Academy of Higher Education and Research,
(Deemed-to-be-University u/s 3 of the UGC Act,1956)
Belagavi-590 010,Karnataka

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Office No. 817, 8th floor
Rupa Solitaire
Building No. A-1, Sector-1
Millenium Business Park
Next to DAKC, Mahape
Navi Mumbai 400701

IF TO INSTITUTION:
K.L.E.S Dr. Prabhakar Kore Hospital and Medical Research Centre
NH Service Rd, Nehru Nagar,
Belgaum, Karnataka 590010, India

IF TO INVESTIGATOR:
Dr. Jayaprakash Appajigol
K.L.E.S Dr. Prabhakar Kore Hospital and Medical Research Centre
NH Service Rd, Nehru Nagar,
Belgaum, Karnataka 590010, India

IF TO SMO:
GDD Experts India Pvt. Ltd,
Ground Floor, Gulmohar Complex,
Opposite Hislop College,
Civil Lines, Nagpur-440001, Maharashtra, India

12 SIGNATURES

This Agreement may only be extended or otherwise amended by written agreement of the Parties. This Agreement, and any subsequent amendment(s), may be executed in counterparts and the counterparts, together, shall constitute a single agreement and shall become binding when any one or more counterparts hereof, individually or taken together, bears the signature of each of the Parties hereto.

13 INDEMNIFICATION

13.1 Sponsor Indemnification. Sponsor will indemnify SMO, Institution and Investigator against any third party claims, including reasonable attorney's fees for defending those claims (each, a "**Claim**") resulting from (a) the use of the Study Drug when administered in strict accordance with the Protocol and Sponsor's written instructions; (b) the negligence or willful misconduct on the part of Sponsor; or (c) Sponsor's breach of its obligations under this Agreement, except to the extent any such Claim falls within the Institution's indemnification under Section 13.2 and SMO's Indemnification under Section 13.3 below.

13.2 Institution Indemnification. Institution will indemnify Sponsor and its affiliates against any Claim resulting from (a) Institution's, Investigator's or Study Personnel's negligence or willful misconduct; or (b) Institution's or Investigator's breach of this Agreement or applicable law.

13.3 SMO Indemnification. SMO will indemnify Sponsor and its affiliates against any Claim resulting from (a) SMO's or its Study Personnel's negligence or willful misconduct; or (b) SMO's breach of this Agreement or applicable law.

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13.4 Indemnification Procedure. Each Party shall promptly notify the other Party in writing of any Claim or potential Claim for which such Party may seek indemnification, but in no event more than fifteen (15) days after the Party seeking indemnification has knowledge of the Claim or potential Claim. Failure to provide timely notice shall not negate the obligation of the other Party to indemnify except to the extent that the delay in notification resulted in additional damages or Claims to the Party seeking indemnification.

13.5 Sponsor Disclaimer. Institution, Investigator and SMO acknowledge that Sponsor will not be liable for and is not a party to warranties made by Institution, Investigator, SMO or any Study Personnel relating to the Study Drug other than any such warranties expressly provided in this Agreement.

13.6 Study Subject Injury. Without limiting Sponsor's rights under Section 13.2 and 13.4, Sponsor will reimburse a Study Subject in accordance with the terms of the Study Subject's signed Consent Documents and subject to such terms being in conformity with the applicable law, for reasonable and necessary out-of-pocket medical expenses incurred by such Study Subject for the diagnosis and treatment of injuries that are determined jointly by Investigator and Sponsor to be the direct result of (a) use of the Study Drug in accordance with the Protocol; or (b) a procedure that the Study Subject would not have undergone but for such Study Subject's participation in the Study; *provided*, that such injuries are not attributable to (i) Institution's, Investigator's, SMO's and any Study Personnel's negligence, willful misconduct or failure to adhere to the Protocol; or (ii) a pre-existing medical condition of the Study Subject or his/her underlying disease.

13.7 Sponsor Insurance. Sponsor has obtained, or will obtain prior to the start of the Study, the clinical trial insurance required by applicable law and will provide Institution or Investigator with evidence of such insurance upon written request by Institution or Investigator.

13.8 Institution Insurance. Institution will maintain medical malpractice insurance, professional liability (financial / E&O) insurance, general liability insurance and other appropriate insurance sufficient to cover Institution's, Investigator's and the Study Personnel's obligations under this Agreement. Institution will provide evidence of such insurance upon written request by Sponsor or its designee.

13.9 SMO Insurance. SMO will maintain medical malpractice insurance, professional liability (financial / E&O) insurance, general liability insurance and other appropriate insurance sufficient to cover SMO's and its Study Personnel's obligations under this Agreement. SMO will provide evidence of such insurance upon written request by Sponsor or its designee.

13.10 Limit of Liability of CRO. CRO expressly disclaims any and all liability whatsoever in connection with the Study Drug or the Protocol except to the extent that such liability arises from CRO's negligent act, omission or willful misconduct.

14 DEBARMENT

Institution, Investigator and SMO each represent that neither it/she/he, nor any Study Personnel (a) is or has been debarred by any Regulatory Authority or is restricted by applicable law from conducting clinical research; or (b) will use in any capacity the services of any person debarred by any Regulatory Authority or restricted from conducting clinical research under applicable law in connection with the conduct of the Study. During the Study and for a period of two (2) years following completion of early termination of the Study, Institution or Investigator or SMO shall immediately notify Sponsor in writing upon becoming aware of any such debarment, threat of debarment, or conviction or other matter that could result in any such debarment.

15 ANTI-BRIBERY/ANTI-CORRUPTION

In carrying out its responsibilities under this Agreement, no Party nor it nor any of its respective representatives will pay, offer or promise to pay, or authorize the payment of, any money, or give or promise to give, or authorize the giving of, any services or anything else of value, either directly or through a third party, to any

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official or employee of any governmental authority or instrumentality, or of a public international organization, or of any agency or subdivision thereof corruptly for the purpose of improperly (i) influencing any act or decision of that person in his official capacity, including a decision to fail to perform his functions with such governmental agency or instrumentality or such public international organization or such political party, (ii) inducing such person to use his/her influence with such governmental agency or instrumentality or such public international organization or such political party to affect or influence any act or decision thereof or (iii) securing any improper advantage.

16 ASSIGNMENT AND DELEGATION

This Agreement shall be binding upon and for the benefit of the Parties hereto, and their successors and permitted assigns. This Agreement, and all rights, duties and obligations hereunder, may not be assigned or delegated by Institution or Investigator or SMO without the prior express written consent of Sponsor. Any attempt made by Institution or Investigator or SMO to assign or delegate this Agreement in violation of this section shall be of no force or effect. If Sponsor provides its consent for Institution or Investigator or SMO to subcontract any of their obligations under this Agreement, Institution and/or Investigator and/ or SMO will (a) execute a written agreement with the permitted third party subcontractor which, at a minimum, provides for terms and conditions (including, but not limited to, ownership of Study Data and Inventions, obligations of confidentiality of information, etc.) that are consistent with the intent and terms of this Agreement; and (b) remain liable for the performance of such third party subcontractor. No assignment, delegation or transfer will relieve any Party of the performance of any accrued obligation that such Party may then have under this Agreement. Institution, Investigator and SMO acknowledge that Sponsor shall have the right to assign or delegate this Agreement or any portion thereof without the consent of Institution and/or Investigator and/ or SMO.

17 INDEPENDENT CONTRACTOR

The relationship of the Parties is that of independent contractors, and no employment or agency relationship shall be construed to exist between the Parties. Sponsor shall not be responsible for any employee benefits, pensions, workers' compensation, withholding or employment-related taxes relating to Institution, Investigator, SMO or any Study Personnel. No Party is authorized or empowered to act as agent for another Party for any purpose and will not, on behalf of another Party, enter into any contract, warranty or representation as to any matter.

18 FINANCIAL CHANGES

No financial adjustments shall be made because of modifications to the Protocol unless the Parties hereto amend this Agreement accordingly.

19 MISCELLANEOUS

19.1 General. This Agreement represents the entire understanding of the Parties and supersedes all prior negotiations, understandings or agreements (oral or written) among the Parties concerning the subject matter hereof. In the event of any inconsistency between this Agreement and the Protocol, the terms of the Protocol will control as to technical research and scientific matters and the terms of this Agreement shall govern for all other matters. If a provision of this Agreement is or becomes (i) illegal under any applicable law or regulation, (ii) invalid or (iii) otherwise unenforceable, such illegality, invalidity or unenforceability shall not affect the validity or enforceability of any other term or provision of this Agreement. Failure to insist upon compliance with any of the terms and conditions of this Agreement shall not constitute a general waiver or relinquishment of a Party's rights to the future enforcement of any such terms or conditions, but the same shall remain at all times in full force and

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effect, except with respect to an express written waiver relating to a particular matter for a particular period of time signed by an authorized representative of the waiving Party, as applicable.

19.2 Certain Disclosures; Transparency. Institution, Investigator and SMO acknowledge that Sponsor and its affiliates are required to abide by United States federal and state disclosure laws and certain transparency policies governing their activities, including providing reports to the government and to the public concerning financial or other relationships with healthcare providers. Institution, Investigator and SMO agree that Sponsor and its affiliates may, in their sole discretion, disclose information about the Agreement and about the Study, including relating to any transfers of value pursuant to this Agreement. Institution, Investigator and SMO agree to supply information reasonably requested by Sponsor for disclosure purposes.

19.3 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of India.

19.4 Dispute Resolution. The Parties will use their best efforts to settle all matters in dispute amicably. All disputes and differences of any kind related to this Agreement, which cannot be solved amicably by the Parties, shall be referred to arbitration as described in this Section 19.4. All disputes arising out of or in connection with this Agreement shall be finally settled under the Rules of Arbitration of the International Chamber of Commerce by one arbitrator appointed in accordance with such rules; provided, however, that during the period of arbitration on any dispute, the Parties shall continue to fulfil their obligations as set forth in this Agreement. The arbitration shall take place in Mumbai, India and shall be conducted in the English language. The award of the arbitrator shall be final and binding on all Parties. The Parties bind themselves to carry out the awards of the arbitrator.

19.5 Headings; Interpretation. This Agreement contains headings only for convenience and the headings do not constitute or form a part of this Agreement, and should not be used in the construction of this Agreement. The words "include," "includes" and "including" when used in this Agreement are deemed to be followed by the phrase "but not limited to."

[SIGNATURE PAGE FOLLOWS]

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IN WITNESS WHEREOF, this Agreement is executed as of the Effective Date by Investigator and by a duly authorized representative of each of Sponsor and Institution.

Sponsor by CRO pursuant to the [Letter of Authorization] dated [5-Feb-2019]	**Institution (K.L.E.S Dr. Prabhakar Kore Hospital and Medical Research Centre)**	**Investigator**
By (signature)	**By (signature)**	**By (signature)** 18/06/2019
Dr. Preeti Kabra	Dr. M. V. JALI MD, FRCP (London) Medical Director & Chief Eye Chief Consultant - Diabetology KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, Belagavi.	Dr. Jayaprakash Appajigol
Name (print or type)	**Name (print or type)**	**Name (print or type)**
Country Manager. India **Title**	**Title**	Principal Investigator **Title**

SMO
(GDD Experts India Pvt. Ltd)

12/Jun/19

By (signature) & date

Dr. Vinod Gyanchandani
Name (print or type)

Country Manager
Title

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SCHEDULE A

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FINAL DOCUMENT
Reviewed by: RA
PAGE

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MEDPACE
THE ADVANTAGE OF FOCUS

SCHEDULE A

ENTASIS THERAPEUTICS

PROTOCOL ID: CS2514-2017-0004

DR. JAYAPRAKASH APPAJIGOL

SITE: 356-005

SCHEDULE A VERSION: VERSION #2

COUNTRY: INDIA

CONFIDENTIAL

FINAL DOCUMENT
Reviewed by: SKS
PACE

Dr. Jayaprakash Appajigol | 356-005

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SCHEDULE A

A1 STUDY BUDGET

Sponsor, either directly or through its designee, shall make payment to the payee specified in the Payee Information Table ("Payee") under this Agreement from funds escrowed by Sponsor for services provided according to the payment schedule below. The budget contained in Schedule A is inclusive of all applicable taxes, overhead, and patient stipend or travel reimbursement, as applicable. **The amounts listed below are inclusive of 18% GST.** Payments are based on electronic case report forms ("eCRFs"), laboratory data, IVRS data or other specific data source. All amounts shown herein are calculated in INR.

A1.1 Fee for Each Evaluable Subject (inclusive of 18% GST) — INR 601,370.48

An "evaluable subject" is one who has been enrolled (randomized to treatment) and in whom all the applicable terms and conditions of the Protocol and this Agreement have been satisfied. Randomization occurs at Visit 2.

A1.2 Total Subject Budget (Estimated) (inclusive of 18% GST) — INR 1,202,740.96

The total subject budget is based on 2 subjects expected to be randomized at site.

A2 SET UP FEE &VISIT PAYMENTS

A2.1 Set up fee

2.1.1. Administrative Fee (inclusive of 18% GST) — INR 41,300

Payment will be made within forty-five (45) days of:

- Sponsor declaring Institution to be ready for Study Initiation (ie., regulatory package complete and approved to receive Study Drug);
- IRB/EC approval; and
- Sponsor's or its designee's receipt of the fully executed Agreement.

A2.2 Ongoing Payments

Payments for Study subject visits, as set forth in Table below, will be paid on a quarterly basis for the actual number of Study subjects for whom eCRFs have been completed less ten percent (10%) of each quarterly payment, which will be withheld until and paid with the final payment. Quarterly payments will be made within forty-five (45) days after the end of each quarter. The quarterly schedule may be offset from the calendar quarter.

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Table 1 - Fees for Completed Clinical Visits for Randomized Subjects

VISIT	Visit Payments	Institute Overheads (25%)	GST Amount (18%)	TOTAL FEE
Visit 1 / -48 hour to D1	INR 29,736.00	INR 7,434.00	INR 6,690.60	INR 43,860.60
Visit 2 / Day 1*	INR 39,051.20	INR 9,762.80	INR 8,786.52	INR 57,600.52
Visit 3 / Day 2	INR 35,851.20	INR 8,962.80	INR 8,066.52	INR 52,880.52
Visit 4 / Day 3	INR 36,639.20	INR 9,159.80	INR 8,243.82	INR 54,042.82
Visit 5 / Day 4*	INR 37,201.60	INR 9,300.40	INR 8,370.36	INR 54,872.36
Visit 6 / Day 5	INR 41,319.20	INR 10,329.80	INR 9,296.82	INR 60,945.82
Visit 7 / Day 6	INR 35,851.20	INR 8,962.80	INR 8,066.52	INR 52,880.52
Visit 8 / Day 7	INR 38,168.80	INR 9,542.20	INR 8,587.98	INR 56,298.98
Visit 9 / Day 8	INR 35,851.20	INR 8,962.80	INR 8,066.52	INR 52,880.52
Visit 16 / EOT	INR 40,383.20	INR 10,095.80	INR 9,086.22	INR 59,565.22
Visit 17 / EOT + 7	INR 18,828.00	INR 4,707.00	INR 4,236.30	INR 27,771.30
Visit 18 / EOT + 14	INR 18,828.00	INR 4,707.00	INR 4,236.30	INR 27,771.30
TOTAL PER PATIENT	**INR 407,708.80**	**INR 101,927.20**	**INR 91,734.48**	**INR 601,370.48**
Total number of patients (Minimum)	2	2	2	2
TOTAL FOR ALL PATIENTS	**INR 815,417.60**	**INR 203,854.40**	**INR 183,468.96**	**INR 1,202,740.96**
Days 9-14 (per day)	INR 35,851.20	INR 8,962.80	INR 8,066.52	INR 52,880.52
LFU (Day 28, on-site)	INR 18,828.00	INR 4,707.00	INR 4,236.30	INR 27,771.30
LFU (Day 28, telephone)	INR 6,020.00	INR 1,505.00	INR 1,354.50	INR 8,879.50
Early Termination	INR 19,683.20	INR 4,920.80	INR 4,428.72	INR 29,032.72

* Includes costs for single PK * It also includes the subject travel reimbursement of 1,000 INR per visit and is to be reimoursed to subjects on actuals
*Applicable visit fees include site's cost of all IV consumables.

A2.3 Screen Failures

Table 2 Screen Failures

VISIT OF FAILURE	SITE AMOUNT	25% OVERHEAD	18% GST AMOUNT	TOTAL COST
Rapid Test Screening Failure* - Negative result	INR 7,224.80	INR 1,806.20	INR 1,625.58	INR 10,656.58
Screening Visit - failure after Screening visit completed	INR 24,507.20	INR 6,126.80	INR 5,514.12	INR 36,148.12

Payment for screen failures will be made based on the corresponding visit(s) eCRF completed with the next scheduled payment owed to the Payee.

* Rapid screening of respiratory samples utilizing the BioFire FilmArray® Pneumonia Panel should be conducted for patients with a definite or probable diagnosis of HABP/VABP that also meet the protocol inclusion and exclusion criteria based on the clinical information available at that time.

A2.4 Final Payment

Final payment for all services performed under this Agreement will be paid to Payee by Sponsor either directly or through its designee after:

- Final resolution of all queries;
- Upon final acceptance of all eCRFs;
- The receipt and approval of any outstanding regulatory documents as required by Sponsor;
- The return of all unused Study Drug, Study supplies (including any equipment provided by Sponsor) and Confidential Information to Sponsor; and
- Upon completion of all other applicable conditions set forth in the Agreement.

A2.5 Unscheduled Visit (inclusive of 18% GST) — INR 12,678

Payable with final payment. Unscheduled Visit must be entered into EDC prior to database lock and visit must occur after randomization. Unscheduled Visit will not be payable if it occurs on the same date as another visit.

A3.4 Archiving Fee (inclusive of 18% GST) — INR 76,700

One-time fee, payable with final payment for a period of 25 years.

A3 INVOICEABLE ITEMS

Payment will be made within forty-five (45) days of receipt of invoice and supporting documentation if applicable and requested.

A3.1 Additional Procedures (inclusive of 18% GST)

Payment will be made for procedures listed below if required by the protocol and not considered as standard of care.

Table 3 – Unlisted Procedures

FEES	COST
X-ray	INR 708
MRI Scan	INR 6,490
CT Scan	INR 9,440
Intense PK	INR 4,909 per Day 1 & Day 4
ICU Hospitalization Fee	INR 5,900 per Day
Non-ICU Hospitalization Fee	INR 4,130 per Day

A3.2 Additional Study-necessitated Fees

Payee will be reimbursed at actual cost for any other unforeseen but reasonable procedures or costs necessitated by the Study or Protocol (and any amendments thereto) and pre-approved by Sponsor or its designee.

A3.3 Nominal equipment

Institution may be provided during the course of the Study small items of equipment necessitated by the Study or Protocol and pre-approved by Sponsor or its designee.

A4 SPONSOR RIGHTS

Sponsor reserves the right to suspend payments due to Payee, if Principal Investigator and/or Institution do not complete data entry, query resolutions, and electronic signatures on eCRFs and/or provide regulatory documents to Sponsor or its designee within timelines defined by the project team. Payments will resume once the missing or incomplete information is resolved.

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A5 SPONSOR INVOICING

All payment inquiries and invoices submitted shall include the Protocol number and Principal Investigator name and be sent to the following Sponsor's designee:

Email: siteinvoices@medpace.com
Phone: 513-579-9911

Medpace Clinical Research, LLC
Attn: Clinical Operations Site Payments
5375 Medpace Way
Cincinnati, Ohio 45227

All invoices must be submitted to Sponsor's designee within ninety (90) days of occurrence or up to thirty (30) days after receipt of the final payment.

A6 PAYEE INFORMATION

All payments made by Sponsor, either directly or through its designee, as set forth herein shall be payable solely to Payee at the address set forth below. Any such payments which are due to any other party performing services in connection with the Study shall be a matter solely between Payee and such party.

Table 4 - For sites receiving payment by foreign wire transfer

PAYEE INFORMATION	
Beneficiary Name	GDD experts (India) Pvt Ltd.
Payee Mailing Address	GDD Experts India Pvt. Ltd Ground Floor, Gulmohar Complex, Opposite Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India
Contact Name	Dr. Vinod Gyanchandani
Email Address	vgyanchandani@gddexperts.com
Bank	AXIS BANK LTD
Account №	910020034162231
BIC Code/Swift Code	AXISINBB046
IFSC Code (India)	UTIB0000048
GST ID#**	27AADCG0363Q1ZA
PAN No.	AADCG0363Q

**Requested for Medpace Accounting tracking purposes only

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SCHEDULE B

EQUIPMENT USE, HANDLING, OWNERSHIP & DISPOSITION

Sponsor or its designee may provide Institution with certain equipment to be used solely in connection with performance of the Study, including but not limited to the items listed in Table 1 below (the "**Equipment**"). Institution, Investigator and SMO will additionally comply with the terms set forth in this Schedule B in connection with all Equipment entrusted to them.

Table 1:

Item:	**Quantity:**	**Estimated Value (INR):**
Infusion pump	3	566,247 (188,749/ piece)
Computer	1	139,918
Printer	1	34,979
BioFire Film Array Device Software	1	1,539,090
BioFire pouches (kit of 6 pouches)	Up to 5 kit	409,255 (81,851 / kit)
BioFire Film Array Device Software	1	175,000

A-1: Facilities; Use; Restrictions.

Adequate Facilities and Access. Institution, Investigator and SMO will ensure that: (i) all Equipment is diligently kept in a safe and secure location compliant with the Requirements (defined below) and industry standard practices; and (ii) Sponsor and Sponsor's designees have sufficient access to such location(s) as reasonably necessary for installing, auditing, providing training for, maintaining, reviewing and/or repairing all Equipment. Institution, Investigator and SMO will inspect all Equipment at the time of delivery and at reasonable intervals throughout the Study and will immediately, upon becoming aware, notify Sponsor or its designee of any shortage or error in delivery, loss of, damage to, defects in, expiration of, malfunctioning of or other similar issues related to the Equipment (each a "**Defect**"). Institution, Investigator and SMO will not use any Equipment containing any Defect unless Sponsor or Sponsor's designee consents to such use in writing, in advance. Further, Institution, Investigator and SMO will not attempt to repair or otherwise correct any Defect without Sponsor's or its designee's prior written consent and, in any event, will comply with Sponsor's and its designees' written instructions regarding repairing or otherwise addressing any Defect, including without limitation, reasonably assisting Sponsor and Sponsor's designees with exercising any warranty claim.

A-2: Use and Handling of Equipment; Publicity.

Unless Sponsor or its designee provides prior, written consent, Institution, Investigator and SMO will not:

- use Equipment for any purpose other than performance of the Study;
- permit any third-party access to or use of the Equipment or non-public information pertaining to Equipment, except, for authorized Study Personnel as reasonably necessary to perform the Study;
- use or handle the Equipment in a manner that is inconsistent with the Requirements. For purposes of this Schedule B, "**Requirements**" means collectively (i) applicable law; (ii) the Protocol; (iii) written

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instructions by or behalf of the Equipment manufacturer, Sponsor or their respective designees, including without limitation, all applicable user's manuals, instructions for use, product labels, package inserts, and similar; and (iv) applicable license terms and restrictions:

- will not modify, copy, reverse engineer, disassemble or otherwise alter the Equipment in any way.
- will not install any components or software.

Upon Sponsor or its designee's request, Institution, Investigator and SMO will, and will ensure relevant Study Personnel will complete any training offered by or on behalf of Sponsor regarding use or handling of Equipment. Institution, Investigator and SMO agree that each will not name or otherwise refer to Equipment or any Equipment manufacturer in any advertising, promotional material or public announcement without first obtaining the Equipment Manufacturer's consent. Further, upon Sponsor's request, Institution and/or Investigator and/or SMO will remove any references to Equipment and/or the Equipment manufacturer in any publication of the Study results made pursuant to this Agreement.

A-3: Ownership; Responsibility.

Unless expressly agreed otherwise by Sponsor in writing, Equipment remains at all times the property of Sponsor or a third party. Equipment must, at Sponsor's direction and expense, be returned to Sponsor or its designee within five (5) days of (i) Sponsor or its designee's request; or (ii) expiration or the earlier termination of this Agreement. Institution and/or Investigator and/or SMO agree to return the Equipment in substantially the same condition as when received by Institution and/or Investigator and/or SMO. Institution and SMO are responsible to cover (a) any loss or destruction to Equipment while in Institution's, Investigator's and SMO's care, which exceeds ordinary wear and tear and/or lacks a reasonable causal relationship to proper performance of the Study; and (b) any damages resulting from Institution's, Investigator's, SMO's or Study Personnel's (1) negligence; or (2) use or handling of Equipment in breach of this Agreement. Sponsor has no liability for damages of any sort, including but not limited to personal injury or property damage, resulting from the use of Equipment by Institution and/or Investigator and/or SMO and/or Study Personnel.

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