KLE ACADEMY OF HIGHER EDUCATION AND RESEARCH
(Formerly known as KLE University)
(Deemed-to-be-University established u/s 3 of the UGC Act, 1956)
Accredited 'A' Grade by NAAC (2nd Cycle) Placed in Category 'A' by MHRD (GoI)
JNMC Campus, Nehru Nagar, Belagavi-590 010, Karnataka State, India
☎: 0831-2444444 FAX: 0831-2493777 Web: http://www.kledeemeduniversity.edu.in E-mail: info@kledeemeduniversity.edu.in

3.7.2:Presence of functional MoUs/linkages with Institutions/ industries in India and abroad for academic, clinical training / internship, on-the-job training, project work, student / faculty exchange, collaborative research programmes etc., during the last five years.

3.7.2.1. Number of functional MoUs / linkages for faculty exchange, student exchange, academics, clinical training, internship, on-the-job training, project work, collaborative research programmes etc., during the last five years.

HEI Input : 238

Provide e-copies of MoU along with dates of starting and completion year-wise signed by both parties

Answer:
The e-copies of MoU along with dates of starting and completion year-wise signed by both parties has been provided

1. B.V.V.S.'s S. N. Medical College, Bagalkot, Karnataka
2. CSIR's Ayurgenomics Unit-TRISUTRA IGIB, DELHI and Shri BMK Ayurveda Mahavidyalaya Belagavi
3. Govindram Seksaria Science College Geology department, Belgaum, Karnataka and Shri BMK Ayurveda Mahavidyalaya Belagavi
4. Interactive Research School for Health Affairs,IRSHA Bharati Vidyapeeth Deemed University, Pune, Maharshtra
5. Elegant Drugs Pvt. Ltd. and KLE College of Pharmacy Hubba1li
6. Prajna Biosciences Pvt. Ltd. BVB College of Engineering and Technology, and KLE College of Pharmacy Hubballi
7. Watson Pharma Pvt Ltd.- Lotus Labs Pvt Ltd. Jasma Bhanvan Road, Opp. Guru Nanak Bhavan, Vasanth Nagar, Bangalore-560052
8. Eli Lilly and Company India Ltd, Plot No 92, Sector 32,Gurgoan-1220001 -Indianapolis, Indiana, United States
9. Kowa Research Institute. Lnc,Quintiles Research (Indla) Private Limited, having a place of business at B 10'1-106, Shapath lV, Opposite Karnavati Club, Sarkhej Gandhinagar Road,, Ahmedabad 380051, Gujarat, India (""Quintiles""),"
10. Amgen Technology,18, Dynasty Business park,Level 4, A wing, A K Road, Andheri, Mumbai- 400059-
11. Sun Pharma Advanced Research companv Ltd,SPARC Ltd,Akota Road, Vadodara, Mumbai-
12. Reliance Life Sciences pvt Ltd , Belapur Road , Navi Mumbai-400701
13. Intas Pharmaceuticals-317 Xinluo St, Lixia District, Jinan, Shandong, China, 250101- Veeda Clinical Research Pvt Ltd. Ahemadabad

Dr V. A. Kothiwale
Registrar
REGISTRAR
KLE Academy of Higher Education and Research, BELAGAVI

KLE Academy of Higher Education and Research
Jawaharlal Nehru Medical College, Belagavi
Women's and Children's Health Research Unit

Ref No. MDC/JNMC/2020-21/ **Date:28.01.2021**

TO WHOMSOEVER IT MAY CONCERN

Women's and Children's Health Research Unit, Jawaharlal Nehru Medical College, KLE Academy of Higher Education and Research, Belagavi has conducted a research project titled – **"Evaluation of the introduction of a novel device in the management of hypertension and shock in pregnancy in low-resource settings"** in collaboration with King's College, London co-funded by UK Medical Research Council and Department of Biotechnology, Govt. of India.

Project Period: July 2015 to March 2018

National Collaborators: S N Medical College, Bagalkot, Karnataka

Dr Shivaprasad S Goudar
Professor of Physiology, J N Medical College &
Director-Research, KLE Academy of Higher Education and Research
(Deemed-to-be-University)
Nehru Nagar, Belagavi-590010
Mobile: +91-94481 26371
Email: sgoudar@jnmc.edu

J.N. Medical College, BELAGAVI

Address for Correspondence:
KLE Academy of Higher Education and Research, J.N. Medical College,
Nehru Nagar, Belagavi-590 010, Karnataka
Phone: +91-831-2474200 / +91 831 244 4190 Fax: +91-831-2472891

ATTESTED
Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

RESEARCH SUB AGREEMENT

This Research Sub Agreement is made and executed on 13th July of 2020 by and between

KLE Academy of Higher Education & Research
Women's and Children's Health Research Unit
Jawaharlal Nehru Medical College,
Nehru Nagar, Belagavi.
Represented by the Principal
Dr N. S. Mahantshetti

Hereinafter referred to as "JNMC"

AND

S Nijalingappa Medical College
Bagalkot,
Represented by its Principal
Dr Ashok Mallapur

(Hereinafter referred to as "SNMC")

Eunice Kennedy Shriver National Institutes of Child Health
and Human Development
Global Network for Women's and Children's Health Research

(Hereinafter referred to as "Sponsor").

Title : "**The A-PLUS Study on Infection**"

Award Title: This Community-based Trial Contract (the "Contract"), effective as of July 13, 2020 (the "Effective Date") is by and between TJU / GLOBAL NETWORK and Jawaharlal Nehru Medical College located at Belgaum 590010 in Karnataka, India ("JNMC"), represented by its employee Dr Shivaprasad Goudar, MD (the "Principal Investigator").

Prime Award: PTE Federal Award No - 5UG1HD076457-08,
Sub-award No: - 080-70000-S22902

Principal Investigator Name : Dr Shivaprasad S Goudar (JNMC)
Facility Director Name : Dr Ashalata Mallapur (SNMC)

Preamble:

WHEREAS, JNMC and Sponsor entered into an agreement on 13 July 2020, attached hereto (Attachment A) and incorporated by this reference, wherein JNMC was to provide certain services to Sponsor for **"Prevention of maternal and neonatal death/infections with a single oral dose of azithromycin in women in labor (in low- and middle-income countries):** titled as **The A-PLUS Study on**

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, Belagavi

J.N.Medical College, BELAGAVI.

Infection" in Bagalkot sub-site. India.

FURTHER SNMC will participate in the conduct of the project and agrees to abide by all the terms and conditions of the Sponsor. Pursuant to the Protocol, SNMC agrees to provide data entry, data management, and data quality control services and to dedicate an employee to serve as a Co-Investigator for the Community-based Trial.

WHEREAS, the Agreement is for work approved by Sponsor as a portion of the statement of work shown in Attachment A & Attachment B;

NOW, THEREFORE, the parties agree that the foregoing statements of fact are true and correct and are incorporated herein by this reference. In consideration of the covenants and conditions contained in this Agreement ("the Agreement"), and other good and valuable consideration, the adequacy and receipt of which are acknowledged, JNMC and SNMC agree as follows:

Definitions:

7. "JNMC" means the Jawaharlal Nehru Medical College, which has its principal office in Belgaum, India
8. TJU / GLOBAL NETWORK
9. "SNMC" means S N Medical College, which has its principal office in Bagalkot, India,

Article I. Scope of Work

SNMC, as a Sub-Contractor of JNMC, agrees to provide all the necessary qualified personnel, equipment, materials (except as otherwise may be provided herein), and facilities to perform the work as described in its proposal, which by this reference is incorporated into this Agreement , Attachment A & Attachment B.

JNMC shall provide the upgraded equipment and material to SNMC for performance of the said project as and when required.

Article II. Period of Performance

The period of this Agreement shall be from June 1, 2020 to May 31, 2021 unless extended by written amendment to this Agreement.

Article III. Consideration

SNMC shall deploy its qualified personnel for accomplishment of the said project. The salaries and other expenses shall be credited directly to the personal account of the employees. SNMC shall provide the details of bank accounts, salary statement and invoices for any incidental expenses incurred by SNMC. JNMC shall reimburse the incidental expenses unconnected with the Prime Award, if any, incurred by SNMC, through cheque/DD drawn in favour of "The Principal, SNMC. SNMC is not entitled to 8% of Indirects' received by the Sponsor, due to amendments to the FCRA Regulations.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Article IV. Authorized Representatives

The authorized representatives of JNMC and SNMC for technical and administrative matters shall be:

S N Medical College, Bagalkot	**J N Medical College, Belgaum**
Technical Representative:	***Technical Representative:***
Dr Ashalata Mallapur,	Dr Shivaprasad S Goudar
Administrative Representative:	***Administrative Representative:***
Dr Ashok Mallapur	Dr.N S Mahantshetti
Dean/Principal	Principal

Article V. Reports

Final Progress Report - A Final Progress Report shall be submitted to the JNMC Technical Representative within sixty (60) days of the close of the final project period for inclusion in the Principal Investigator's Final Progress Report.

Article VI. General Provisions

The work to be performed under this Agreement is being supported by the Sponsor under Agreement Attachment B. Therefore, wherever applicable, the rules and regulations governing the award to JNMC are by this reference hereby incorporated into this Agreement, including, but not limited to, provisions governing care and treatment of laboratory animals, civil rights and equal employment opportunity, protection of human subjects, patents and inventions , publications and rights in data.

Article VII. Additional General Provisions

The following general provisions shall apply to this Agreement:

A. Allowable Costs

Allowable costs shall be determined by JNMC in accordance with cost principles generally accepted by, or required to be used by, similar institutions or organizations, that are in effect as of the effective date of this Agreement.

B. Billing

JNMC shall reimburse the SNMC 's payment within forty (40) days after receipt of an acceptable invoice provided in accordance with the terms and conditions of this Agreement.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

The performance of JNMC of any of its obligations under this Agreement shall be subject to and contingent upon the availability of funds, and the obligation of funds by the prime funding agency (Sponsor), or otherwise lawfully expendable for the purposes of this Agreement for the current and future periods. JNMC shall give notice to SNMC of the non-availability of such funds when JNMC has knowledge of such fact. Upon receipt of such notice by SNMC, the employees of SNMC shall be entitled to payment only for those services performed and expenses incurred prior to the date notice is received.

C. Equipment

JNMC and SNMC agree that if SNMC purchases permanent equipment under this Agreement, title to such equipment will vest in the JNMC under the same conditions as apply under JNMC's grant with the Sponsor and that JNMC shall have the same rights to require transfer of equipment as the Sponsor has.

Further if JNMC provides any equipment to SNMC for implementation of the present agreement, the title to such equipment shall vest in SNMC exclusively and SNMC shall not transfer such equipment to JNMC upon accomplishment of the project.

D. Indemnification

Each party hereby assumes any and all risk of personal injury and property damage attributable to the negligent acts or omissions of that party and the officers, employees and agents thereof. SNMC will assure that persons subcontracting with or otherwise acting or engaged to act at the instance of SNMC in furtherance of SNMC fulfilling its obligations under this Agreement will assume such risk with respect to the willful or negligent acts or omissions of their personnel. SNMC shall provide professional liability coverage for its employees discharging services as per the provisions of this contract and accident insurance coverage for all equipment/material procured for conducting the trial as specified in Attachment B.

E. Amendments

Any amendments, including renewals, alterations or modifications to the Agreement must be signed by the signatories to this Agreement.

F. Governance

The validity, construction and effect of this Agreement shall be governed by the prevailing laws. In the event either party is required to obtain from any governmental authority any permit, license or authorization as a prerequisite to perform its obligations under this Agreement, the cost shall be borne by the party required to obtain such permit, license or authorization.

SNMC shall allow access to all documents, papers, letters or other material subject

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

to the provisions of this Contract, and made or received by SNMC in conjunction with this Agreement to JNMC or its representatives, the regulatory authorities or the representatives of the sponsor as specified in Attachment B. Refusal by SNMC to allow such access shall be grounds for cancellation of this Agreement by JNMC.

SNMC may not, without the advance written approval of JNMC, assign any right or delegate any duties under this Agreement nor may it transfer, pledge, surrender or otherwise encumber or dispose of its interest in any portion of this Agreement

It is understood and agreed that nothing contained in this Agreement is intended, or should be construed, as creating or establishing the relationship of partners between the parties, or as constituting SNMC as the agent or representative of JNMC for any purpose in any manner whatsoever. SNMC is not authorized to bind JNMC to any contracts or other obligations. SNMC shall not expressly or impliedly represent to any party that University of British Columbia and JNMC are partners or that JNMC is the agent or representative of TJU / GLOBAL NETWORK for any purpose or in any manner whatsoever.

G. Termination

JNMC or SNMC may terminate this Agreement upon thirty (30) days written notice to the other party. However, in the event that the Sponsor terminates the Agreement with JNMC prior to the period end date, this Agreement will be immediately terminated. In the event of termination JNMC will pay for costs incurred and non-cancelable commitments through the date of termination, contingent upon JNMC having received sufficient funds from Sponsor. SNMC will furnish all necessary reports of research completed or in progress through the date of termination.

H. Publications

Any publications resulting from this Agreement shall be governed by the policies laid out in Attachment B.

III. Arbitration

If any dispute arises in between JNMC and SNMC the same should be referred to Chancellor, KLE University and Chairman, KLE Society, Belgaum and The Chairman, Basaveshwar Veerashaiva Vidyavardhaka Sangha, Bagalkot and the decision of the Arbitrators shall be final and the same shall be binding on the both the parties.

SNMC certifies that to the best of its knowledge and belief that it and its principals will abide by the payment Standard Operating Procedures in Attachment A and Attachment B

This Contract includes the following Appendices (incorporated herein):
Attachment A: Prime Award Title no: 5UG1HD076457-08 for A-PLUS Study
Attachment B: Protocol Version Number:1.4.1
Attachment C: Budget Sheet for 12 months Version 1.4.1

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research BELAGAVI

J N Medical College BELAGAVI
WOMEN'S AND CHILDREN'S HEALTH RESEARCH UNIT - JNMC

IN WITNESS WHEREOF, JNMC and SNMC have executed and delivered this agreement by and through their duly authorized representatives below

Jawaharlal Medical College (JNMC)

By:

Name: Dr N S Mahantshetti

Title: Principal

Date: 13/07/2020

S N Medical College (SNMC)

By:

Name: Dr Ashok Mallapur

Title: Dean/Principal

Date:

Principal Investigator

By:

Name: Dr Shivaprasad S Goudar

Title: Professor Department of PHYSIOLOGY

Date: 13/07/2020

By:

Name: Dr Ashalata Mallapur

Title: Professor and Head , Department of OBGYN

Date:

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

RESEARCH SUB AGREEMENT

This Research Sub Agreement is made and executed on this the 7th day of April 2020 by and between

KLE Academy of Higher Education & Research
Women's and Children's Health Research Unit
Jawaharlal Nehru Medical College,
Nehru Nagar, Belagavi.
Represented by the Principal
Dr N. S. Mahantshetti

Hereinafter referred to as "JNMC"

AND

Shri B M Patil Medical College
Bijapur,
Represented by its Principal
Mr Aravind. V. Patil

(Hereinafter referred to as "BLDE")

Eunice Kennedy Shriver National Institutes of Child Health
and Human Development
Global Network for Women's and Children's Health Research

(Hereinafter referred to as "Sponsor").

Award Title: This Community-based Trial Contract (the "Contract"), effective as of April 07, 2020 (the "Effective Date") is by and between JHPIEGO CORPORATION (Jhipiego) and Jawaharlal Nehru Medical College located at Belgaum 590010 in Karnataka, India ("JNMC"), represented by its employee Dr Shivaprasad Goudar, MD (the "Principal Investigator").

Federal Award Number: NIH Award No: UH3CA189923,
Jhpiego Document No: 20-SBA-094

Principal Investigator Name: Dr Shivaprasad S Goudar (JNMC)
Facility Director Name: Dr Shailaja Bidari (BLDE)

WHEREAS, JNMC and Sponsor entered into an agreement on April 07, 2020, attached hereto (Attachment A) and incorporated by this reference, wherein JNMC was to provide certain services to Sponsor for the "**CRYOPOP STUDY**"

WHEREAS, JNMC and BLDE wish to enter into a subcontract wherein BLDE will provide certain services to JNMC in JNMC's performance of the contract with JHPIEGO CORPORATION (Jhipiego);

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

WHEREAS, BLDE agrees to abide by all of the terms and conditions of the Sponsor- National Institutes of Health and National Cancer Institute agreement;

WHEREAS, the Agreement is for work approved by Sponsor as a portion of the statement of work shown in Attachment A & Attachment B;

NOW, THEREFORE, the parties agree that the foregoing statements of fact are true and correct and are incorporated herein by this reference. In consideration of the covenants and conditions contained in this Agreement ("the Agreement"), and other good and valuable consideration, the adequacy and receipt of which are acknowledged, JNMC and BLDE agree as follows:

Definitions:

1. "JNMC" means the Jawaharlal Nehru Medical College, which has its principal office in Belgaum, India
2. "Jhpiego" Corporation, Maryland corporation affiliated with the Johns Hopkins University
3. "BLDE" means Shri B M Patil Medical College, which has its principal office in Bijapur, India, and which pursuant to the Protocol, agrees to provide data entry, data management, and data quality control services and to dedicate an employee to serve as a Co-Investigator (as defined below) for the Community-based Trial.

Article I. Scope of Work

BLDE, as a Sub-Contractor of JNMC, agrees to provide all the necessary qualified personnel, equipment, materials (except as otherwise may be provided herein), and facilities to perform the work as described in its proposal, which by this reference is incorporated into this Agreement , Attachment A & Attachment B.

Article II. Period of Performance

The period of this Agreement shall be from May 1, 2020 to April 30, 2021 unless extended by written amendment to this Agreement.

Article III. Consideration

BLDE shall deploy its qualified personnel for accomplishment of the said project. The salaries and other expenses shall be credited directly to the personal account of the employees. BLDE shall provide the details of bank accounts, salary statement and invoices for any incidental expenses incurred by BLDE. JNMC shall reimburse the incidental expenses unconnected with the Prime Award, if any, incurred by BLDE, through cheque/DD drawn in favour of "The Principal, BLDE. BLDE is not entitled to 8% of Indirects' received by the Sponsor, due to amendments to the FCRA Regulations.

WOMEN'S AND CHILDREN'S HEALTH RESEARCH UNIT - JNMC
J.N.Medical College, BELAGAVI

KAHER BELAGAVI MEDICAL COLLEGE

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

ArticleIV. Authorized Representatives

The authorized representatives of JNMC and BLDE for technical and administrative matters shall be:

Shri B M Patil Medical College, Bijapur

Technical Representative:
Dr Shailaja Bidari,

Administrative Representative:
Dr Aravind V Patil
Principal

J N Medical College, Belgaum

Technical Representative:
Dr Anita Dalal

Administrative Representative:
Dr.N S Mahantshetti
Principal

Article V. Reports

Final Progress Report - A Final Progress Report shall be submitted to the JNMC Technical Representative within sixty (60) days of the close of the final project period for inclusion in the Principal Investigator's Final Progress Report.

Article VI. General Provisions

The work to be performed under this Agreement is being supported by the Sponsor under Agreement Attachment B. Therefore, wherever applicable, the rules and regulations governing the award to JNMC are by this reference hereby incorporated into this Agreement, including, but not limited to, provisions governing care and treatment of laboratory animals, civil rights and equal employment opportunity, protection of human subjects, patents and inventions , publications and rights in data.

Article VII. Additional General Provisions

The following general provisions shall apply to this Agreement:

A. Allowable Costs

Allowable costs shall be determined by JNMC in accordance with cost principles generally accepted by, or required to be used by, similar institutions or organizations, that are in effect as of the effective date of this Agreement.

B. Billing

JNMC shall reimburse the BLDE 's payment within forty (40) days after receipt of an acceptable invoice provided in accordance with the terms and conditions of this Agreement.

The performance of JNMC of any of its obligations under this Agreement shall be

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

J.N.Medical College, BELAGAVI

subject to and contingent upon the availability of funds, and the obligation of funds by the prime funding agency (Sponsor), or otherwise lawfully expendable for the purposes of this Agreement for the current and future periods. JNMC shall give notice to BLDE of the non-availability of such funds when JNMC has knowledge of such fact. Upon receipt of such notice by BLDE, the employees of BLDE shall be entitled to payment only for those services performed and expenses incurred prior to the date notice is received.

C. Equipment

JNMC and BLDE agree that if BLDE purchases permanent equipment under this Agreement, title to such equipment will vest in the JNMC under the same conditions as apply under JNMC's grant with the Sponsor and that JNMC shall have the same rights to require transfer of equipment as the Sponsor has.

Further if JNMC provides any equipment to BLDE for implementation of the present agreement, the title to such equipment shall vest in BLDE exclusively and BLDE shall not transfer such equipment to JNMC upon accomplishment of the project.

D. Indemnification

Each party hereby assumes any and all risk of personal injury and property damage attributable to the negligent acts or omissions of that party and the officers, employees and agents thereof. BLDE will assure that persons subcontracting with or otherwise acting or engaged to act at the instance of BLDE in furtherance of BLDE fulfilling its obligations under this Agreement will assume such risk with respect to the willful or negligent acts or omissions of their personnel. BLDE shall provide professional liability coverage for its employees discharging services as per the provisions of this contract and accident insurance coverage for all equipment/material procured for conducting the trial as specified in Attachment B.

E. Amendments

Any amendments, including renewals, alterations or modifications to the Agreement must be signed by the signatories to this Agreement.

G. Governance

The validity, construction and effect of this Agreement shall be governed by the prevailing laws. In the event either party is required to obtain from any governmental authority any permit, license or authorization as a prerequisite to perform its obligations under this Agreement, the cost shall be borne by the party required to obtain such permit, license or authorization.

BLDE shall allow access to all documents, papers, letters or other material subject to the provisions of this Contract, and made or received by BLDE in conjunction with this Agreement to JNMC or its

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

representatives, the regulatory authorities or the representatives of the sponsor as specified in Attachment B. Refusal by BLDE to allow such access shall be grounds for cancellation of this Agreement by JNMC.

BLDE may not, without the advance written approval of JNMC, assign any right or delegate any duties under this Agreement nor may it transfer, pledge, surrender or otherwise encumber or dispose of its interest in any portion of this Agreement

It is understood and agreed that nothing contained in this Agreement is intended, or should be construed, as creating or establishing the relationship of partners between the parties, or as constituting BLDE as the agent or representative of JNMC for any purpose in any manner whatsoever. BLDE is not authorized to bind JNMC to any contracts or other obligations. BLDE shall not expressly or impliedly represent to any party that University of British Columbia and JNMC are partners or that JNMC is the agent or representative of JHPIEGO CORPORATION (Jhipiego) for any purpose or in any manner whatsoever.

H. Termination

JNMC or BLDE may terminate this Agreement upon thirty (30) days written notice to the other party. However, in the event that the Sponsor terminates the Agreement with JNMC prior to the period end date, this Agreement will be immediately terminated. In the event of termination JNMC will pay for costs incurred and non-cancelable commitments through the date of termination, contingent upon JNMC having received sufficient funds from Sponsor. BLDE will furnish all necessary reports of research completed or in progress through the date of termination.

I. Publications

Any publications resulting from this Agreement shall be governed by the policies laid out in Attachment B.

J. Arbitration

If any dispute arises in between JNMC and BLDE the same should be referred to Chancellor, KLE University and Chairman, KLE Society, Belgaum and President, BLDE University's Bijapur and the decision of the Arbitrators shall be final and the same shall be binding on the both the parties.

BLDE **certifies that** to the best of its knowledge and belief that it and its principals will abide by the payment Standard Operating Procedures in Attachment A and Attachment B

This Contract includes the following Appendices (incorporated herein):

Attachment A: Federal Award Title no: UH3CA189923 for Cryopop Study
Attachment B: Protocol for Cryopop Study
Attachment C: Budget Sheet for 12 months

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher
and Research, BELAG

IN WITNESS WHEREOF, JNMC and BLDE have executed and delivered this Contract by and through their duly authorized representatives below

Jawaharlal Medical College (JNMC)

By: _____

Name: Dr N S Mahantshetti

Title: Principal

Date: 07/04/2020

Shri B M Patil Medical College (BLDE)

By: _____

Name: Dr Aravind V Patil

Title: Principal

Date: 07/04/2020

Principal Investigator

By: _____

Name: Dr Shivaprasad S Goudar

Title: Professor Department of PHYSIOLOGY

Date: 07/04/2020

By: _____

Name: Dr Shailaja Bidari

Title: Asst. Professor and Head, Department of OBGYN

Date: 07/04/2020

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

MEMORANDUM OF UNDERSTANDING

BETWEEN

KLE University's
Shri B. M. Kankanawadi Ayurveda
Mahavidyalaya
Belgaum, Karnataka

AND

CSIR's Ayurgenomics Unit-TRISUTRA
IGIB, DELHI

REGARDING

COLLABORATIVE RESEARCH

May 2012

ATTESTED
Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

MEMORANDUM OF UNDERSTANDING
BETWEEN
KLE UNIVERSITY'S
SHRI B. M. KANKANAWADI AYURVEDA MAHAVIDYALAYA
BELGAUM, KARNATAKA

AND
CSIR -TRISUTRA, DELHI
FOR
COLLABORATIVE RESEARCH

KLEU's Shri B. M. Kankanawadi Ayurveda Mahavidyalaya, will be hereinafter referred to as **BMK Ayurveda Mahavidyalaya** and the CSIR's Ayurgenomics unit TRISUTRA at Institute of Genomics and Integrative Biology, Delhi, a unit of Council of Scientific and Industrial Research as **CSIR-TRISUTRA.**

This **MOU** sets down the mutually agreed broad framework for joint research and academic activities in various fields of interest. It also incorporates the modalities for collaboration.

1. PREAMBLE:

1.1 BMK Ayurveda Mahavidyalaya is a premier Ayurvedic Medical Research Institute/hospital, having extraordinary infrastructure, specialized medical/paramedical staff, management and facilities for patient care, training programmes and research activities.

1.2 CSIR-IGIB is one of the premier research laboratories of the CSIR, with an extensive array of sophisticated equipment and highly qualified staff, carrying out advanced research in biochemical technology and genomics including various aspects of molecular medicine. Scientists at CSIR- IGIB have been pursuing research integrating Ayurveda with Modern Genomics and have established a new field of research called Ayurgenomics. This has led to the set up of a new unit CSIR-TRISUTRA dedicated for the research in the field of Ayurgenomics. This

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

unit would aim to develop affordable health care solutions based on traditional knowledge of Ayurveda and modern genomic knowledge and medicine. This inter-disciplinary networked unit would enable cross talk between Ayurveda, modern medicine and genomic science.

1.3 The activities of BMK Ayurveda Mahavidyalaya and CSIR-TRISUTRA are in several ways complementary. It is therefore felt that initiating collaborative research programmes would be of considerable mutual benefit.

2. PURPOSE:

BMK Ayurveda Mahavidyalaya and CSIR-TRISUTRA desire to implement, in the areas of mutual interest, cooperative and collaborative activities, which would address multidisciplinary scientific, technological and educational problems of relevance to the country. This is facilitated by the instrument of this **MOU** as follows:

ARTICLE - 1

Consistent with the goals and purpose of the collaboration, BMK Ayurveda Mahavidyalaya and CSIR-TRISUTRA propose to initiate joint multidisciplinary research, to begin with in the area given below:

1.To conduct research aimed at validation and providing scientific evidence to principles/concepts described in Ayurveda for predictive, personalized and pre-emptive approach to health and diseased conditions
2. To develop data and sample repositories for prospective research studies
3. To develop interdisciplinary human resources

Other projects would be taken up to include other areas as mutually agreed upon involving faculty, research scholars and students from different departments/ divisions of both the Institutes.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

ARTICLE - 2

a) The faculty and staff of BMK Ayurveda Mahavidyalaya and CSIR-TRISUTRA will hold regular meetings on problems of mutual interest.

b) The faculty and research scholars of BMK Ayurveda Mahavidyalaya and CSIR-TRISUTRA will have access to the facilities of both Institutes, subject to their respective rules and regulations.

c) The faculty and staff of BMK Ayurveda Mahavidyalaya and CSIR-TRISUTRA will jointly apply to the funding agencies for financial support for the collaborative research and academic programmes undertaken under this MoU.

d) The faculty and staff will jointly report progress and accomplishment annually.

ARTICLE - 3

Provision is hereby made for:

a) The exchange of Faculty, research scholars, staff and students between the two institutes.

b) The joint organization of Symposia, Seminars, Workshops and Lectures; and mutual sharing of data on collaborative projects.

c) No formal day-to-day permission will be necessary for the faculty, research scholars, staff and students of the two institutes to work in the laboratories of other institute in connection with the research work/ projects approved jointly by the heads of the respective departments of BMK Ayurveda Mahavidyalaya and CSIR-TRISUTRA.

ARTICLE - 4

INTELLECTUAL PROPERTY:

a) Important research findings arising out of the activities covered under this **MOU** may be published in/presented at national and international Journals/Conferences jointly with the mutual consent of collaborators.

b) Knowledge developed, which can result in commercial exploitation would be IPR protected and filed jointly by both the institutes. The expenses involved in

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

protecting the IPR shall be shared equally. However, if one of the institute decides not to share the expenses for protecting IPR, then it should assign its rights to the other institute to enable the other institute to file for IPR protection

c) Neither party shall reveal intellectual property belonging to the other to any third party without the prior written concurrence of the other party.

d) Any returns arising of commercialization of the Intellectual Property generated out of the programmes undertaken under this MoU, will be shared in proportion to be decided mutually by both the parties, on case-to-case basis and through exchange of letters.

e) Both parties shall abide by the Government Rules as applicable time-to-time.

ARTICLE - 5

NON-EXCLUSIVITY OF THE MOU

Notwithstanding anything contained in the provisions excepting Article - 4 of the **MOU,** either party or both parties together have the unrestricted right to seek additional funds for and/or to cooperate with any agency/institute for any of the projects covered by the **MOU.**

ARTICLE - 6

Any article of the **MOU** may be modified or changed by mutual agreement of the parties hereto in writing. The modifications/changes shall be effective from the date on which they are modified/extended unless otherwise agreed to.

ARTICLE - 7

All disagreements/differences of opinion/disputes regarding the interpretation of the provisions of this **MOU** shall be resolved by mutual consultation by the signatories. However, in case the dispute persists, the matter shall be referred jointly to the DG-CSIR and the Secretary, Health, Government of India, Delhi, whose decision shall be final and binding on both the parties.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

ARTICLE -8

GOVERNING LAW:

All research activities undertaken jointly by BMK Ayurveda Mahavidyalaya and CSIR-TRISUTRA under this **MOU** will be governed by the Laws of the Republic of India.

ARTICLE -9

The tenure of the **MOU** shall be for three years from the date of signing the **MOU.** Unless opted otherwise by either of the signatory parties to this **MOU**, the tenure shall be renewed automatically for another three years from the date of expiry of the first tenure.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

In witness whereof the undersigned, duly authorized thereto, have signed this **MOU** on this day, _____.

11/6/12

PRINCIPAL
BMK Ayurveda Mahavidyalaya
Address:
BMK Ayurveda Mahavidyalaya
Shahapur
Belgaum-590003
Karnataka

25/5/2012

Head PME Division
CSIR-IGIB
Address:
CSIR-Institute of Genomics and Integrative Biology
Near Jubilee Hall,
Mall Road, Delhi-110 007

डॉ0 ज्योति यादव/Dr.JYOTI YADAV
वैज्ञानिक एव प्रमुख पी0 एम0 ई0
Scientist & Head P. M. E.
जीनोमिकी और समवेत जीवविज्ञान संस्थान
Institute of Genomics and Integrative Biology
मॉल रोड, दिल्ली-110007/Mall Road, Delhi-110007

Witnesses : (Name & Address)

1. _____
Dr R C Mathad
KLE's BMK AYU COL Belgaum

_____
Mr. S. K. Patil
KLE's BMK Ayu College Belgaum

Date : 11.6.12

Witnesses : (Name & Address)

2. _____ 25/5/12
(Rakesh Kapur
STO- PME Div.
CSIR-IGIB

_____
(Manish Patidar)
T.O CSIR-IGIB

Date : _____

ATTESTED
Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

MEMORANDUM OF UNDERSTANDING BETWEEN

GOVINDRAM SEKSARIA SCIENCE COLLEGE
AND
K.L.E.UNIVERSITY'S
SHRI.B.M.K.AYURVEDA MAHAVIDYALAYA

DATE: 27-01-2014

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

MEMORANDUM OF UNDERSTANDING

This Memorandum of Understanding ("MOU") is made, effective as of the Monday 27th day of the month of January 2014 ("Effective Date"),

Between

Govindram Seksaria Science College Geology department, Belgaum, Karnataka, (hereinafter called "GSS College" which expression shall where the context so admits include its successors and permitted assigns) of the one part;

And

KLE University`s SHRI B. M. KANKANWADI AYURVEDA MAHAVIDYALAYA, a Company registered in India under the Companies Act, 1956 and having its registered office at SHAHPUR, BELGAUM, (hereinafter called "BMK", which expression shall, where the context so admits, include its successors and permitted assigns) of the second part.

PREAMBLE

It is the need of hour to work in collaborations to achieve and maintain the Education and Research standards in any institute. Individual academicians from University campus schools and constituent/private Institute should join their hands in academics and research. This helps to increase the academic and research standards as well as the student quality. This also helps in tackling the local problems and work towards the sustainable development of the region.

SKE Society and Govindram Seksaria Science College, Belgaum:

South Konkan Education Society (commonly known as SKE Society) had started the Rani Parvati Devi College with Arts and Science course way back in 1945 at Savantwadi, Maharashtra. Later the Rani Parvati Devi College was relocated to Belgaum in 1948. Durig 1966 due to increase in student strength the college was bifurcated as Rani Parvati Devi College of Arts and Govindram Seksaria Science College. Presently, GSS College is affiliated to Rani Channamma University, Belagavi (RCU), and is a premier educational institute in North Karnataka imparting quality education in Science and committed to overall development of students. The college is re-accredited with "A" Grade (3.10 CGPA) by NAAC and enjoys CPE status of UGC. The college has a proud track record of consistent high results at degree level.

It is engaged in providing quality education through well qualified and dedicated teaching staff. Several departments have shown high quality research by receiving funding from UGC, DST, MoES etc. Through this MoU these departments will be strengthened further in their researches. The department of Geology, Chemistry, Zoology and Physics are engaging major and minor projects. Department of Chemistry also has a PG programme in Organic Chemistry.

The Geology Department especially has completed four major and one minor research projects. 18 students have bagged gold medals at Karnataka University, Dharwad for securing highest marks in Geology since 1984. The students of this department are settled worldwide. The faculty of the school is having expertise in Sedimentation, sediment transport, coastal dynamics,

watershed development, Geological mapping, geophysical exploration, geochemical modeling, remote sensing; Environmental aspects such as pollution assessment, land use-land cover changes, etc. The department is equipped with geophysical resistivity meter, surveying equipment, Sieve analyses, heavy mineral analysis, ERDAS Imagine Remote Sensing software, Binocular petrological microscope with photographic attachment etc., to cater the training and research needs of the students. The department also has collaborative research with Department of Rasashastra, BMK Ayurveda Mahavidyalaya for their MD dissertations. Till now, 5 collaborative MD dissertations have been completed.

About KLEUniversity's Shri.BMK Ayurveda Mahavidyalaya:

Inspired by the way an Ayurvedic Physician diagnosed the miserable condition of wife, Late Sri Basapanna Mallappanna Kankanwadi, a retired Police Officer established this institute in 1933 by donating all his retirement earnings of Rs.50,000/-. Presently the institute is spread in 12 acres of land under three major establishments

- Shri B.M.K Ayurved Mahavidyalaya
- KLE Ayurveda Hospital
- KLE Ayurveda Pharmacy

The college is imparting Ayurveda education up to Post Doctoral Level. Graduation i.e. BAMS (75 intake), Post Graduation in Nine disciplines viz. Rasashastra, DravyaGuna, Shalya Tantra, Agada Tantra, Kayachikitsa, Kaumarabhritya, Panchakarma, Bhaishajya Kalpana &Sagnyaharana. The institute is well established with well equipped laboratories including Digital Library. Central Research Facility comprising of Analytical Laboratory, Microbiology Laboratory, Medical Research Center and Animal House are main attraction for research scholars. Herbal garden spread with rare and endangered species is the special feature of this institute.

The hospital worth six crores spread over 67,000 sq.ft with state of art facilities offering clinical training to UG, PG students as well as research scholars. All specialty OPD including super specialty OPD and various classical treatments are made available for health seekers. Panchakarma with all the modern gadgets and learned therapists offers panchakarma treatments for about 80 to 100 patients per day. Rejuvenation programmes through department of Swasthavritta are being offered for health promotion. Apart from these the hospital is having physiotherapy, OT complex, Labour Theater, Kangaroo Mother Care Center, NICU, Dental Wing, Ayurveda Fertility Center. Suvarnabindu an Ayurveda immunization is attracting large group of people and around 3000 kids attend the programme on every PushyaNakshatra day. Garbhasanskar is another unique approach of Ayurveda through which pregnant women will be taken care by Ayurveda management, yoga, medication, music therapy and mantra therapy. Samvardhana a rehabilitation center for mentally and physically challenged children is an added advantage of Kaumarabhritya department. Priyangu a Skin & Hair Care Clinic deals with skin analysis, hair analysis, relaxing head massage etc. Obesity Cell offers multi dimension approach like Panchakarma, Physiotherapy, Yoga & Naturopathy. Separate Chakshushya & Kankayana units offer special Kriyakalpa procedures for the ailments of Eye & ENT.

The pharmacy with GMP certification is producing quality medicines to meet the demands of KLE Ayurveda Hospital. Well established quality control laboratory is assuring the quality of the products. The pharmacy is manufacturing 70 classical and 7 proprietary products.

New Library & PG Block:

To meet the increase demand of the Post Graduates and Doctoral Research requirements, the new Library & PG Block worth Rs.4 Crores has been constructed with the financial aid of Rs.1.2 Crore by Department of AYUSH, Ministry of Health & Family Welfare, Government of India, New Delhi under the Centre of Excellency Scheme.

The block contains spacious well furnished Library with huge number of literature i.e. about more than 16000 books. The accommodating capacity of the library is around 125. A provision of round the clock reading room has been made. Digital Lab with 30 High Configured Systems provides e-literature and web browsing to the students. Sound Proof discussion room in library is a unique feature which facilitates the research scholars to discuss the critical points in the library without disturbing others.

The PG Block accommodates Nine PG Departments, each having Department PG Seminar Hall, Museum cum Laboratory. All Seminar Halls are well equipped with proper audio-visual aids.

Department of Rasashastra:

Inorganic matter in fact provides in ways that are still not fully understood, an extremely powerful source of energy, not only for plants but for all living beings. However, inorganic matter in its natural form cannot be easily metabolized by humans unlike plants and other autotrophs. A special branch of Ayurveda pharmacy called Rasashastra developed around the 8th century, innovated and introduced complex process(using the then available primitive technologies), to convert ingeniously, outside of biological systems, metals and minerals into bio available drugs for powerful curative, preventive and health promoting uses.

Today, Rasashastra is considered as a specialized, almost secretive branch of Ayurvedic pharmacy and therapeutics. It is Ayurveda's most powerful pharmaceutical form. It is a complex branch of pharmacy and designed to be practiced only by experts. It requires several years of training under expert teachers. It deals with the medicinal uses of around 70 different metals and minerals, along side organic substances (herbs), to make extremely potent medicines.

In the context of Ayurveda, the 'rasa' refers to 'Parad' or 'mercury'. This is because the science of Rasashastra is centrally based on the use of mercury. Mercury is known by the name 'Rasa' or 'Rasendra' and 'Parada'. It is called 'Rasa' because it has the power to the transform various metals and minerals. It is used for both loha siddhi (conversion of base metals) and deha siddhi (used in the preparation of medicines for prevention and treatments). Rasashastra is considered as superior to all forms of medicine as it is fast acting and medicines prepared with strict adherence to methods prescribed in texts of Ayurveda alleviate many complex disorders. Metal and mineral preparations are therapeutically effective even when administered in small doses (unlike plant origin drugs which are generally required to be administered in a much larger dose). Properly prepared mineral drugs are bio- assimilable and produce their intended therapeutic results instantaneously. Improperly prepared drugs can however be toxic and harmful. This is the reason why only experts are advised to practice Rasashastra.

While mercury is the most important metal used in Rasashastra, there are other metals and minerals also used. They are grouped under Maharasa and Sadharana Rasa. Maharasa are the drugs that are widely used in formulations and are used in processing mercurial preparations, Uparasas are slightly lower in the effect, compared to the Maharasa and Sadharanarasas have limited power of

transformation. The Maharasa are Abhraka (Mica), Vaikranta (Tourmaline), SvarnaMakshika (Chalcopyrites), Vimala (Iron pyrites), Shilajit (Bitumen), Tutha (Copper sulphate), Bismuth and Zinc oxidw. The Uparasas are Gandhaka (Sulphur), Gairika (Red ochre), Kasisa (Iron sulphate), Kankshi (Alum), Talak (Orpiment), Manashila (Realgar), Anjana (Stibnite) and Kankushta (Gamboze). The Sadharana rasas consists of Kampillaka (obtained from fruits of mallotus trees), Arsenic oxide, Ammonium chloride, Cowrie, Ambergris, Red oxide of mercury, Mercury sulphide and Lead oxide.

Ayurveda obtained global recognition as science of life. Though people understand Ayurveda is an herbal medicine yet several preparations are Herbo mineral and Mineral formulations. The safety of the mineral ingredients in various formulations has been questioned and has become the concern of all Ayurvedic fraternity. Considering the global demand of Ayurvedic medicine, several business people started adulterating raw materials and this has contributed some more controversy to the existing controversies in raw material identification. Hence, this is the right time to identify genuine raw materials to preserve the global faith in Ayurveda.

In this aspect, the Department of Geology has made several advances and developed various methodologies for identification of Minerals and ores. Considering the need of identification, the Rasashastra department and department of Geology G.S. Science College, Tilakwadi-Belgaum has decided to make MoU.

1. **Objectives**

The objectives of the MoU are the following:

(i) Collaborative research by sharing knowledge and research facilities.
(ii) Conducting workshops/seminars/group discussions/ crash courses/bridge courses/ field visits etc.
(iii) Guiding research and publishing the data.
(iv) Up gradation of knowledge and technology development.

2. **Financial Arrangements**

Each party shall bear its own expenses incurred in the course of its performance under this Agreement.

3. **Intellectual property (IP)**

Credit of outcome of the collaboration should accrue credit to both the institutions.

4. **Confidentiality**

The parties understand that in the course of their association, they shall have access to confidential information provided by the other party. Accordingly, the parties agree that such information shall be maintained in the strictest confidence and trust, expect such information which is by its nature, not confidential or which is in the public domain or which the party comes to know about other than through violation of any law of legal obligation, provided that such party may be entitled to disclose such information if legally required to be disclosed to a competent authority. Failure to maintain confidentiality shall entitle the affected party to terminate the MoU.

(i) During and for a period of 3 year from the date of termination of this MOU, each party undertakes on their behalf and on the behalf of their subcontractors

/employees /representatives/ associates to maintain strict confidentiality and prevent disclosure of the information/data exchanged / generated pursuant to this MOU for any purpose other than in accordance with this MOU.

(ii) Upon termination or dissolution of this MOU, or upon earlier determination there of, each party shall return to the other party all disclosing party's known tangible forms of the confidential information and copies thereof in the receiving party's possession and shall delete or erase all tangible/intangible confidential information of the disclosing party in its possession. If requested by the disclosing party an officer of the receiving party shall certify in writing that all such confidential information of the other was returned, erased or deleted.

5. **Term of MoU and termination**

a. GSS College and BMK Ayurveda Mahavidyalaya, agree to enter into detailed agreements on case-to-case basis, with a defined objective, specifying the scope of work and mutual obligations, terms and conditions, financial arrangements, Intellectual Property Rights and similar contractual obligations.

b. Both the Institutes agree to obtain prior permission from each other for using the infrastructural or intellectual facilities.

c. Both the Institutes agree to obtain prior permission from each other to state in any project proposal that the project would be carried out by using the Institutes infrastructural or intellectual facilities.

d. In case either party wins a consultancy project by projecting this MOU, a liability is created immediately in respect of royalty/premium/over head expenses due to either party. Either party shall concur with the liability to the extent of contribution to the output of the project. Both the parties will arrive at the exact amount of liability after mutual consent.

This MoU unless extended by a mutual written agreement of both the parties shall expire 5 years after the effective date specified in the opening paragraph. This MoU may be amended or terminated earlier by mutual written consent by both the parties at any time. Either party shall have the right to unilaterally terminate this MoU upon 30 days prior written notice to the other party. Failure of either party to terminate the MoU on account of breach or default by the other party shall not constitute a waiver of that party's right to terminate this MoU.

Upon Termination or Expiration of this MoU, any equipment, data, literature, books, journals, dissertations, thesis etc., shall be returned to the respective institutions, within 15 working days.

6. **Representations, Warranties and Liability**

GSS College and **BMK** will hold each other unconditionally harmless from any possible claims or damages brought by THIRD PARTIES against each other in connection with the performance of this Agreement.

GSS College shall not be responsible or liable for any damage to the property, material or personnel of the **BMK** or any monitory losses to the **BMK**, in consequence of the jobs taken up by **BMK**, as a result of this MoU. GSS

College shall also not be responsible for any procedural or legal matters pertaining to this assignment.

7. **Rights in Results**

7.1 Copyright in the generated Results shall vest with both the parties.

7.2 Each Party shall be free to use the Results as it deems fit and to grant use rights in respect of the Results to whomsoever they want without any liability, financially or otherwise, to other party, but with prior consent of both the parties.

7.3 The weight age for the order of authorships in the publications arisen out of the collaboration depends upon the amount and importance of the data used in the paper.

8. **Relationship**

Nothing in this MoU shall be construed to make party a partner, an agent or legal representative of the other party for any purpose. Neither party has any right or authority to accept any service, or receive any notices on behalf of the other party or to enter into any commitments, undertakings, or agreements purporting to obligate such other party in any way, or to amend, modify or vary any existing agreements to which such other party may be a party.

9. **Assignment**

The rights and/or liabilities arising to any party to this MoU shall not be assigned except with the written consent of the other party and subject to such terms and conditions as may be mutually agreed upon.

10. **Force Majeure**

Neither party shall be held responsible for non-fulfillment of their respective obligations under this MOU due to the exigency of one or more of the force majeure events such as but not limited to acts of god, war, flood, earthquakes, strike, lockouts, epidemics, riots, civil commotion, etc. provided on the occurrence and cessation of any such events, the party affected thereby shall give a notice in writing to the other party within one month of such occurrence or cessation. If the force majeure conditions continued beyond six months, the parties shall then mutually decide about the future course of action.

11. **Arbitration**

Any disputes arising out of this MoU shall be settled amicably through negotiations in good faith failing which the same shall be referred to and settled in accordance with the provisions of Arbitration & Conciliation Act, 1996 or any amendment thereof. This clause shall survive expiration or earlier determination of this MOU.

12. **Jurisdiction**

This MOU shall be subject to the jurisdictions of the courts in Belgaum only.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

College shall also not be responsible for any procedural or legal matters pertaining to this assignment.

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This MOU shall be subject to the jurisdictions of the courts in Belgaum only.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

In witness whereof the parties intending to be legally bound have caused this MOU to be duly executed in two originals by their authorized representatives, each to be version of equal authenticity as of the date first written above.

GSS College	KLEU's BMK AYURVEDA MAHAVIDYALAYA
Signature:	**Signature:**
Name: Prof.A.K.MENSE	**Name:** Dr. B.SREENIVAS PRASAD
Designation: Principal	**Designation:** Principal
Date: 27-01-2014	**Date:** 27-01-2014

Witnesses:

1. **Dr.P.T.Hanamgond**

2. **Dr.P.G.Jadar**

MEMORANDUM OF UNDERSTANDING

BETWEEN

Interactive Research School for Health Affairs,
Bharati Vidyapeeth Deemed University,
Pune, Maharashtra
(Re-Accredited 'A' Grade NAAC & placed in 'A' Category by MHRD)

AND

KLE University's
Shri B. M. Kankanawadi Ayurved Mahavidyalaya
Belgaum, Karnataka
(Accredited 'A' Grade NAAC & placed in 'A' Category by MHRD)

REGARDING

Collaborative Research

2014-2018

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

MEMORANDUM OF UNDERSTANDING (MOU)

BETWEEN

Interactive Research School for Health Affairs,
Bharati Vidyapeeth Deemed University,
Pune, Maharshtra

AND

KLE University's
Shri B. M. Kankanawadi Ayurved Mahavidyalaya
Belgaum, Karnataka

FOR

COLLABORATIVE REASERCH

The Interactive Research School for Health Affairs, Bharati Vidyapeeth Deemed University, Pune, Maharshtra hereinafter referred to as IRSHA while KLE University's Shri B. M. Kankanawadi Ayurved Mahavidyalaya, Belgaum, Karnataka will be referred as KLEU BMKAM.

This MOU sets down the mutually agreed broad framework for joint/collaborative research and academic activities in various fields of interest. It also incorporates the modalities for collaboration.

PREAMBLE:

IRSHA, a constituent unit of Bharati Vidyapeeth Deemed University, is a premier research institute totally dedicated to research on human health and nutrition with a special attention on Mother and Child Health and adult disorders. It has a team of Scientists with diverse expertise in Biochemistry, Molecular Biology, Ayurveda, Ethnobotany and Taxonomy, Biotechnology and Cell Biology. IRSHA has in-campus facility for animal experiments and clinical trials along with well Equipped Research Labs with State of Art facilities.There is a vibrant inhouse Ph.D program with full time Ph.D students working under various research programs.

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

KLEU BMKAM is a premier Ayurved Medical Research Institute/Hospital, having extraordinary infrastructure, specialized medical/paramedical staff, management and facilities for patient care, training programmes and research activities.

The activities of IRSHA and KLEU BMKAM could be successfully and complementarily conducted in areas of mutual interest and benefit.

PURPOSE: IRSHA and KLEU BMKAM desire to implement cooperative and collaborative activities, which would address multidisciplinary scientific, technological and educational issues/problems/challenges of relevance to the country. This is facilitated by the instrument of this MOU as follows:

ARTICLE-1

Consistent with the goals and purpose of the collaboration, IRSHA and KLEU BMKAM propose to initiate joint multidisciplinary research to begin with in areas given below:-

a) Metabolic syndrome with special focus on Obesity
b) Other projects/studies would be taken up to include areas as mutually agreed upon involving faculty, research scholars and students from different departments/divisions of both the Institutes.

ARTICLE-2

a) The faculty and staff of IRSHA and KLEU BMKAM will hold regular meetings on research issues of mutual interest.
b) The faculty and research scholars of IRSHA and KLEU BMKAM will have access to the facilities of both Institutes, subject to their respective rules and regulation.
c) The faculty and staff of IRSHA and KLEU BMKAM will jointly apply to the funding agencies for financial support for the collaborative research and academic program undertaken under this MOU.
d) The faculty and staff will jointly report progress and accomplishment annually. As of now Dr. Prabhakar Ranjekar, Director, IRSHA and Dr. BS

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Prasad, Principal, KLEU BMKAM shall co-ordinate the research work embodied in this MOU.

ARTICLE-3

Provision is hereby made for:

a) The exchange of faculty, research scholars, staff and students between the two institutes

b) The IRSHA staff based at KLEU BMKAM shall primarily report to Principal, KLEU BMKAM and report to Director, IRSHA as may be needed by the study. Likewise, the KLEU BMKAM staff based at IRSHA shall primarily report to Director, IRSHA and report to his/her Principal, KLEU BMKAM as may be needed by respective study.

c) The joint organization of Symposia, Seminars, Workshops, trainings and Lectures; and mutual sharing of data on collaborative projects

d) Collaborate/work jointly with other national and international partners of each other's institutions in mutual consultation and agreement time to time for conducting collaborative research.

e) No formal day to day permission will be necessary for the faculty, research scholars, staff and students of the two institutes to work in the laboratories of other institute in connection with the research work/ projects approved jointly by the Heads/Coordinators of the respective departments of IRSHA and KLEU BMKAM.

ARTICLE-4

INTELLECTUAL PROPERTY:

a) Research findings arising out of the activities covered under this MOU may be published in/presented at national and international journals/conferences jointly with the mutual consent of collaborators.

b) Knowledge developed which can result in commercial exploitation would be Intellectual Property Rights act (IPR) Protected and filed jointly by both the institutes. IPR shall be based on contributions made by each party. However, the expenses involved in protecting the IPR shall be shared equally. However, if one of the institutes decides not to share the expenses for protecting IPR

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Prof. Dr. V.A.KOTHIWALE
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then it should assign its rights to other institute to enable the other institute to file the IPR protection.

c) Either party may make use of, for its own internal purpose, all information and data generated during this program of collaborative work. However neither party shall reveal intellectual property belonging to the other to any third party without the prior written concurrence of the other party.

d) Any returns arising of the commercialization of the Intellectual Property generated out of the programs undertaken under this MOU, will be shared in proportion to be decided mutually by both the parties, on case to case basis and through exchange of letters.

ARTICLE-5

NON-EXCLUSIVITY OF THE MOU

Not withstanding anything contained in the provisions excepting Article-4 of the MOU, either party or both parties together have the unrestricted right to seek additional funds for and/or cooperate with any agency/institute for any of the projects covered by the MOU.

ARTICLE-6

Any article of the MOU may be modified or changed by mutual agreement of the parties here to in writing .The modification/changes shall be effective from the date on which they are modified/extended unless otherwise agreed to.

ARTICLE-7

All disagreements/differences of opinion /disputes regarding the interpretation of the provision of this MOU shall be resolved by mutual consultation by the signatories. However, in case the dispute persists, the matter shall be referred jointly to Prof. Sahebrao Mahadik, Advisor, IRSHA and Dr B.S.Prasad, Principal whose decision shall be final and binding on both the parties.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

ARTICLE-8

GOVERNING LAW

All research activities undertaken jointly by IRSHA and KLEU BMKAM under this MOU will be governed by the laws of Republic of India.

ARTICLE-9

The tenure of the MOU Shall be for five years from the date of signing the MOU unless opted otherwise by either of the signatory parties to this MOU. The tenure may be renewed for further period provided both parties agree in writing.

In witness where of the undersigned, duly authorized there to, have signed this MOU on this Tuesday, the 17th day of June 2014.

PKRanjekar

Dr. Prabhakar Ranjekar
Director, IRSHA

Dr. B.S.Prasad 17/6/2014
Principal, KLEU BMKAM

Witness

1. Bhalerao Dr. Supriya Bhalerao
2. O.P.Kulkarni DR.OMKAR KULKARNI

Witness
1. Dr. Govindhan Vedantam
2. Dr S.V. Patil

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

Tel. : 283650
Telefax : 08370-283651
Email : elegant@bsnl.in

ELEGANT DRUGS PVT. LTD.

PHARMACEUTICAL MANUFACTURERS

Manufacturing Unit : R. S. No. 59/3A, HUBLI-KARWAR HIGHWAY,
CHALMATTI - 581 196.
(Dist : Dharwad, Taluk : Kalghatagi, State : Karnataka)

Ref. No.: MISC/EDPL/092/16-17

Date: 17/06/2016

TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Mr. AZHAR AHMED N. KHALASI,** student of KLEU'S COLLEGE OF PHARMACY, VIDYANAGAR, HUBLI has successfully completed 50 hours in plant training in our organization between 02.06.2016 to 16.06.2016. He has worked in all departments related to Tablets & Capsules.

His conduct and performance during above period was found to be satisfactory.

This certificate is issued to Mr. AZHAR AHMED N. KHALASI, only to complete the formalities of the academic course.

We wish all the best for his future.

FOR ELEGANT DRUGS PVT. LTD.,

Mr. Mahadev Chougule
Plant Manager

PRINCIPAL, KLE UNIVERSITY'S
COLLEGE OF PHARMACY
HUBLI.

ATTESTED

Corporate Office :
New Cotton Market, HUBLI - 580 029. (Karnataka)
Tel : 2252007, 3350609 Fax : 0836-2253386 Email : elegant@bsnl.in

Tel. : 283650
Telefax : 08370-283651
Email : elegant@bsnl.in

ELEGANT DRUGS PVT. LTD.

PHARMACEUTICAL MANUFACTURERS

Manufacturing Unit : R. S. No. 59/3A, HUBLI-KARWAR HIGHWAY,
CHALMATTI - 581 196.
(Dist : Dharwad, Taluk : Kalghatagi, State : Karnataka)

Ref. No.MISC/EDPL/025/16-17

Date : 17.06.2016

TO WHOM SO EVER IT MAY CONCERN

This is to certify that Mis.JERUSHA JOSESPH IRUDAYARAJ, student of COLLEGE OF PHARMACY, VIDYANAGAR, HUBLI has successfully completed 15 days (50 hours) in plant training in our organization between 01.06.2016 to 15.06.2016. She has worked in all departments related to Tablets & Capsules.

Her conduct and performance during above period was found to be satisfactory.

This Certificate is issued to Ms.JERUSHA JOSEPH IRUDAYARAJ, only to complete the formalities of the academic course.

We whish all the best for her future.

Thanking you,

19/8/16
PRINCIPAL, KLE UNIVERSITY'S COLLEGE OF PHARMACY HUBLI.

ELEGANT DRUGS PVT. LTD. CHALMATTI VILLAGE

Yours faithfully,
For ELEGANT DRUGS PVT.LTD.,

Rajashekar C.Pattanshetty
(Managing Director)

ATTESTED

Corporate Office :
New Cotton Market, HUBLI - 580 029. (Karnataka)
Tel : 2252607, 2250603 Fax : 0836-2253386 Email : elegant@bsnl.in

KLE UNIVERSITY'S
COLLEGE OF PHARMACY
(A constituent unit of KLE Academy of Higher Education & Research- Deemed University)
Vidyanagar, HUBBALLI-580 031. Karnataka, India
Recognised by Government of Karnataka
Approved by Pharmacy Council of India (PCI) & All India Council for Technical Education (AICTE), New Delhi
(Accredited by NBA, AICTE, New Delhi)

Ref. No. : KLECOP HBL/IT/2016-17/139(A) Date : 23/08/2016

To,

The Production Manager,
Elegant Drugs Pvt. Limited,
R.S.No.59/3A,
Hubli-Karwar Highway,
CHALAMATTI – 581 204.

Sub: Permission to visit your esteemed Industry
by the final year B.Pharm. & M.Pharm. Students.

****

Sir,

We are pleased to inform you that, we are running B.Pharm. & M.Pharm. Courses since 1991 & 1999 respectively. These courses are approved by AICTE & PCI, New Delhi and Institution is reaccredited by NBA, AICTE, New Delhi. As per the regulations of B.Pharm. Course, the students studying in Final year B.Pharm are required to visit several Pharmaceutical manufacturing units and laboratories as supplement to their academic training and they are required to submit the report to the Head of the institution where he / she is studying.

In this context, our Final year B.Pharm. & M.Pharm. students intend to visit your esteemed Industry / Laboratory in third week of February, 2016. We will be grateful to you, if you permit us to visit your Industry / Laboratory. I am confident that your good self will permit us and widen the knowledge.

Hoping for your early and favorable reply.

Thanking you,

KLE UNIVERSITY'S ★ HUBLI-580 031. ★ COLLEGE OF PHARMACY

Yours faithfully,

PRINCIPAL

Note: 15 students and 2 staff members will be visiting in one batch or as per your convenience.

ATTESTED

☎ : 0836-2373174, Fax No. 0836-2371694/2371048, Web : http://www.klescoph.org, Email : principal.klescoph@gmail.com

Tel. : 283650
Telefax : 08370-283651
Email : elegant@bsnl.in

ELEGANT DRUGS PVT. LTD.

PHARMACEUTICAL MANUFACTURERS

Manufacturing Unit : R. S. No. 59/3A, HUBLI-KARWAR HIGHWAY,
CHALMATTI - 581 196.
(Dist : Dharwad, Taluk : Kalghatagi, State : Karnataka)

Ref. No.: MISC/EDPL/090/16-17

Date: 17/06/2016

TO WHOMSOEVER IT MAY CONCERN

This is to certify that **Mr. SACHIN HAVERI ASHOK,** student of COLLEGE OF PHARMACY, VIDYANAGAR, HUBLI has successfully completed 50 hours in plant training in our organization between 02.06.2016 to 16.06.2016. He has worked in all departments related to Tablets & Capsules.

His conduct and performance during above period was found to be satisfactory.

This certificate is issued to Mr. SACHIN HAVERI ASHOK, only to complete the formalities of the academic course.

We wish all the best for his future.

FOR ELEGANT DRUGS PVT. LTD.,

Mr. Mahadev Chougule
Plant Manager

PRINCIPAL, KLE UNIVERSITY'S
COLLEGE OF PHARMACY
HUBLI

ATTESTED

Corporate Office :
New Cotton Market, HUBLI - 580 029. (Karnataka)
Tel : 2352037, 2350500 Fax : 0836-2253386 Email : elegant@bsnl.in

Tel. : 283650
Fax : 08370-283651
Email : elegant@bsnl.in

ELEGANT DRUGS PVT. LTD.
PHARMACEUTICAL MANUFACTURERS

Manufacturing Unit : R. S. No. 59/3A, HUBLI-KARWAR HIGHWAY,
CHALMATTI - 581 196.
(Dist : Dharwad, Taluk : Kalghatagi, State : Karnataka)

Ref. No.MISC/EDPL/027/16-17

Date : 17.06.2016

TO WHOM SO EVER IT MAY CONCERN

This is to certify that Mis.PRATIBHA HUDED MALLAPPA, student of COLLEGE OF PHARMACY, VIDYANAGAR, HUBLI has successfully completed 15 days (50 hours) in plant training in our organization between 01.06.2016 to 15.06.2016. She has worked in all departments related to Tablets & Capsules.

Her conduct and performance during above period was found to be satisfactory.

This Certificate is issued to Ms. PRATIBHA HUDED MALLAPPA, only to complete the formalities of the academic course.

We whish all the best for her future.

Thanking you,

Yours faithfully,
For ELEGANT DRUGS PVT.LTD.,

Rajashekar C.Pattanshetty
(Managing Director)

ELEGANT DRUGS PVT. LTD. CHALMATTI VILLAGE

PRINCIPAL, KLE UNIVERSITY'S COLLEGE OF PHARMACY HUBLI.

ATTESTED

Corporate Office :
New Cotton Market, HUBLI - 580 029. (Karnataka)
Tel : 2252607, 2250108 Fax : 0836-2253386 Email : elegant@bsnl.in

Tel. : 283650
Telefax : 08370-283651
Email : elegant@bsnl.in

ELEGANT DRUGS PVT. LTD.
PHARMACEUTICAL MANUFACTURERS

Manufacturing Unit : R. S. No. 59/3A, HUBLI-KARWAR HIGHWAY,
CHALMATTI - 581 196.
(Dist : Dharwad, Taluk : Kalghatagi, State : Karnataka)

Ref. No.MISC/EDPL/029/16-17

Date : 17.06.2016

TO WHOM SO EVER IT MAY CONCERN

This is to certify that Mis.SONAM NANDGERIKAR VINAYAK, student of COLLEGE OF PHARMACY, VIDYANAGAR, HUBLI has successfully completed 15 days (50 hours) in plant training in our organization between 01.06.2016 to 15.06.2016. She has worked in all departments related to Tablets & Capsules.

Her conduct and performance during above period was found to be satisfactory.

This Certificate is issued to Ms. SONAM NANDGERIKAR VINAYAK, only to complete the formalities of the academic course.

We whish all the best for her future.

19/8/16
PRINCIPAL, KLE UNIVERSITY'S COLLEGE OF PHARMACY HUBLI.

Thanking you,

Yours faithfully,

For ELEGANT DRUGS PVT.LTD.,

ELEGANT DRUGS PVT. LTD. CHALMATTI VILLAGE

Rajashekar C.Pattanshetty
(Managing Director)

ATTESTED

Corporate Office :
New Cotton Market, HUBLI - 580 029. (Karnataka)
Tel : 2252607, 2350108 Fax : 0836-2253386 Email : elegant@bsnl.in

Tel. : 283650
Telefax : 08370-283651
Email : elegant@bsnl.in

ELEGANT DRUGS PVT. LTD.
PHARMACEUTICAL MANUFACTURERS

Manufacturing Unit : R. S. No. 59/3A, HUBLI-KARWAR HIGHWAY,
CHALMATTI - 581 196.
(Dist : Dharwad, Taluk : Kalghatagi, State : Karnataka)

Ref. No.MISC/EDPL/026/16-17

Date : 17.06.2016

TO WHOM SO EVER IT MAY CONCERN

This is to certify that Mis.AKSHATA. MENSHINKAI, student of COLLEGE OF PHARMACY, VIDYANAGAR, HUBLI has successfully completed 15 days (50 hours) in plant training in our organization between 01.06.2016 to 15.06.2016. She has worked in all departments related to Tablets & Capsules.

Her conduct and performance during above period was found to be satisfactory.

This Certificate is issued to Ms. AKSHATA. MENSHINKAI, only to complete the formalities of the academic course.

We whish all the best for her future.

Thanking you,

Yours faithfully,

For ELEGANT DRUGS PVT.LTD.,

Rajashekar C.Pattanshetty

(Managing Director)

PRINCIPAL, KLE UNIVERSITY'S COLLEGE OF PHARMACY HUBLI.

ELEGANT DRUGS PVT. LTD. CHALMATTI VILLAGE

ATTESTED

Corporate Office :
New Cotton Market, HUBLI - 580 029. (Karnataka)
Tel. 2352037, 2350108, Fax : 0836-2253386 Email : elegant@bsnl.in

Tel. : 283650
Telefax : 08370-283651
Email : elegant@bsnl.in

ELEGANT DRUGS PVT. LTD.
PHARMACEUTICAL MANUFACTURERS

Manufacturing Unit : R. S. No. 59/3A, HUBLI-KARWAR HIGHWAY,
CHALMATTI - 581 196.
(Dist : Dharwad, Taluk : Kalghatagi, State : Karnataka)

Ref. No.MISC/EDPL/028/16-17

Date : 17.06.2016

TO WHOM SO EVER IT MAY CONCERN

This is to certify that Mis.MANJULA CHIKKAMATH KUMARSWAMY, student of COLLEGE OF PHARMACY, VIDYANAGAR, HUBLI has successfully completed 15 days (50 hours) in plant training in our organization between 01.06.2016 to 15.06.2016. She has worked in all departments related to Tablets & Capsules.

Her conduct and performance during above period was found to be satisfactory.

This Certificate is issued to Ms. MANJULA CHIKKAMATH KUMARSWAMY, only to complete the formalities of the academic course.

We whish all the best for her future.

Thanking you,

Yours faithfully,

For ELEGANT DRUGS PVT.LTD.,

Rajashekar C.Pattanshetty

(Managing Director)

19/6/16
PRINCIPAL, KLE UNIVERSITY'S COLLEGE OF PHARMACY HUBLI.

ELEGANT DRUGS PVT. LTD. CHALMATTI VILLAGE

ATTESTED

Corporate Office :
New Cotton Market, HUBLI - 580 029. (Karnataka)
Tel : 2252027, 2350300 Fax : 0836-2253386 Email : elegant@bsnl.in

Tel. : 283650
Fax : 08370-283651
Email : elegant@bsnl.in

ELEGANT DRUGS PVT. LTD.
PHARMACEUTICAL MANUFACTURERS

Manufacturing Unit : R. S. No. 59/3A, HUBLI-KARWAR HIGHWAY,
CHALMATTI - 581 196.
(Dist : Dharwad, Taluk : Kalghatagi, State : Karnataka)

Ref. No.MISC/EDPL/027/16-17

Date : 17.06.2016

TO WHOM SO EVER IT MAY CONCERN

This is to certify that Mis.PRATIBHA HUDED MALLAPPA, student of COLLEGE OF PHARMACY, VIDYANAGAR, HUBLI has successfully completed 15 days (50 hours) in plant training in our organization between 01.06.2016 to 15.06.2016. She has worked in all departments related to Tablets & Capsules.

Her conduct and performance during above period was found to be satisfactory.

This Certificate is issued to Ms. PRATIBHA HUDED MALLAPPA, only to complete the formalities of the academic course.

We whish all the best for her future.

Thanking you,

Yours faithfully,
For ELEGANT DRUGS PVT.LTD.,

Rajashekar C.Pattanshetty
(Managing Director)

ELEGANT DRUGS PVT. LTD. CHALMATTI VILLAGE

PRINCIPAL, KLE UNIVERSITY'S COLLEGE OF PHARMACY HUBLI.

ATTESTED

Corporate Office :
New Cotton Market, HUBLI - 580 029. (Karnataka)
Tel : 2252637 2350108 Fax : 0836-2253386 Email : elegant@bsnl.in

Prajna Biosciences Pvt. Ltd.
Center for Technology Entrepreneurship
BVB College of Engineering & Technology, Hubli - 580 031, Karnataka, India.
Cell: +91 9686145135 E-mail: vineeth@prajnabio.com Web: www.prajnabio.com

80
Dr. P. S. Patharoppa
to discuss

Ref:

Date:

OFFICE OF THE PRINCIPAL
K.L.E.S. COLLEGE OF PHARMACY
VIDYANAGAR HUBLI-31
Date 23/06/2016
Inward No. 130

To

The Principal
KLE University's College of Pharmacy
Hubballi-580031.

Date: 22/06/2016

Sir,

SUB: Request for Development of Product Formulation

This is to bring to your kind notice that Prajna Biosciences, Hubballi has developed a product based on Microbial Consortium for environmental applications. The present formulation is in the form of liquid preparation and we need to formulate it into solid form (cake form / compact form). Hence we request your kind self to extend your technical expertise through faculty to develop an effective formulation.

We abide by the rules and regulations of KLE University and KLE Society.

Kindly do the needful.

Thanks and Regards,

Mr.Vineeth A. Shettar
Managing Director
Prajna Biosciences Pvt Ltd
Vidyanagar, Hubballi-580031.

ATTESTED

3 In case of any discrepancy

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

सत्यमेव जयते

Certificate No.	:	IN-KA97144430181613N
Certificate Issued Date	:	22-Jul-2015 11:03 AM
Account Reference	:	NONACC (FI)/ kasfinc01/ BANGALORE/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKASFINC0143359202469422N
Purchased by	:	LOTUS LABS PVT LTD
Description of Document	:	Article 12 Bond
Description	:	AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	DR SMITHA K S
Second Party	:	LOTUS LABS PVT LTD
Stamp Duty Paid By	:	LOTUS LABS PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

eStamp Cell Authorised Signatory

Please write or type below this line

CLINICAL TRIAL AGREEMENT

THIS AGREEMENT FOR "CLINICAL TRIAL" ("Agreement") is made and entered into this 24th day of July by and among Dr. Smitha KS, "KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehrunagar, Belgaum-590010. Karanataka, India" (hereinafter referred to as the **"Principal Investigator"** or **"PI"**)

AND

KLE'S Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehrunagar, Belgaum-590010. Karanataka, India herein after called the **"Institution"** (which expression shall wherever the context so admits include its successor and assignees) of the second part

ATTESTED

LOTUS LABS PVT. LTD.

Prof. Dr. V.A. KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

366

AND

CMS clinical research Pvt. Ltd, # 51, 3rd Floor, Paigah Colony, S P Road, Secunderabad—500003, Telangana, INDIA (SMO) (herein after called as "Site Management Organisation" which expression shall wherever the context so admits include its successor and assignees) of the Third Part

AND

Lotus Labs Pvt. Ltd, a company incorporated under the Companies Act, 1956 of India having its registered Office at No. 7, Jasma Bhavan Road, Millers Tank Bed Area, Opp. Gurunanak Bhavan, Vasanthnagar, Bangalore – 560 052, India and include its successors and assignees (hereinafter referred to as **"Lotus"**) representing the interests of Sponsor **Watson Pharma Pvt. Ltd.**, (hereinafter referred to as **"Sponsor"**) in connection with conduct of clinical trial "An Open Label, Randomized, Multicentric, Two Treatment, Single Dose, Parallel Group Two Stage Adaptive Design Bioequivalence Study Of Loteprednol Etabonate Ophthalmic Suspension, 0.5 % In Aqueous Humor Of Patients Undergoing Indicated Cataract surgery." (**"Study"**) bearing the protocol/study number: WAT/LTPNL/2015 (**"Protocol"**) attached hereto as Exhibit A.

PI, Institution and Lotus hereinafter are individually referred to as **"the Party"** and are jointly referred to as **"the Parties"**.

WHEREAS:

1. Sponsor is a pharmaceutical company and had engaged the services of Lotus for execution of a clinical trial in **India.**
2. Lotus is in the business of providing contract research services and has necessary infrastructure and facilities to provide such services for the clinical trial and in turn desires to engage the services of the Institution to conduct/assist in such a trial;
3. Institution represents that it has qualified personnel and adequate facilities and equipment to competently conduct the Study and is desirous of rendering such services upon such terms and conditions as envisaged below.
4. Institution and PI desires to engage SMO to provide qualified manpower services as required for conducting the clinical study under this agreement and rendering such services upon such terms and condition set forth herein.
5. SMO is a site management organization has qualified and trained personnel to competently conduct the Study and is desirous of rendering such services upon such terms and conditions as envisaged below.
6. SMO hereby agrees to provide its services in connection with the clinical trial and as per the approved study protocol and the terms and conditions set forth therein.

1. Provision of Services

1.1 Scope of Work.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

The Study to be performed under this Agreement shall be performed in accordance with the terms of the final Protocol, including as it may be amended in accordance with the terms of this Agreement, for the Study. Institution and Principal Investigator agree that all aspects of the Study will be conducted in conformity with all applicable laws and regulations, the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use Good Clinical Practice: Consolidated Guideline ("ICH Guideline,) and applicable requirements of the United States Food and Drug Administration ("FDA"). Institution and Principal Investigator further agree not to conduct any research activities with the Study Drug (as such term is defined below), which are contrary to the provisions of the Protocol or outside the scope of the Protocol.

Institution shall use best efforts to enrol up to 30 study participants capable of being evaluated and having analyzable data in the treatment portion of the Study, within 06 months of receipt of investigational supplies. The enrolment period may be extended or shortened at the sole discretion of Sponsor at any time.

1.2 **Principal Investigator.**

Institution shall appoint [Dr. Smitha KS] as Principal Investigator having the requisite education, experience and expertise to competently perform the Study according to the terms and conditions as hereafter set forth, and that said Principal Investigator shall act as representative of the Institution for medical and scientific matters arising under this Agreement. Principal Investigator will be responsible for the direction and supervision of all Study efforts in accordance with applicable Institution policies, the Protocol and this Agreement. Principal Investigator and Institution will ensure that any sub-investigators and any other staff comply with the terms of this Agreement and the Protocol. In the event that Principal Investigator leaves or is removed from the Institution, then Institution shall, within ten (10) days of such departure by Principal Investigator, provide written notice of such event to Lotus and Sponsor. Any successor to Principal Investigator must be approved, in writing, by Lotus and Sponsor and such successor shall be required to agree to all the terms and conditions of the Protocol and this Agreement and to sign each such document as evidence of such agreement (although failure to so sign will not relieve such successor from abiding with the terms and conditions of the Protocol and this Agreement).

Institution and Principal Investigator represent and warrant that they will not use in any capacity, in connection with any services to be performed under this Agreement, any individual who has been debarred pursuant to any applicable laws or regulations, including debarments under the United States Federal Food, Drug and Cosmetic Act, or exclusion from a United States federal healthcare program.

Institution and Principal Investigator agree to immediately inform Lotus and Sponsor in writing if any person who is performing services hereunder is debarred or if any action, suit, claim, investigation or legal or administrative proceeding is pending, or, to the best of their knowledge, is threatened, relating to the debarment of Institution or any person performing services hereunder. Principal Investigator represents and

warrants that no action, suit, claim investigation or legal or administrative proceeding is pending or threatened relating to Principal Investigator's debarment and Principal Investigator agrees to immediately inform Lotus and Sponsor in writing if any such action, suit, claim, investigation or legal or administrative proceeding is threatened or commenced for Principal Investigator's debarment.
Details of Principal Investigator's responsibilities are set forth in the Protocol and on Exhibit A attached hereto.

1.3 **SMO (Site Management Organisation)**
SMO will provide the manpower services like clinical research co-ordinator(s) (hereinafter "co-ordinators") for clinical study. Such number of co-ordinators will be appointed by the institution and PI as and when required for the clinical study. All such co-ordinators will perform their services under the direction and supervision of the Institution and PI. The consultant will provide the number and details of the co-ordinators appointed for clinical study to the sponsor/Lotus.

1.4 Lotus will provide the PI with all the information, documents, and materials which, in Lotus' reasonable opinion, are required in order to carry out activities in a clinical trial.
Lotus transfers the obligations, explicitly detailed in **Exhibit A** to this Agreement, for this clinical study to the PI and the PI accepts the same and shall diligently carry them out along with other obligations under this Agreement. The PI will take all reasonable steps to ensure that personnel used to perform his/her obligations under this Agreement are appropriately trained and qualified.

1.5 Records and Reports.
Principal Investigator and Institution shall have the following record keeping and reporting obligations:
(i) preparation and maintenance of complete, accurately written records, accounts, notes, reports and data relating to the Study under this Agreement; and
(ii) preparation and submission to Lotus and Sponsor (in a periodic and timely manner during the term of this Agreement) of all raw data and other material called for in the Protocol in the form of properly completed patient case report forms ("Case Report Forms") or into an electronic database (i.e., remote data entry) supplied by Sponsor for each patient as provided in the Protocol. Case Report Forms and the electronic database shall be the exclusive property of Sponsor.

Principal Investigator and Institution agree to notify Sponsor and Lotus within one day after learning of any serious and/or unexpected adverse drug reaction affecting any patient in the Study. Principal Investigator and Institution further agree to follow up such notification of adverse drug reaction with appropriate reports in compliance with the Protocol and all applicable legal and regulatory requirements. In the event Principal Investigator and Institution become aware of any quality complaints

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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associated with the Study Drug provided under this Agreement, they agree to notify Sponsor in compliance with the Protocol.

Principal Investigator and Institution further agree to conduct the Study and maintain records and data during and after the term or early termination of this Agreement in compliance with all applicable legal and regulatory requirements, including without limitation, any applicable requirements of the FDA that are provided to Principal Investigator, local regulations, applicable GCP and per the directions of Lotus. Principal Investigator and Institution further agree to permit Sponsor or Sponsor's representatives to examine and audit all records and reports, with prior written notification from Sponsor and during normal business hours (subject to applicable patient confidentiality considerations). Principal Investigator and Institution agree to take any action necessary, as reasonably requested by Lotus and Sponsor, to properly correct or address any deficiencies noted during any audit and agree to cooperate with Lotus and Sponsor with respect to any action taken to address any such deficiencies.

Principal Investigator or Institution agree to notify Sponsor within twenty-four (24) hours in the event that the FDA or any other regulatory authority notifies the Study site of a pending inspection/audit. In addition, Principal Investigator and Institution will forward to Lotus and Sponsor any written communication received as a result of the inspection/audit within twenty-four (24) hours of receipt of such communication and agrees to allow Lotus and Sponsor to assist in responding to any citations. Such responses shall be made within two (2) weeks of issuance of any citations or within any earlier deadline set by the issuing regulatory authority. Principal Investigator and Institution shall also provide to Lotus and Sponsor copies of any documents provided to any inspector or auditor. In the event the FDA or other regulatory authority requests or requires any action to be taken to address any citations, Principal Investigator and Institution agree, after consultation with Lotus and Sponsor, to take such action as necessary to address such citations, and agree to cooperate with Lotus and Sponsor with respect to any such citation and/or action taken with respect thereto.

1.6 **Project Monitor and Inspection Rights.** It is agreed that the project monitor(s) and others designated by Lotus and/or Sponsor may, at mutually agreeable times during the Study and for a reasonable time after completion or early termination of the Study, arrange with Principal Investigator or his/her designee:

(i) to examine and inspect, at regular business hours, Institution facilities required for performance of the Study; and

(ii) subject to applicable patient confidentiality considerations, to inspect, audit, and to copy or have copied, all data and work product relating to the Study conducted under this Agreement and to inspect and make copies of all data necessary for Lotus and Sponsor to confirm that the Study is being conducted in conformance with the Protocol and in compliance with all applicable legal and regulatory

requirements, including without limitation, any applicable FDA requirements that Lotus and/or Sponsor has provided in writing.

Institution agrees to assist Lotus and Sponsor in order to facilitate the Lotus and Sponsor representatives' examination, inspection, auditing and copying of materials relating to the Study and in order to enforce the rights granted to Sponsor as per ICH Guidelines.

1.7 **Clinical Trial Approvals.**

Institution and Principal Investigator shall be responsible for obtaining the following:

(i) approval of the Protocol, any informed consent relating to the Study and advertisement, if any, pertaining to the enrolment of subjects in the Study by the appropriate Ethics Committee ("EC") prior to beginning any Study on human subjects; and

(ii) an informed consent which complies with all applicable laws and regulations signed by or on behalf of each human subject prior to the subject's participating in the Study. Additionally, Institution and Principal Investigator shall also obtain an audio-visual recording of the informed consent process of each Study subject while maintaining principles of confidentiality.

In the event the EC requires changes in the Protocol or informed consent, Lotus and Sponsor shall be advised in advance and all modifications to the Protocol and informed consent must be approved in advance by Sponsor. Institution and Principal Investigator shall not modify the Study described in the Protocol once finalized and after approval by the EC without the prior written approval of Sponsor.

2. Payment

2.1 The total fees and expenses payable by Lotus to the Institution/ SMO for the services set forth herein shall not exceed the Budget as per **Exhibit B**. However the payment to the SMO will be adjusted against the payment to the institution/site on a pro rata basis. The payments set forth in the budget are acknowledged by the Parties hereto to be adequate consideration for the work taken hereunder.

2.2 Lotus shall pay the Institution and SMO against the submission of the invoice in accordance with the terms set forth herein after deducting there from any tax as applicable.

2.3 Payment shall be made by account payee Cheque/ DD /NEFT only.

2.4 Institution agrees that, in the event of a dispute regarding Sponsor and Lotus' approval of documentation supporting costs incurred under this Agreement, data and information resulting from the Study cannot be withheld by Institution or Principal Investigator prior to the resolution of the dispute because such withholding of data may cause irreparable harm to Sponsor. The Institution further agrees to use reasonable efforts to resolve any disputes of this type in a timely manner.

3. Term

This Agreement shall commence on the date of execution and shall continue until the date of payment of the last sum due hereunder or until the date when the last services required to be performed hereunder are performed, whichever date shall last occur, unless terminated earlier as provided herein.

4. **Termination and Consequences of Termination**

Termination:

4.1 Either Party may terminate this Agreement without any notice, only for subjects' safety or medical reasons.

4.2 Either Party may terminate this Agreement by written notice of sixty (60) days to the other Party without assigning any reason thereof and **with no penalty on either side**.

4.3 Either Party may terminate this Agreement for cause upon thirty (30) days prior written notice, provided the Party receiving such notice has neither remedied nor sufficiently explained the breach within the period specified in the notice. Notices shall be deemed delivered upon receipt by the recipient designated for each party. "Cause" shall be defined to include a material breach of this Agreement, a material violation of the Protocol, or a lack of enrolment of the stated study participant population, as described in Section 1.1.

4.4 Any failure by a Party to carry out all or part of its obligations under this Agreement resulting in such detriment to the other Party as to substantially deprive such other Party of what it is entitled to expect under this Agreement, shall be considered a substantial breach for the purpose of clause 4.3 above.

4.5 Upon receipt of a written termination notice, both the parties will work diligently, in good faith and in cooperation with each other, to conduct the orderly termination of the services set forth under this Agreement.

Consequences of Expiry or Termination:

4.6 Unless terminated pursuant to Section 4.3 above, upon the expiry or termination of this Agreement, Lotus shall, in accordance with the payment provisions of Clause 2, pay for all reasonable, verifiable and completed activities up to the date of actual termination. In no event will payments made by Lotus to the PI under this Agreement exceed the project costs as set forth in the Study Budget.

4.7 Upon expiry or termination of this Agreement, the Institution and PI shall, at Lotus' option, either immediately transfer to Lotus or destroy any or all Confidential Information, including any copies thereof, except for those materials or copies that are required by law or regulation or for archival purposes.

4.8 The expiry or termination of this Agreement shall not relieve any Party of its obligation to the other with respect to:

(i) retaining in confidence all Confidential Information;
(ii) complying with record keeping and reporting obligations;
(iii) complying with any publication obligations and obtaining any written approval and consents for any publicity and promotional purposes;
(iv) complying with obligations relating to clinical supplies;
(v) indemnification and insurance obligations;
(vi) inspection rights; and
(vii) the obligation to assist in obtaining patent protection

all of which obligations are binding on the appropriate party and shall remain in full force and effect as set forth in this Agreement.

5. **Intellectual Property Ownership, Invention & Discoveries and Publication**

5.1 **Inventions and Patents**. The sole and exclusive right to any inventions, discoveries or innovations, whether patentable or not, arising from the performance of the Protocol and Study under this Agreement, and using Study funds or otherwise arising out of use, misuse or modification of the Study Drug provided under this Agreement (the "**Inventions**"), shall be the property of the Sponsor. Institution or Principal Investigator will promptly notify Sponsor in writing of any such Inventions, and at Sponsor's request and expense Institution and Principal Investigator will cause to be assigned to Sponsor all right, title and interest in and to any such Inventions and provide reasonable assistance to obtain patents, including causing the execution of any invention assignment or other documents.

5.2 **Data Ownership**. All case report forms and other data (including, without limitation, written, printed, graphic, video and audio material and information contained in any computer data base or computer readable form) generated by the Institution and the PI in the course of conducting the Study (the "**Data**") and results shall be the exclusive property of Sponsor, and Sponsor reserves the right to use the Data and results for any corporate purpose

5.3 The PI acknowledges that all the intellectual property rights in the Confidential Information of and belonging to Sponsor and/or Lotus which is disclosed to the PI is and shall always remain the sole and exclusive property of Sponsor and/or Lotus.

5.4 **Publication.**
As this is a multi-center study, publications derived from this Study must include input from one or more investigators, their colleagues, Lotus and Sponsor personnel. Such input shall be reflected in publication authorship, and agreement regarding order of authors shall be established before writing a manuscript. Unless specifically approved by Sponsor, results from a single center in a multi-center study will not be submitted for publication separately before results of the multi-center study are published, unless (1) more than eighteen (18) months have elapsed since completion of the Study, and (2) the Institution provides Sponsor with a proposed manuscript for review

and comment prior to publication. Sponsor shall complete review within sixty (60) days of receipt of a manuscript, during which time Institution shall not permit publication or presentation. Sponsor shall notify Institution of any comments, deletions or modifications requested in the proposed manuscript to protect its proprietary rights, and Institution shall make any such changes reasonably requested by Sponsor.

In the event Sponsor, pursuant to this Section elects to file one or more patent applications relating to any invention made in the course of the Study, any publications and presentations will be delayed for an additional ninety (90) days to permit the preparation and filing of such patent applications.

Subject to the publication restrictions in this Agreement, Institution shall have the right to use the results of the Study provided by Institution under this Agreement, including, but not limited to the results of tests and any raw data and statistical data generated therefrom, for its own internal teaching and research purposes.

6. Representations.

6.1 The PI hereby warrants and represents that the following are true and correct on the date of entering into this Agreement:

(i) The PI is an individual and has the requisite qualification, legal power to enter into this Agreement and to perform his/her obligations hereunder. This Agreement, when duly executed, shall constitute the legal, valid and binding obligation on the PI and is enforceable against the PI in accordance with its terms;

(ii) All acts and conditions required by the laws in force at the date thereof to be done, fulfilled and performed in order (i) to enable him/her lawfully to enter into this Agreement and to exercise his/her rights and perform his/her obligations under this Agreement and (ii) to make this admissible in evidence have been done, fulfilled and performed in strict compliance with the applicable laws.

7. Indemnification.

7.1 Sponsor shall indemnify, defend and hold harmless Institution, its trustees, officers, agents, employees and Principal Investigator, (and any named co-investigator) from and against any demands, claims, actions, proceedings or costs of judgments ("**Claims**") which may be made or instituted against any of them by reason of personal injury (including death) to any person, or damage to property, arising out of or connected with the performance of the activities to be carried out pursuant to the Protocol.

Notwithstanding the foregoing, Sponsor shall have no indemnification obligation or liability and Institution and Principal Investigator shall indemnify, defend and hold harmless Sponsor, its parent corporation, subsidiaries, affiliates, officers, directors, agents, and employees for loss or damage resulting from:

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(i) failure of Institution or Principal Investigator to adhere to the terms and provisions of the Protocol or agreed amendments thereto or Sponsor's written recommendations and instructions relative to the administration and use of any drug substances involved in the Study, including, but not limited to, the Study Drug, any comparative drug and any placebo;

(ii) failure of Institution or Principal Investigator to comply with any applicable FDA or other governmental or state requirements, law, rules, ICH Guidelines or regulations applicable to the performance of its obligations under this Agreement;

(iii) failure of Institution or Principal Investigator to render professional service or to conduct the Study in a normal, prudent manner; or

(iv) negligent act or omission or willful misconduct by Principal Investigator, Institution, its trustees, officers, agents or employees related to the performance of services under this Agreement.

7.2 Institution agrees to indemnify and hold Sponsor and Lotus harmless from liability for any claim, demand or lawsuit arising out of (i) the willful, reckless or negligent act or failure to act of Institution (including failure to comply with the terms of the Study Protocol), or (ii) the breach of any of the Institution's or PI's covenants or representations contained in this Agreement.

7.3 Institution and/or Principal Investigator shall secure and maintain in full force and effect through the performance of the Study (and following termination or early termination of the Study to cover any claims arising from the Study) insurance coverage in amounts as required by applicable legal requirements and appropriate to the conduct of Institution's and Principal Investigator's activities and the services contemplated by the Study. Upon request of Lotus or Sponsor, copies of certificates evidencing such insurance coverage will be made available to Sponsor. Institution and/or Principal Investigator shall provide thirty (30) days' prior written notice to Lotus and Sponsor in the event of cancellation or any material change in such insurance.

7.4 These indemnification obligations of the Parties shall only apply provided that in regards to the Claim (i) the indemnified party promptly notifies the indemnifying party of such Claim; (ii) the indemnified party allows the indemnifying party and/or its insurers the right to assume direction and control of the defense (including settlement) of any such claim, demand or lawsuit (the indemnifying party shall not admit fault on any one or all of the indemnified party's behalf without the indemnified party's advance written permission); (iii) the indemnified party cooperates fully with the indemnifying party and/or its insurers in the defense of such claim, demand or lawsuit; and (iv) the indemnified party agrees not to settle or

compromise any claim, demand or lawsuit without prior written authorization of the indemnifying party.

8. Confidentiality

8.1 Upon execution of this Agreement a confidential relationship shall exist between Lotus, Sponsor, Institution and Principal Investigator and SMO, whereby Institution and Principal Investigator and SMO agree to hold in confidence confidential information disclosed by Lotus and/or Sponsor, in connection with the Study. As used in this Agreement "Confidential Information" shall be understood to include information disclosed by Lotus and/or Sponsor which is not in the public domain, including but not limited to: technical, scientific, market and marketing information, know-how, data, formulae, processes, plans, assessments and methods for Study Drug and/or its uses or modes of action, as well as similar information relating to any other Sponsor compound. Confidential Information shall also include all test articles and proprietary data and/or information generated pursuant to the Study, including, but not limited to the Protocol, the investigator's brochure, interim results and any other information or material disclosed under secrecy agreements preciously entered into by the Parties. For purposes of this Agreement, Confidential Information supplied by Lotus and/or Sponsor to Institution shall be deemed to be in the public domain or in the possession of Institution only if the Confidential Information as a whole is in the public domain or in the prior possession of Institution.

8.2 Confidential Information shall not be deemed to include information which: (i) is in or enters the public domain through no act or omission of Institution; (ii) is lawfully in Institution's or Principal Investigator's possession prior to disclosure, which possession can be documented through business records maintained in the ordinary course of Institution's business; (iii) is obtained by Institution or Principal Investigator from a third party having an apparent lawful right to provide such information and having no known obligation of confidentiality to Lotus or Sponsor; (iv) is independently developed by Institution personnel not privy to Lotus or Sponsor Confidential Information, as applicable, disclosed under this Agreement; or (v) is required by law to be disclosed.

8.3 Institution and Principal Investigator shall limit disclosure of Confidential Information received hereunder to only those of its (i) representatives, agents and officers bound by a written agreement with terms equivalent to or more stringent than this Agreement, and (ii) employees (collectively, "**Agents**") who are directly involved with the Study and only on a need to know basis. Institution and Principal Investigator shall advise its Agents upon disclosure to them of any Confidential Information of the proprietary nature thereof and the terms and conditions of this Agreement and shall use all reasonable safeguards to prevent unauthorized use or disclosure by such Agents. Institution and Principal Investigator shall be responsible for any breach of these confidentiality provisions by its Agents.

8.4 Institution and Principal Investigator acknowledge and expressly agree that any disclosure of Confidential Information in violation of this Agreement would be detrimental to Sponsor's business and cause it irreparable harm and damage. In accordance with applicable law and in addition to any other rights and remedies provided herein, Sponsor shall be entitled to seek equitable relief by way of injunction or otherwise.

8.5 The disclosure of Confidential Information to Institution and Principal Investigator shall not be construed in any way as a license or transfer of other rights.

9. Miscellaneous

9.1 **Governing Law**

This Agreement and the rights and obligations of the parties hereunder shall be governed by and construed in accordance with the laws of **India.**

9.2. **Arbitration**

Any dispute, controversy or claim arising out of or in connection with this agreement including any question regarding its existence, validity, interpretation or termination, shall be conclusively settled by referring the same to arbitration. The arbitration proceedings shall be conducted in the English language and be governed by the provisions of the Arbitration and Conciliation Act, 1996. The venue for arbitration proceedings shall be **Bangalore.**

9.3 **Force Majeure (Act of God)**

In the event either Party is delayed or hindered in or prevented from the performance of any act required hereunder by reasons of restrictive government or judicial orders or decrees, riots, burglary, insurrection, war, acts of God, inclement weather or other similar reasons or causes beyond such Party's control, and such Party has exerted all reasonable efforts to avoid or remedy such event, then performance of such act shall be excused for the period of such delay (which is reasonable and consented by the other Party in writing). Notice of the start and stop of any such force majeure shall be provided to the other Party.

9.4 **Record Keeping**

During the term of this Agreement, PI shall maintain all materials and all other data obtained or generated by PI in the course of providing the services in a secure area reasonably protected from fire, theft and destruction.

9.5 **Headings.**

The headings used in this Agreement are for the sake of convenience and the same are not to be construed to define, limit or affect the construction of interpretation of this Agreement.

9.6 **Publicity.**

Except as required by applicable law, neither Institution nor PI shall use, or authorize others to use, the name, symbols, or marks of Sponsor in any advertising or publicity material or make any form of representation or statement in relation to the Study, which would constitute an express or implied endorsement by Sponsor of any commercial product or service without prior written approval from Sponsor.

9.7 **Independent Contractors.**

It is agreed by the parties that Institution and Principal Investigator are acting in the capacity of independent contractors hereunder and not as employees, agents or joint venturers of or with Sponsor. Neither Institution nor Principal Investigator shall have any authority to represent, bind or act on behalf of Sponsor. Institution represents that Principal Investigator is an employee of the Institution. Investigator acknowledges and agrees that Principal Investigator's sole recourse for compensation for his or her services, as well as the services of Principal Investigator's staff affiliated with the Study, shall be from Institution and not Watson.

9.8 **Assignment.**

This Agreement is, not assignable by Institution or Principal Investigator and any attempted assignment or delegation in violation hereof shall be void. Sponsor may assign this Agreement to an affiliated company without the prior consent of Institution or Principal Investigator. Notwithstanding such assignment, Sponsor shall remain liable for all of its obligations under this Agreement.

9.9 **No Modifications.**

Neither this Agreement nor the Protocol may be altered, amended or modified except by written document signed by the Parties.

9.10 **Severability.**

If any term or condition of this Agreement, the deletion of which would not adversely affect the receipt of any material benefit by a Party hereunder, shall be held illegal, invalid or unenforceable, the remaining terms and conditions of this Agreement shall not be affected thereby and such terms and conditions shall be valid and enforceable to the fullest extent permitted by law.

9.11 **No Waiver.**

Failure on the part of a Party to exercise or enforce any right conferred upon it hereunder shall not be deemed to be a waiver of any such right nor operate to bar the exercise or enforcement thereof at any time or times thereafter.

9.12 **Compliance with Anti-Corruption Laws**

(i) PI, Institution and SMO agrees to comply with applicable anti-corruption laws such as the U.S. Foreign Corrupt Practices Act (FCPA) and the UK Bribery Act of 2010 as well as any laws implementing the U.N. Convention Against Corruption and the OECD Anti-bribery Convention (collectively, "**Anti-Corruption Laws**"). PI, Institution and SMO undertakes that, in connection with its performance of its obligations under this Agreement, they will not and shall not directly or indirectly (a) offer, provide, authorize for or promise to another person, or (b) request, accept or agree to accept from another person any financial or other advantage or anything of value ("**Benefit**"), if such Benefit is for the purpose of influencing the receiving person improperly in his or her official capacity for the purpose of obtaining a business advantage, or where such Benefit would constitute a violation of any applicable Anti-Corruption Law.

(ii) In the event that PI, Institution and SMO is accused of or becomes subject to investigation by a governmental authority for an alleged violation of applicable Anti-Corruption Laws in connection with this Agreement, or LOTUS notifies PI and Institution that it has a reasonable basis for believing that PI, Institution and SMO has not complied with applicable Anti-Corruption Laws in connection with this Agreement (and discloses in reasonable detail the evidence underlying such belief), LOTUS shall have the right to request in writing that PI, Institution and SMO provide access to (either directly or through legal counsel or an internationally recognized independent auditor) such written records or other information reasonably required to credibly refute such alleged non-compliance.

(iii) If, in connection with this agreement, PI and Institution breaches its obligations under Sections 9.12(i) and 9.12(ii) above or admits to a violation or is determined by a governmental authority to have violated applicable Anti-Corruption Law, then LOTUS shall be entitled to immediately terminate this Agreement upon written notice to PI, Institution and SMO

By signing this agreement "You are required to refer and adhere to our Business Partner Guide hosted on our website. URL for the same is http://www.lotuslabs.com/Uploads/Lotus_business_partner_guide.pdf. It gives our expectations with regard to your conduct as a Lotus Business Partner."

9.13. **Notices & Service of documents**

The notice and documents required to be given under this Agreement shall be deemed to be sufficiently given if hand delivered by one Party to the other or sent by Registered Mail with acknowledgement due.

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Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

All the correspondence/ notices to be sent by the PI to Lotus shall be addressed to:

Lotus Labs Pvt. Ltd.
No. 7, Jasma Bhavan Road,
Millers Tank Bed Area,
Opp. Gurunanak Bhavan,
Vasanthnagar,
Bangalore – 560 052
Phone No. 080-22370982/22370912/13/14/15
Fax No. 080-2237091

All the correspondence/ notices to be sent by Lotus to PI shall be addressed to:

Dr. Smitha KS, "KLES Dr. Prabhakar Kore Hospital and Medical Research Centre, Nehrunagar, Belgaum-590010.

For LOTUS LABS PVT LTD

24/07/15	12/08/2015	07/08/15	
S. Hari Sankar **Managing Director**	**Dr. Mallikarjun V. Jali** **Managing Director**	**Dr. Smitha K.S.** **Principal Investigator**	**A.V.A.Suresh Babu** **Director** **CMS Clinical Pvt. Ltd. (SMO)**
Seal: LOTUS LABS PVT. LTD. BANGALORE	**Seal:** Medical Director & Chief Executive Officer KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, BELAGAVI	**Seal:** Dr. Smitha K.S. Consultant in Ophthalmology Dr. Prabhakar Kore Hospital & MRC, BELGAUM.	**Seal:** CMS CLINICAL PVT. LTD. MYD.
Witness	**Witness**	**Witness**	**Witness**
Venkatesh. Hegde Executive Legal	Prashant Bandiwadi	Dr. Vishwendra Sisodia.	K. Kiran Kandhan.

Exhibit A

Responsibilities of PI for

"An Open Label, Randomized, Multicentric, Two Treatment, Single Dose, Parallel Group Two Stage Adaptive Design Bioequivalence Study Of Loteprednol Etabonate Ophthalmic Suspension, 0.5 % In Aqueous Humor Of Patients Undergoing Indicated Cataract surgery." bearing the protocol / study number: WAT/LTPNL/2015.

1. PI has sufficient time, adequate staff, and appropriate facilities to conduct and complete the clinical study. PI agrees to make these resources available for the duration of the study and agrees that other studies will not divert essential subjects or facilities away from this trial.

   PI assures Lotus Labs Pvt. Ltd., that no other clinical study conducted by him shall give rise to a conflict of interest or interfere with the clinical trial.

   PI will endeavor to ensure an adequate recruitment rate during the clinical investigation.

2. Lotus Labs Pvt. Ltd. will furnish PI with copies of the Investigator's Brochure, the Study Plan and Protocol and agrees:

   a. To become thoroughly familiar with the properties of the investigational product as described in the Investigator's Brochure, which provides full information concerning the pre-clinical investigations that justify clinical studies, together with informative material describing any prior investigations, side effects, and precautions to be taken into account in the course of the clinical investigation; and
   b. To become well acquainted with the Study Plan before signing it.

3. PI agrees to make the necessary arrangements, including provisions for emergency treatment, to ensure the proper conduct of the study.

4. PI understands that along with the Institution, he will have primary responsibility for the accuracy, legibility, and security of all study data, documents, and subject records both during and after the study. PI will be responsible for electronic signature of the Electronic Case Report Forms (e-CRF).

   PI agrees to abide by the following conditions governing his/her handling of the data associated with this study.

   a. PI is required to maintain adequate records regarding all investigational product received and used by him/her including batch numbers, dates, and quantities. If the study is terminated, suspended, discontinued, or completed, PI shall return to Lotus Labs Pvt. Ltd., any unused supplies other than retention samples unless other arrangements are made by Lotus Labs Pvt. Ltd.

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Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

b. PI is required to prepare and maintain adequate and accurate patient case histories, recording all observations and other data pertinent to the clinical investigation of each subject in the clinical study.

c. PI understands to furnish records of the study to Lotus Labs Pvt. Ltd./Sponsor.

d. PI will maintain records of the disposition of the investigational product and other records for the longer of the following periods:
   I. the period defined by national or local law and rules
   II. five years after the study is terminated or completed, or
   III. Five years after the records are no longer required for purposes of supporting the relevant United States, other national, European (EU), or other international regulatory applications.
   IV. To avoid any possible errors PI will contact Lotus Labs Pvt. Ltd. prior to the destruction of records or in the event of accidental loss or destruction of any Study records.

e. PI, along with Institution, agrees to provide accurate information to the Ethics Committee upon request. PI, along with Institution, also agrees to provide accurate information to the regulatory authorities upon their request and within the scope of the agencies' authorities and ethical obligations, as set forth below:

   I. The patient's identity will not be released except under the following limited circumstances
      i. Upon the request of a scientifically trained and specifically authorized employee of national or international regulatory agencies, PI will make records related to the clinical study available for inspection and copying

   II. Where data verification procedures demand inspection of patient's personal identity or personal medical information, in which case this inspection may be performed only by a properly authorized person

   III. The patient's identity shall not be released to third parties without the patient's and/ or impartial witness prior consent. Accordingly, the study patient's and/ or impartial witness consent to the potential release of patient identity information to regulatory bodies for data verification purposes will be obtained as part of the informed consent procedure.

5. PI agrees to be responsible for submitting the Investigational Protocol for opinion or approval, to an appropriate Ethics Committee and shall transmit the results to Lotus Labs Pvt. Ltd.

   PI shall not commence the study without an approval or favorable opinion from the Ethics Committee of the Investigational Protocol, informed consent forms, subject

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KLE Academy of Higher Education and Research, BELAGAVI

recruitment procedures, and any written material to be provided to the patient's and/ or impartial witness.

PI shall provide the Institutional Ethics Committee or Institutional Review Board with all required information.

6. PI certifies that the investigational products for clinical investigation will be provided only to patient under his personal supervision or under the supervision of the Co-investigator/ Sub-investigator (if any) responsible to him.

   PI further certifies that the investigational products will not be supplied by him to any investigator, other than those listed above as Co-Investigator/ Sub-investigators, or to any clinic, medical facility, or study site for use.

7. No procedure will be performed until all personnel have been properly trained.

8. PI shall be responsible for completing and signing the FDA form 1572.

9. PI agrees to be responsible for the personal safety and well-being of the subjects. To this end, PI agrees to abide by the Declaration of Helsinki and their subsequent amendments, national policy, and the following conditions governing the ethical treatment of subjects in this clinical investigation:

   Following national policy and the Declaration of Helsinki, informed consent shall be documented by the subject or subject's legal representative with dated signature:

   a. PI ensures that patient and/ or impartial witness or their guardians receive adequate information to make informed consents. This information will be provided both in oral and in written form and shall be in a form easily understood by the patient's and/ or impartial witness. Additionally, as required by Indian law, Principal Investigator shall also obtain an audio-visual recording of the informed consent process for each Study subject. Such process shall be undertaken while maintaining principles of confidentiality.

      The informed consent information shall include the aims, expected benefits, risks and inconveniences of the clinical investigation, an explanation of any alternative methods or treatments available, and an explanation of possible consequences of any withdrawal from the clinical investigation.

   b. PI will ensure that the patient and/ or impartial witness are given the opportunity to inquire about the details of the clinical study. The information given to the subject /subject's legal representatives shall make clear to them that they remain free to refuse to participate in and free to withdraw from the clinical study at any time without any sanction. PI will make an effort to ascertain the reasons for any

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withdrawal while fully respecting the subject's and/ the subject's legal representative's rights.

c. PI will ensure that the patient and/ or impartial witness are provided adequate time to decide whether or not they wish to participate/ wish their ward to participate in this clinical investigation.

10. PI will discuss with Lotus Labs Pvt. Ltd. any question of modification of the study plan and obtain Lotus Labs Pvt. Ltd./ Sponsor written agreement and also approval from the ethics committee prior to implementation of any modification. PI will not proceed with a non-emergency deviation from the Clinical Protocol without approval from Lotus Labs Pvt. Ltd. and as needed the Ethics Committee. It is PI's responsibility to inform the Ethics Committee about any protocol amendment or any significant change in the Investigational Plan or Protocol that has been approved by Lotus Labs Pvt. Ltd., including the reason for the change, and to obtain the Ethics Committee's approval or favorable opinion regarding the change.

11. PI will report all adverse events/ serious adverse events to Lotus Labs Pvt. Ltd./ Sponsor.

a. PI will report within one day:
   - Deviations from or changes to the protocol to eliminate immediate hazards to the study patients.
   - Changes increasing the risk to patients and/or affecting significantly the conduct of the study.
   - All adverse drug reactions (ADRs) and Adverse Events (AEs) those are both serious and unexpected.
   - New information that may affect adversely the safety of the patients or the conduct of the study.

b. All staff in contact with the patient should be aware of their responsibility to note and report all adverse events reported by the patient's and/ or impartial witness

c. The Principal Investigator or designate should assess the patient at each visit for adverse event or serious adverse event that may have occurred since the previous visit.

d. All serious adverse events (SAEs) should be reported to Lotus within 24 hours.

e. The immediate reports should be followed promptly by detailed written reports including the completed Adverse Event Forms.

f. The immediate and follow-up reports should identify patients by unique code numbers assigned to the study patients rather than by the patients' names, personal identification numbers and/or addresses.

www.lillyindia.co.in

Eli Lilly and Company (India) Pvt. Ltd.
Plot No. 92, Sector-32, Gurgaon - 122001
Haryana

Phone : +91-124-4753000
Fax : +91-124-4753012-13-14

CIN – U24239HR1993PTC034844

Date: 11-Sep-15

7(P)

To:
Dr. Shailesh Veerbhadrappa Udapudi
K.L.E.S Dr. Prabhakar Kore Hospital &
Medical Research Centre
Nehrunagar, Belgaum – 590010
Karnataka.

Sub: Status of Clinical Trial I4V-MC-JADX, I4V-MC-JADZ & I4V-MC-JADY

Dear Dr. Udapudi,

We would like to thank you for your active participation and continued interest in Eli Lilly Clinical Studies I4V-MC-JADX, I4V-MC-JADZ & I4V-MC-JADY as Principal Investigator.

The Current Status of these studies is as follows:

1. Protocol I4V-MC-JADX: LPV Achieved, Database Lock Completed and Site Closed

2. Protocol I4V-MC-JADZ: LPV Achieved, Database Lock Completed

3. Protocol I4V-MC-JADY: This is an 48 months Extension study of Feeder studies JADX and JADZ, All subjects who completed JADX and JADZ and given consent to participate in the extension has been enrolled into JADY study. JADY Study is expected to achieve LPV in India by September 2018.
   From your site we currently have 3 Active Subjects in Trial I4V-MC-JADY.

We thank you and your entire team for the active participation and support in these studies.

Regards,

Sanjay Majumdar
Senior Manager, Clinical Research
Eli Lilly & Company (India) Pvt. Ltd
Phone: +91 9871707965
Mail: majumdar_sanjay_in@lilly.com

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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Government of Karnataka

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Certificate No.	:	IN-KA78601703451461Q
Certificate Issued Date	:	05-Nov-2018 02:18 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ UTTARHALLI1/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKAKSFCL0894226271073682Q
Purchased by	:	IQVIA RDS INDIA PRIVATE LIMITED
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	IQVIA RDS INDIA PRIVATE LIMITED
Second Party	:	KLES KARNATAKA
Stamp Duty Paid By	:	IQVIA RDS INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	300 (Three Hundred only)

UTTARAHALLI SOUHARDA CREDIT CO-OPERATIVE LTD

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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 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.

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

AMENDMENT NUMBER ONE TO CLINICAL TRIAL AGREEMENT

This Amendment to the Clinical Trial Agreement ("Amendment #1") is between **IQVIA RDS (India) Private Limited**, (formerly **Quintiles Research (India) Private Limited)** having a place of business at III Floor, Etamin Block, Prestige Technology Park, Sarjapur- Marathahalli Outer Ring Road Bangalore – 560103, Karnataka, India ("**IQVIA**") and **KLES Dr. Prabhakar Kore Hospital & Medical Research Centre** having a place of business at NehruNagar, Belgavi-590 010, Karnataka, India ("**Institution**") and **Dr.Veerappa Annasaheb Kothiwale** having a place of business at KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, NehruNagar, Belgavi-590 010, Karnataka, India ("**Investigator**") and **GDD Experts India Pvt. Ltd** having a place of business at Ground floor,Gulmohar Apartment, Opposite Hislop College, Nagpur-440 001,Maharashtra,India ("**Research Company**") and is effective as of the date last signed below.

WITNESSETH:

WHEREAS, IQVIA, Institution, Investigator and Research Company are parties to an agreement entitled **PROMINENT** ***"PEMAFIBRATE TO REDUCE CARDIOVASCULAR OUTCOMES BY REDUCING TRIGLYCERIDES IN PATIENTS WITH DIABETES"*** bearing the **Protocol number K-877-302** effective as of 25 November 2017 (the "**Agreement**"), and the parties desire to amend such Agreement;

WHEREAS, IQVIA is providing clinical research organisation services to Kowa Research Institute, Inc. ("**Sponsor**") under a separate contract between IQVIA and Sponsor, and IQVIA's services include monitoring of the Study and contracting with clinical research sites;

NOW THEREFORE, in consideration of the mutual promises and covenants set forth herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties hereby agree to amend the Agreement as follows:

1. **Change in Quintiles' corporate name.** As of the Effective Date of this **Amendment #1**, following the name change described in the above recital, the parties acknowledge that:

   (a) all references to **Quintiles Research (India) Private Limited** in the Agreement shall be updated to refer to **IQVIA RDS (India) Private Limited** (formerly **Quintiles Research (India) Private Limited**) and

   (b) all references to the defined term **"Quintiles"** shall now be deemed replaced by references to **"IQVIA"**.

AMENDMENT NUMBER ONE TO CLINICAL TRIAL AGREEMENT

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   (b) all references to the defined term **"Quintiles"** shall now be deemed replaced by references to **"IQVIA"**.

2. **Change in the notice details.** Section K, on Invoices, as found in Attachment A, Budget and Payment Schedule portion of the Agreement is hereby amended by deleting it in its entirety and replacing it with the paragraph below:

K. INVOICES

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

IQVIA RDS (India) Private Limited
(formerly Quintiles Research (India) Private Limited)
Attn: Accounts Payable
Address: III Floor, Etamin Block, Prestige Technology Park,
Sarjapur - Marathahalli Outer Ring Road Bangalore – 560103,
Karnataka, India
Phone: +91 80 71317779/78

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

1. Attachment **A BUDGET & PAYMENT SCHEDULE**, Section N. Budget Table of the Agreement shall be deleted in its entirety and replaced as follows, to reflect the Protocol Amendment Visit 4 change from a phone visit to an on-site visit with the addition of the following assessments:
   - Blood sample collection
   - Lab handling and/or shipping of specimen
   - Physician, Simple (e.g. interim visits) - Per Visit
   - Patient Reimbursement, Expenses, Patient Travel - Per Visit

N- BUDGET TABLE:

Visit	Total Cost Per Visit including 20% Overhead (INR)
PreScreen	13,578
Screen	19,998
Visit 2	17,331
Visit 3	4,679
Visit 4	8,229
Visit 5	13,304
Visit 6	12,535
Visit 7	12,616
Visit 8	4,679

Visit	Total Cost Per Visit including 20% Overhead (INR)
Visit 9	13,790
Visit 10	4,679
Visit 11	12,616
Visit 12	4,679
Visit 13	12,616
Visit 14	4,679
Visit 15	13,790
Visit 16	4,679
Visit 17	12,616
Visit 18	4,679
Visit 19	12,616
Visit 20	4,679
Visit 21	13,790
Visit 22	4,679
Visit 23	12,616
Visit 24	4,679
Visit 25	12,616
Visit 26	4,679
Visit 27	13,790
Visit 28	4,679
Visit 29	12,616
Visit 30	4,679
Visit 31	12,616
Visit 32	4,679
Visit 33	13,790
Visit 34	4,679
CSED Visit	15,515
Post Study Safety Call	4,060
Retest	8,169
Off*	11,931
Total Cost Per Patient (Rs)**	357,229

* Visit can occur more than once
**The total does not include Retest & Off.

All terms and conditions of the Agreement not expressly amended by this Amendment #1 remain in full force and effect.

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Certificate No.	:	IN-KA26553303732998P
Certificate Issued Date	:	03-Nov-2017 12:31 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ RAJARAJESHWARI NAGAR1/ KA-BN
Unique Doc. Reference	:	SUBIN-KAKAKSFCL0803156565987465P
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	:	KLES KARNATAKA
Stamp Duty Paid By	:	QUINTILES RESEARCH INDIA PVT LTD
Stamp Duty Amount(Rs.)	:	300 (Three Hundred only)

SHIVABHAVA SOUHARDA PATHINA SAHAKARI NIYAMITHA BANGALORE

Please write or type below this line

ATTESTED

PROF. UMA A. KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

CLINICAL TRIAL AGREEMENT

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

KLES Dr. Prabhakar Kore Hospital & Medical Research Centre having a place of business at NehruNagar, Belagavi - 590 010, Karnataka, India (the "**Institution**"), and

Dr. Veerappa Annasaheb Kothiwale having a place of business at KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, NehruNagar, Belagavi - 590 010, Karnataka, India (the "**Investigator**"), and

GDD Experts India Pvt. Ltd at Ground Floor, Gulmohar Apartment, Opposite Hislop College, Nagpur - 440 001, Maharashtra, India (the "Research Company"), and

Quintiles Research (India) Private Limited, having a place of business at B 101-106, Shapath IV, Opposite Karnavati Club, Sarkhej Gandhinagar Road,, Ahmedabad 380051, Gujarat, India ("**Quintiles**"),

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

Protocol Number:	K-877-302
Protocol Title:	PROMINENT PEMAFIBRATE TO REDUCE CARDIOVASCULAR OUTCOMES BY REDUCING TRIGLYCERIDES IN PATIENTS WITH DIABETES
Protocol Date:	16 November 2016
Sponsor:	Kowa Research Institute, Inc.
Country where Site is Conducting Study	India
Investigator:	Dr. Veerappa Annasaheb Kothiwale *"an employee of Institution"*
Key Enrollment Date:	**100 Calendar Days after Site Initiation Visit date (being the date by which Site must enroll at least one [1] subject as more specifically set out in section 1.8 "Key Enrollment Date" below)**
IRB/IEC	Ethics Committee of KLE University, Belagavi, JNMC Campus, NehruNagar, Belagavi-590 010, Karnataka, India EC chairperson name : Dr. Subarna Roy Contact No. of the EC chairperson: +91-9449033133

The following additional definitions shall apply to this Agreement:

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

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

Study: the clinical trial that is to be conducted in accordance with this Agreement and the Protocol for purposes of gathering information about the Investigational Product identified in the Protocol.

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

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

Investigational Product: the investigational drug identified in the Protocol that is being tested in the Study.

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

Sponsor: an individual, institution, company or organization that takes the responsibility to initiate, manage or finance the Study, but does not actually conduct the Study.

Medical Records: the Study Subjects' primary medical records kept by the Institution on behalf of the Investigator.

Source Documents: all recorded original observations and notations of clinical activities and all reports and records necessary for the evaluation and reconstruction of the Study, regardless of form, as maintained by the Investigators, including all laboratory reports, ECG tracings, x-rays, radiologist reports, biopsy reports, ultrasound photographs, Study Subject progress notes, hospital charts, pharmacy records and any other similar reports or records of any procedure performed during the Study. Source Documents include workbooks only when information is recorded directly onto such forms. In the event that the workbook is used as a Source Document by a physician not identified as a primary or secondary investigator in the Protocol or not under the direct supervision of the Investigator, the workbook must be signed and dated by the individual making the entry.

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

Study Data: all data relating to Subjects that are, collected by or on behalf of the Site in connection with the Study.

Study Documentation: all (i) Source Documents, (ii) Study Data and, (iii) to the extent not included in (i) or (ii), all records, accounts, notes and reports relating to the Study, whether in written, electronic, video or other tangible form, including: Case Report Forms; data correction forms; monitoring logs; appointment schedules; case histories; informed consent forms and related documentation; records of receipt, use, processing and disposition of the Investigational Product approvals of (a) the applicable Protocol and any amendments thereto and (b) the informed consent forms by the Investigator, Site and the IRB/IEC; copies of all correspondence to or from Quintiles related to the Study; the Investigator, any other Study Staff, any IRB/IEC and any Governmental Official with respect to the Study; any other documentation required by the Protocol, this Agreement, or Applicable Law. While "Study Documentation" may include information derived from a Study Subject's Medical Record, "Study Documentation" does not include any portion of the Medical Record.

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

healthcare professional who works for or in any hospital, pharmacy or other healthcare facility owned or operated by a government agency, ministry or department.

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

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

RECITALS:

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

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

NOW THEREFORE, the following is agreed:

1. CONDUCT OF THE STUDY

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

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

1.2. Informed Consent Form

Site agrees to use an informed consent form ("**ICF**") that has been reviewed by Sponsor and is approved by and in accordance with applicable regulations and the requirements of the Institutional Review Board ("**IRB**") or Independent Ethics Committee ("**IEC**") that is responsible for reviewing the Study. Prior to a Study Subject participating in the Study,Site shall obtain from such Study Subject a properly executed ICF.

1.3. Medical Records and Study Documentation

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

Site shall

(i) maintain and store Medical Records and Study Documentation in a secure manner with physical and electronic access restrictions, as applicable and environmental controls appropriate to the applicable data type and in accordance with Applicable Laws, and industry standards; and

(ii) protect the Medical Records and Study Documentation from unauthorized use, access, duplication, and disclosure. If directed by Sponsor or Quintiles, Site will

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Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

submit Study Documentation using the electronic system provided by Sponsor or Quintiles or their designated representative and in accordance with Sponsor's instructions for electronic data entry. Site shall prevent unauthorized access to the Study Documentation by maintaining physical security of the electronic system and ensuring that Study Staff maintain the confidentiality of their passwords. Investigator agrees to collect all Study Documentation in Medical Records prior to entering it into the CRF. Site shall ensure the prompt submission of CRFs; and

(iii) take measures to prevent accidental or premature destruction or damage of these documents, for as long as required by Applicable Law. . Neither Institution nor Investigator shall destroy or permit the destruction of any Medical Records or Study Documentation and Institution shall continue to store Medical Records and Study Documentation, at the Sponsor's expense, for any period that the Sponsor may request in writing after retention is no longer required by any Applicable Law.

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

1.3.2. Ownership. Institution shall retain ownership of Medical Records. Subject to Applicable, Laws, Sponsor shall have the right to access, use and disclose the Medical Records during the term of this Agreement and thereafter. The Institution and the Investigator hereby assign to Sponsor all of their rights, title and interest, including intellectual property rights, to all Confidential Information (as defined below) and any other Study Documentation.

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

Site shall afford regulatory authorities reasonable access to Site's facilities and to Medical Records and Study Documentation, and the right to copy Medical Records and Study Documentation.

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

The Site shall immediately notify 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 (i) cooperate with any regulatory authority regarding an audit or inspection related to such Study, including audit or inspection of Site, (ii) permit Quintiles and Sponsor to attend any such inspections or audits and permit Sponsor and Quintiles to assist Site in responding to any such inquiries, correspondence or communications, (iii) promptly provide copies of any documents, correspondence, reports and other materials to or from the regulatory authority and/or the Institution relating to the audit, inspection, or regulatory action and (iv) keep apprised of the regulatory action, audit, or inspection and the accompanying findings and response in a timely manner. The Site will make reasonable efforts to separate, and not disclose, all Confidential Information that is not required to be disclosed during such inspections.

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

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

1.4. Duties of Investigator

Investigator is responsible for the conduct of the Study at Institution and for supervising any individual or party to whom the Investigator delegates Study-related duties and function. In particular, but without limitation, it is the Investigator's duty to review and understand the information in the Investigator's Brochure or device labeling instructions, to ensure that all informed consent requirements are met, to ensure that all required reviews and approvals by applicable regulatory authorities and IRBs or IECs are obtained, and to review all CRFs to ensure their accuracy and completeness. If Investigator is an employee of Institution or an affiliate of Institution, then Institution shall ensure that Investigator complies with the terms and conditions of this Agreement and shall be responsible for Investigator's performance of this Agreement and the Study.

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

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

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

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

1.5. Adverse Events

The Site shall report adverse events and serious adverse events as directed in the Protocol and by Applicable Law. The Site shall cooperate with Sponsor in its efforts to follow-up on any adverse events. The Site shall comply with the applicable IRB/IEC reporting obligations.

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

1.6. Use and Return of Investigational Product and Equipment

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

The Site shall use the Investigational Product and any comparator products provided in connection with the Study, solely for the purpose of properly completing the Study and shall

maintain the Investigational Product as specified by Sponsor and according to Applicable Law, including storage in a locked, secured area at all times.

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

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

Based on assessment of Site's facilities and needs in connection with the conduct of the Study, Sponsor may provide to Site certain electronic and other equipment as necessary (the "**Equipment**") solely for use in performance of the Study. Such Equipment may be leased by Sponsor and provided to Site through a third party ("**Lessor**") on behalf of Sponsor or provided directly by Sponsor to Site. Equipment shall be returned to Lessor or Sponsor, as applicable, at the expense of Sponsor, upon the completion or termination of the Study or upon Sponsor's request, or shall otherwise be disposed of pursuant to the written direction of Lessor or Sponsor as applicable. Site shall implement reasonable and appropriate administrative, physical and technical safeguards to protect the Equipment, shall at all times while the Equipment is in its possession maintain adequate and appropriate insurance coverage for the Equipment, and shall promptly notify Sponsor or its designee of any malfunctioning Equipment. Sponsor shall use reasonable efforts to repair or replace any malfunctioning Equipment at its own expense.

SPONSOR MAKES NO REPRESENTATIONS OR WARRANTIES OF ANY KIND CONCERNING THE EQUIPMENT, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR TITLE.

1.7. Enrollment of Patients

The Effective Date of this Agreement is as listed in Section 15. 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 Agreement is reached.

1.8. Key Enrollment Date

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

1.9. Minimum Goal

Site acknowledges that Site's minimum randomized goal is 13 subjects and that Site will use best efforts to reach the goal within a reasonable time after commencement of the Study at Site. If Site fails to adhere to this principle Quintiles may reconsider Site's suitability to continue participation in the Study.

1.10 Subcontracting. No rights or obligations of Site or Investigator under this Agreement may be assigned or subcontracted to others without Quintiles' prior written consent and pursuant to a written agreement approved by Quintiles. Site and Investigator shall ensure that all third parties who provide any services on their behalf relating to the Study comply with the terms of this Agreement, and Site and Investigator remain liable for any breach by such third parties. Site and Investigator shall cause each such subcontractor or third party to secure and maintain appropriate insurance to the reasonable satisfaction of Quintiles in amounts that will be adequate to cover the activities and obligations of the subcontractor or third party related to the Study.

1.11. Biological Samples.
Investigator shall collect, retain, analyze and/or use biological samples from subjects enrolled in the Study solely according to the Protocol and consistent with the ICF. All biological samples shall be transferred to the organization identified in the Protocol. Sponsor shall own rights and interest in biological samples collected in connection with the Study and shall have the sole right to use the samples as permitted under the ICF and Applicable Law.

2. PAYMENT

2.1 Budget.

2.1.1 In full consideration for the performance of the Study, Quintiles shall pay Payee (as defined below in Attachment A) those fees, expenses and costs, at such times and in accordance with the payment schedule set forth in Attachment A of this Agreement. No payments shall be made for the conduct of the Study that are deemed violations or breaches of or deviations (unless approved by Sponsor or Quintiles) from the Protocol, this Agreement or Applicable Law. In no event shall the fees, expenses and costs exceed the amount set forth in Attachment A without the written prior consent of Quintiles. 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.

2.1.2 The Parties represent that the compensation provided for the conduct of the Study represents the fair market value of the fees, expenses and costs associated with the Study and has not been determined in a manner that takes into account the volume or value of any past, present or anticipated future referrals or business.

2.1.3 To the extent permissible under Applicable Law, budget information shall remain confidential and shall be considered Confidential Information (as defined below). Site acknowledges and agrees that in order to comply with certain legal requirements, Sponsor may be required to publicly disclose payments, gifts, and other transfers of value it provides to physicians and certain hospitals, regardless of whether such payment is remitted directly to such physicians or hospitals or passes through a separate legal entity and that Quintiles or Sponsor may report to relevant regulatory agencies the total amount paid by Quintiles for purposes of conducting the Study under this Agreement, including the estimated fair market value for Equipment and supplies provided under this Agreement. Claims for services and/or products in connection with the Study that Site and/or any Investigator may submit for reimbursement to government entitlement programs or third-party payors shall at all times be in compliance with Applicable Law, including notices, issuances and national and local coverage decisions. Neither Site nor any Investigator shall, under any circumstances, submit any invoice or charges to any subject, government entitlement program, insurer or any other person for payment with respect to the Investigational Product or any other procedures or products provided at no charge by Sponsor or Quintiles.

3. CONFIDENTIALITY

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

and from regulatory authorities, information relating to the regulatory status of the Investigational Product, and Study Documentation and Inventions (as defined in Section 4).

Confidential Information shall not include information that:

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

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

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

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

3.2 Obligations

Site and Site's personnel, including Study Staff shall not

(i) use Confidential Information for any purpose other than the performance of the Study or

(ii) disclose Confidential Information to any third party, except as permitted by this Section 3 or by Section 5 "Publication Rights", or as required by law or by a regulatory authority or as authorized in writing by the disclosing party.

To protect Confidential Information, Site agrees to:

(i) limit dissemination of Confidential Information to only those Study Staff having a need to know for purposes of performing the Study;

(ii) advise all Study Staff who receive Confidential Information of the confidential nature of such information; and

(iii) use reasonable measures to protect Confidential Information from disclosure.

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

3.3 Compelled Disclosure

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

3.4 Return or Destruction

Upon termination of this Agreement or upon any earlier written request by Sponsor at any time, Site shall return to Sponsorall Confidential Information other than Study Documentation.

3.5 Survival

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

4. INTELLECTUAL PROPERTY

4.1 Pre-existing Intellectual Property

Ownership of inventions, discoveries, works of authorship and other developments existing as of the Effective Date and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "**Pre-existing Intellectual Property**"), is not affected by this Agreement, and no Party or Sponsor shall have any claims to or rights in any Pre-

existing Intellectual Property of another, except as may be otherwise expressly provided in any other written agreement between them.

4.2 Inventions

Sponsor shall own all right, title and interest in and to each invention, discovery, know-how, trade-secret and other intellectual property, including improvements, whether patentable or not, that is conceived, reduced to practice or otherwise made by Institution, the Investigator or any other person (other than Sponsor) who assists in performing the Study (whether solely or jointly with others) (each, an "**Inventor**") as a result of or in connection with the Study, the performance of obligations under this Agreement, or its/their access to or knowledge or use of Confidential Information or any drug or device which is the subject of the Study, including any patent, trade secret, trademark, copyright or other proprietary right with respect thereto (collectively, the "**Invention(s)**").

4.3 Assignment of Inventions

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

4.4 Patent Prosecution

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

4.5 Survival

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

5. PUBLICATION RIGHTS

5.1 Publication and Disclosure

Institution and Investigator shall have the right to publish or present the results of Institution's and Investigator's activities conducted under this Agreement, including Study Documentation, only in accordance with the requirements of this Section. Institution and Investigator agree to submit any proposed publication or presentation to Sponsor for review at least sixty (60) calendar days prior to submitting any such proposed publication to a publisher or proceeding with such proposed presentation. Within thirty (30) calendar days of its receipt, Sponsor shall advise Institution and/or Investigator, as the case may be, in writing of any information contained therein which is Confidential Information (other than Study Documentation) or which may impair the availability of patent protection for Inventions. Sponsor shall have the right to require Institution and/or Investigator, as applicable, to remove specifically identified Confidential Information (other than Study Documentation) and/or to delay the proposed publication or presentation for an additional sixty (60) calendar days to enable Sponsor to seek patent protection for Inventions.

5.2 Multi-Center Publications

If the Study is a multi-center study, Institution and Investigator agree that they shall not, without the Sponsor's prior written consent, independently publish, present or otherwise disclose any results of or information pertaining to Institution's and Investigator's activities conducted under this Agreement until a multi-center publication is published; provided, however, that if a multi-center publication is not published within eighteen (18) months after completion of the Study and lock of the database at all research sites or any earlier termination or abandonment of the Study, Institution and Investigator shall have the right to publish and present the results of Institution's and Investigator's activities conducted under this Agreement, including Study Documentation, solely in accordance with the provisions of Section 5.3 "Confidentiality of Unpublished Data."

5.3 Confidentiality of Unpublished Data

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

5.4 Media Contacts

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

5.5 Use of Name, Registry and Reporting

No Party hereto shall use any other Party's name, or Sponsor's name, in connection with any advertising, publication or promotion without prior written permission, except that the Sponsor and Quintiles may use the Site's name in Study publications and communications, including clinical trial websites and Study newsletters. Sponsor will register the Study with a public clinical trials registry in accordance with applicable laws and regulations and will report the results of the Study publicly when and to the extent required by applicable laws and regulations.

5.6 Survival

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

6. PERSONAL DATA

6.1 Study Team Member Personal Data

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

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

(i) the conduct of clinical trials;
(ii) verification by governmental or regulatory agencies, the Sponsor, Quintiles, and their agents and affiliates;
(iii) compliance with legal and regulatory requirements;

(iv) publication on www.clinicaltrials.gov and websites and databases that serve a comparable purpose;
(v) storage in databases to facilitate the selection of investigators for future clinical trials; and
(vi) anti-corruption compliance.

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

6.2 Study Subject Personal Data

The Investigator shall obtain Study Subject written consent for the collection and use of Study Subject personal data for Study purposes, including the disclosure, transfer and processing of data collected in accordance with the Protocol, in compliance with applicable data protection provisions.

6.3 Data Controller

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

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

6.4 Survival

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

7. INDEMNIFICATION : STUDY SUBJECT INJURY

To the extent not expressly prohibited by state law, Institution shall indemnify and hold harmless Sponsor, its affiliates and their respective employees, officers, and directors ("**Sponsor Indemnitees**") from and against any claims, liabilities, losses, demands, causes of action, judgments, settlements and expenses (including, but not limited to, reasonable attorneys' fees and court costs) (each a "**Claim(s)**") arising out of (i) the failure of an Institutional Indemnitee to comply with Applicable Law, rule, or Good Clinical Practices or adhere to the terms of the Protocol or this Agreement, or (ii) the negligence or willful misconduct of Institution, Institution's affiliates, Investigator, GDD Experts India Pvt. Ltd., or its or their employees, agents or contractors, provided, however, that Institution shall have no such obligation with respect to Claims arising out of the negligence or willful misconduct of Sponsor or its employees, agents or contractors.

In the event a Study Subject requires medical treatment for physical injury, Sponsor shall reimburse Site for the direct, reasonable and necessary costs associated with the treatment of the physical injury sustained as a direct result of taking the Investigational Product or undergoing a procedure required by the Protocol ("**Covered Injury**"), provided that such injury does not arise out of the negligence, willful misconduct, breach of this Agreement, Applicable Law or failure to follow and comply with the Protocol by Institution, Investigator, the sub-investigator, the Study Staff, or their employees or agents. Site shall notify Sponsor in advance of treatment, whenever practicable, but in any event within twenty-four (24) hours of provision of treatment.

Site shall coordinate and manage the request from a Study Subject for treatment and reimbursement of a Covered Injury, and shall provide to Sponsor in a timely manner, such

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supporting documentation and reports as Sponsor may reasonably request. Such documentation and reports shall include, but not be limited to, the government entitlement program health insurance claim number or, if none is available, the social security number of the Study Subject and such other information relating to the treatment and insurance coverage of the Study Subject as may be reasonably requested by Sponsor and/or as Sponsor reasonably determines is required or appropriate under Applicable Law. Reimbursement by Sponsor for a Covered Injury or otherwise shall be limited to those costs not covered by such Study Subject's insurance, excluding government entitlement programs. No party shall submit any claim for reimbursement to government entitlement programs until Sponsor has satisfied its reimbursement obligations under this Agreement and Applicable Law.

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

8. QUINTILES DISCLAIMER

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

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

9. CONSEQUENTIAL DAMAGES

Neither Quintiles nor Sponsor shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages, nor shall Site be responsible to Quintiles or Sponsor for any lost profits, lost opportunities, or other consequential damages.

This Section 9 "Consequential Damages" shall survive termination or expiration of this Agreement.

10. DEBARMENT

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

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

11. FINANCIAL DISCLOSURE AND CONFLICT OF INTEREST

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

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

Site shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one (1) year after Study completion.
Site agrees that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, 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., even though data protection may not exist or be as developed in those countries as in the Site's own country.

This Section 11 "Financial Disclosure and Conflict of Interest" shall survive termination or expiration of this Agreement.

12. ANTI-KICKBACK AND ANTI FRAUD

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

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

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

13. ANTI-BRIBERY

Institution and Investigator agree that the fees to be paid pursuant to this Agreement represent fair compensation for the services to be provided by Site. Institution and Investigator represent and warrant that payments or Items of Value received pursuant to this Agreement or in relation to the Study will not influence any decision that Institution, Investigator or any of their respective owners, directors, employees, agents, consultants, or any payee under this Agreement may make, as a Government Official or otherwise, in order to assist Sponsor or Quintiles to secure an improper advantage or obtain or retain business.

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

In addition to other rights or remedies under this Agreement or at law, Quintiles may terminate this Agreement if Site breaches any of the representations or warranties contained in this Section

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or if Quintiles or Sponsor learns that improper payments are being or have been made to or by Institution or Investigator or any individual or entity acting on its or their behalf.

14. INDEPENDENT CONTRACTORS

The Investigator and Institution and GDD Experts India Pvt. Ltd and Study Staff are acting as independent contractors of Quintiles and Sponsor and shall not be considered the employees or agents 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 Investigator or Institution or GDD Experts India Pvt. Ltd or their staff.

It is hereby agreed and acknowledged by the Parties and Sponsor that Quintiles has no relationship whatsoever with the Research Company and that the Research Company is acting as an independent contractor of the Institution.

15. TERM & TERMINATION

15.1 Term

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

15.2 Termination

Quintiles may terminate this Agreement for any reason effective immediately upon written notice. The Site may terminate upon written notice if at any time in the Investigator's professional judgment, a material adverse safety concern for the Study subjects makes continued testing inadvisable. Upon notice of termination or upon notice of suspension of the Study or this Agreement, Site shall immediately cease enrollment of subjects into the Study and, at the election of Quintiles shall (a) either (i) terminate the Agreement with respect to the enrolled subjects in an orderly and prompt manner and pursuant to consultation with Quintiles and Sponsor, including any required follow-up treatment with previously enrolled subjects, or (ii) transfer the enrolled subjects to another clinical site in accordance with Quintiles' instructions. Sponsor or its designee shall have the right to assume full control of the terminated Study and Site shall turn over all Study Documentation and materials in its possession associated with the Study, as expeditiously as possible, and shall provide such other assistance as is necessary to ensure a smooth and orderly transition of the Study without any disruption of the Protocol and (b). Site shall 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 Attachment A; provided, however, that ten percent (10%) of this final payment will be

withheld until final acceptance by Sponsor of all Study or data clarifications requested and satisfaction of all other applicable conditions set forth herein. If a material breach of this Agreement appears to have occurred and termination may be required, then, except to the extent that Study Subject safety may be jeopardized, Quintiles may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

16. NOTICE

Any notices required or permitted to be given hereunder shall be given in writing and shall be delivered

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

To Sponsor:	Gary Gordon, M.B.A., M.D. President Kowa Research Institute, Inc. 430 Davis Drive, Suite 200 Morrisville, NC 27560 919-433-1600 phone 919-433-1620 fax
To Quintiles	Name: Quintiles Research (India) Private Limited Address: B 101-106, Shapath IV, Opposite Karnavati Club, Sarkhej Gandhinagar Road, Ahmedabad 380051, Gujarat, India Tel: +91-79-66303300
To Institution	Name: Dr. M. V. Jali Address: KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, NehruNagar, Belagavi – 590010, Karnataka, India Tel: +91-831-2473777
To Investigator	Name: Dr. Veerappa Annasaheb Kothiwale Address: KLES Dr. Prabhakar Kore Hospital & Medical Research Centre, NehruNagar, Belagavi - 590010, Karnataka, India Tel: +91-9448119899
To Research Company	Name: Dr. Vinod Gyanchandani Address: GDD Experts India Pvt. Ltd, Ground Floor, Gulmohar Complex, Opposite Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India Tel: +91 9923000560

17. FORCE MAJEURE

The performance by either Party of any obligation on its part to be performed hereunder shall be excused by floods, fires or any other Act of God, accidents, wars, riots, embargoes, delay of carriers, inability to obtain materials, failure of power or natural sources of supply, acts, injunctions, or restraints of government or other force majeure preventing such performance,

whether similar or dissimilar to the foregoing, beyond the reasonable control of the Party bound by such obligation, provided, however, that the Party affected shall exert its reasonable efforts to eliminate or cure or overcome any of such causes and to resume performance of its obligations with all possible speed.

18. MISCELLANEOUS

18.1 Entire Agreement

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

18.2 No Waiver/Enforceability

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

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

18.3 Assignment of the Agreement

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

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

Upon Sponsor's request, Quintiles may assign this Agreement to Sponsor or to a third party, and Quintiles 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. Sponsor shall have the right to assign all of its rights under this Agreement without Site's prior written consent.

18.4 Third Party Beneficiary

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

18.5 Governing Law

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

18.6 Survival:

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

THIS SECTION IS INTENTIONALLY LEFT BLANK

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

By: Suneela Thatte

Title: VP, Global Operations

Signature: _____

Date: 10 | NOV | 2017

ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:

Name: Dr. Veerappa Annasaheb Kothiwale

Title: Principal Investigator

Signature: _____

Date: 23 | NOV | 2017

ACKNOWLEDGED AND AGREED BY KLES DR. PRABHAKAR KORE HOSPITAL & MEDICAL RESEARCH CENTRE:

By: Dr. M. V. Jali

Title: Medical Director

Signature: _____

Date: 25 | 11 | 17

Research Company agrees to abide by all obligations placed on Institution in the provisions of this Agreement concerning Confidentiality (Section 3); Intellectual Property (Section 4); Publication Rights (Section 5); Debarment (Section 10); Anti Kickback and Anti Fraud (Section 12); and Anti-Bribery (Section 13)

ACKNOWLEDGED AND AGREED BY GDD EXPERTS INDIA PVT. LTD.

By: Dr. Vinod Gyanchandani

Title: Head- Clinical Operations

Signature: _____

Date: 13 | NOV | 2017

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Registrar
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ATTACHMENT A
BUDGET & PAYMENT SCHEDULE

A. PAYEE DETAILS

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

Payee Name	GDD Experts India Pvt. Ltd.
Payee Address	GDD Experts India Pvt. Ltd, Ground Floor, Gulmohar Apartment, Opposite Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India
Bank Name	Axis Bank Ltd
Bank Account Number	910020034162231
IFSC code	UTIB0000048
GST Registration Number	27AADCG0363Q1ZA
Permanent Account Number (PAN) of Payee	AADCG0363Q
PAYMENT METHOD	Electronic Fund Transfer

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

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

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

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

B. PAYMENT TERM

Quintiles will pay the Payee Quarterly, on a completed visit per subject basis in accordance with the attached budget. Ninety percent (90%) of each payment due, including any Screening Failure monies that may be payable under the terms of this Agreement, will be made based upon prior 3 months' randomization data confirmed by subject 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 and Investigational Product to Quintiles or its designee, and upon satisfaction of all other applicable conditions set forth in the Agreement.

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

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

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

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

Major, disqualifying Protocol violations are not payable under this Agreement

C. PAYMENT DISPUTE

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

D. OVERPAYMENT

In the event that Quintiles determines that (i) a mistaken or otherwise erroneous payment has been made or (ii) payment was made for services that were not provided (each an "**Overpayment**") Quintiles will enter a payment adjustment against future payments and Site will not receive payment until such Overpayment is earned. If, upon completion or termination of this Agreement, the payment adjustment does not cover the Overpayment, Quintiles will issue a notice letter to the Site. Upon receipt of written notice, Site shall immediately refund such remaining Overpayment to Quintiles.

E. DISCONTINUED OR EARLY TERMINATION

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

F. SCREENING FAILURE

Reimbursement of screen failure will be at the amount indicated on the pre-screening and screening visits of the attached budget, not to exceed 3 Screen Failur(s) paid per 1 subject randomized.

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

G. UNSCHEDULED VISITS

Payment for unscheduled visits will be reimbursed in the amount of is Nine Thousand Five Hundred Forty Five Rupees (INR 9,545) which includes overhead. To be eligible for reimbursement for unscheduled visits, completed CRF pages must be submitted to Quintiles along with any additional information which may be requested by Quintiles to appropriately document the unscheduled visit.

H. START UP FEE

A one-time, non-refundable Study Start-Up payment of INR 80,000 will be made after site initiation and receipt by Quintiles of all original contractual and regulatory documentation and receipt of an original invoice.

I. RECORD STORAGE FEE/ARCHIVING TOTAL COST FEE

A one-time, long-term Study document storage, archiving payment of INR 133/box/month will be made to Payee following the completion of the Study at the Institution, receipt by Quintiles of all completed contractual and regulatory documentation and receipt of invoice. Trial documents will be kept in a controlled, secure facility.

J. PATIENT TRAVEL EXPENSES

Patient travel expenses will be reimbursed upon receipt of original supporting invoices up to INR 1000 per visit per patient per round trip] and are not included in the attached Budget. Invoices must contain the Patient number, amount paid, and visit number and visit date in which patient travel is being requested.

K. 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
Phone: [Insert Phone Number]

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

L. EC/IRB/IEC FEES

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

M. CONDITIONAL PROCEDURES

The following conditional procedures and related costs will be reimbursed on a pass-through basis upon receipt of an invoice at the amount indicated in the below table. Subject number and visit/dates must be included on the invoice for payment to be issued.

	Procedure Amount (INR)
Blood sample collection	300
Lab handling and/or shipping of unscheduled blood samples	130
12-lead ECG: Tracing only	500
EQ-5D-5L	500

Problem focused physical exam	2,298
Serious adverse events (SAE)	1000
Genetic testing consent	330
Endpoint package preparation	13,389

NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED

These amounts exclude all applicable taxes.

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

N. BUDGET TABLE

Visit	Total Cost Per Visit including 20% Overhead (INR)
PreScreen	13,578
Screen	19,998
Visit 2	17,331
Visit 3	4,679
Visit 4	4,679
Visit 5	13,304
Visit 6	12,535
Visit 7	12,616
Visit 8	4,679
Visit 9	13,790
Visit 10	4,679
Visit 11	12,616
Visit 12	4,679
Visit 13	12,616
Visit 14	4,679
Visit 15	13,790

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Visit 16	4,679
Visit 17	12,616
Visit 18	4,679
Visit 19	12,616
Visit 20	4,679
Visit 21	13,790
Visit 22	4,679
Visit 23	12,616
Visit 24	4,679
Visit 25	12,616
Visit 26	4,679
Visit 27	13,790
Visit 28	4,679
Visit 29	12,616
Visit 30	4,679
Visit 31	12,616
Visit 32	4,679
Visit 33	13,790
Visit 34	4,679
CSED Visit	15,515
Post Study Safety Call	4,060
retest	8,169
Off *	11,931
Total Cost Per Patient (Rs)	3,53,676

**** Visit can occur more than once***

CLINICAL TRIAL AGREEMENT ORDER

This Order ("**Order**"), effective as of the Effective Date (defined below), is entered into by and among Amgen Technology Pvt. Ltd., Dynasty Business Park, A Wing, Level 4, Andheri-Kurla Road, Andheri (East), Mumbai, 400059 India ("**Company**"); KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belgaum-590010, Karnataka, India ("**Institution**"); and Dr. Rohan Bhise, KLES Dr. Prabhakar Kore Hospital & MRC, Department of Medical Oncology, Nehru Nagar, Belagavi-590010, Karnataka, India ("**Principal Investigator**"), in accordance with, and shall be governed by, the terms of that certain Clinical Trial Agreement (contract number 181106) ("**Agreement**").

1. GOVERNING TERMS AND EFFECTIVE DATE

1.1 Governing Terms. By executing this Order, the parties agree that this Order and the parties' performance hereunder shall be governed by the terms and conditions of the Agreement, which are incorporated by this reference as if fully set forth herein. The parties hereto agree that for purposes of this Order, the term "**Site**" as used herein and in the Agreement shall be defined to include each and every non-Company party identified above, and their respective representatives. Terms used but not otherwise defined herein shall have the meanings ascribed to such terms under the Agreement.

1.2 Effective Date. For purposes of this Order, "**Effective Date**" shall mean the last date on which a party executes this Order. This Order shall remain in full force and effect until the completion by the Site of the Study or earlier termination pursuant hereto.

1.3 Records. The parties agree that for this Order the provision regarding Records in the Agreement shall be amended to state: "Site shall maintain all records required under Applicable Law and the Protocol for ten (10) years following completion of a Study or longer if required by Applicable Law. Site shall take reasonable and customary precautions to prevent the loss or alteration of any such records."

1.4 Indian Law. Without limiting the generality of Site's obligations, the Site shall carry out the Study with due observance of safety of Subjects, confidentiality and protection of Subjects' rights. The Study will be conducted by the Site in accordance with the Ethical Guidelines for Biomedical research on Human Subjects issued by the Indian Council of Medical Research Guidelines, 2000, Schedule Y of the Drug and Cosmetics Act of 1945, the Central Drugs Standard Control Organization's Good Clinical Practices Guidelines in India, and all applicable Indian regulatory requirements, whichever affords the greater protection to the Subject.

2. STUDY CONDUCT

2.1 Protocol. The Protocol for the Study is Company Protocol No. 20070782 entitled "A Randomized, Double-blind, Placebo-controlled Study to Evaluate the Long-term Safety and Efficacy of Darbepoetin Alfa Administered at 500 µg Once-Every-3-Weeks in Anemic Subjects With Advanced Stage Non-small Cell Lung Cancer Receiving Multi-cycle Chemotherapy ", as may be amended.

Site Representatives and/or Principal Investigator shall attend any meetings regarding the Study as reasonably requested by Company ("**Investigator Meetings**"). Such meetings may be conducted by Company to convey or exchange information with principal investigators, sub-investigators, or other research site staff to support the effective conduct or close-out of a Study. Site and Principal Investigator each agree that no additional compensation shall be due hereunder for Site Representatives or Principal Investigators respective participation in Investigator Meetings. Company may reimburse or pay Site for reasonable pre-approved expenses incurred by Site Representatives or Principal Investigator for participating in Investigator Meetings upon receipt of documentation in form and detail sufficient for Company to recognize such expenses for Company's tax reporting purposes, provided that Site complies with Company instructions and Company's applicable standards and policies related to travel and hospitality and other policies governing interactions with healthcare professionals.

The Principal Investigator will direct and supervise the Study.

ATTESTED
Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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2.2 Data Protection. Subject to applicable law, Company may collect and process information regarding investigators or other personnel involved in Studies. Company will notify such personnel as required by applicable law.

2.3 Use of Electronic Data Capture. Electronic Data Capture ("**EDC**") is a technique for collecting clinical trial data where study data is delivered to Company in electronic form. For this Study, EDC will be utilized to collect Study information, specifically as the electronic case report form ("**eCRF**"), from Site. Site agrees that it shall (i) enter such Study data into EDC within five (5) business days of the Subject visit, and (ii) resolve all queries issued in the EDC system within five (5) business days of the query being issued. Site acknowledges and agrees that time is of the essence with respect to such Study data entry and query resolution. Any delay by Site in complying with these timelines may, in Company's sole discretion, result in delay of payment, lock of IVRS, suspension of enrollment, quality audit or any other remedy. Principal Investigator is responsible for and warrants quality data entry. Data entry shall be conducted under the supervision of the Principal Investigator.

2.4 Supervision. The Principal Investigator shall supervise and be responsible for all activities performed by members of the Study team or other external personnel to whom the investigator delegates some of his/her responsibilities under the Protocol. The Principal Investigator shall ensure compliance with the Protocol at all times.

2.5 Informed Consent. Site agrees and warrants that it will obtain a valid informed consent form from each Subject in the Study or its legal representative in accordance with Applicable Laws and this Agreement. Site shall ensure that such consent permits Company's use of the Biological Materials and Study data for at a minimum the purposes of monitoring the accuracy and completeness of the research data, performing clinical and scientific research, and medical product development.

3. REAGENTS AND STUDY DRUG

3.1 Company shall provide or reimburse the following Study Drug(s) to Site as required by Protocol: darbepoetin alfa ("**Study Drug(s)**"). If Site is responsible for obtaining Study Drug for use in the Study, Company will reimburse Site for purchase costs of Study Drug as detailed in a proper invoice. Such purchase or reimbursement cost shall not exceed the amount set forth in Schedule A. The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of the Study Drug(s) or the Study Drug that is provided without charge or reimbursed by Company under this Order.

3.2 The cost of non-Company drug(s) and/or materials and/or reagents is not paid or reimbursed by a third party; however it is required by the Protocol for Subjects participating in the Study ("**Required Material(s)**"). Company will reimburse the Site for the cost of the Required Material(s) as detailed in a proper invoice. Such purchase or reimbursement costs shall not exceed the amount set forth in Schedule A. The Site agrees and warrants that it will not seek payment or reimbursement from any Subject or third party for the cost of any Required Material(s) that is provided without charge or reimbursed by Company under this Order. Site also warrants that it shall not seek or accept reimbursement from any Subject or third party payor for procedures, tests, treatments, items or services that are funded or provided by Company pursuant to the Agreement.

4. PERFORMANCE PERIOD AND ENROLLMENT OF SUBJECTS

4.1 The Study will commence upon execution of this Order, approval of the IRB/IEC, and any required approvals of applicable governmental authorities, including the Drug Controller General of India (DCGI), and will continue until completion of the Study as required by the Protocol (including any amendments thereto) unless this Order is terminated earlier pursuant to the Agreement.

5. REQUIRED EQUIPMENT

5.1 The parties acknowledge that Site will require the following equipment for the performance of the Study ("**Required Equipment**"): Laptop. Such Required Equipment will be lent by Company or its representative to Site for use in the Study.

5.2 Delivery. As necessary, Company or its representative shall arrange for the delivery of the Required Equipment, which such equipment shall be delivered to the Site at the following address: KLES Dr. Prabhakar Kore Hospital and Medical Research Center, Nehru Nagar, Belgaum-590010, Karnataka, India.

5.3 Installation of Required Equipment. Company or its representative shall provide for installation of the following equipment: Laptop.

5.4 Technical Support of Required Equipment. Company or its representative shall provide for technical support and maintenance of the following equipment: Laptop.

6. COMPENSATION

6.1 Compensation and payment terms are as set forth in Schedule A, attached hereto and incorporated herein.

6.2 Unless otherwise specified in Schedule A, in consideration for performance under the terms of this Order, Company will make payment within a reasonable time after receipt of (i) a proper invoice and (ii) the Case Report Forms or any similar document detailing the procedures performed and/or visits completed as set forth in Schedule A, as monitored by Company or its representative. It is expected that the Case Report Forms will be completed between monitoring visits.

6.3 Payments from Company to Site due hereunder shall be made payable and sent to the following:

Payments payable to:	KLES Dr. Prabhakar Kore Hospital and Medical Research Center **"Payee"**

From time to time, the Site may request in writing a change in Payee information. If Company agrees to the requested change, no additional amendment of the Order will be necessary.

7. MISCELLANEOUS

7.1 Principal Investigator understands and agrees that his/her personal information including name, contact details, financial information relating to, among other matters, compensation and reimbursement payments for study conduct, and other personal data in connection with Principal Investigator's conduct of the Study will be processed both by computer and manually, by Company and its affiliates and contractual partners in order to comply with Company's and its affiliates' obligations imposed by law, guidance or regulatory authorities and for other purposes including considering from time to time potential investigators for future studies or organizing safety reporting. Principal Investigator further understands and agrees that his/her personal data may, if necessary for these purposes, be made available to regulatory authorities and ethics committees. Principal Investigator understands and agrees that the Company's use and disclosure of personal data may involve use and disclosure in countries other than that where the Principal Investigator is located. Such countries may include but not be limited to: the United States, Japan, Canada, Australia, New Zealand, Switzerland, or countries in Latin America or Asia. Principal Investigator further understands that not all countries to which personal information may be transferred offer an equivalent level of protection of privacy of personal information. Principal Investigator is entitled to request access to his/her personal data held by Company or its affiliates and to have such data corrected if necessary.

7.2 Site acknowledges and agrees that Company shall have the right to disclose publicly the terms and conditions of the Agreement and this Order, including, without limitation, Site's name, description of services, and amount of payment.

7.3 Company Inspections/Monitoring/Audit. The parties agree that for this Order the provision regarding **Company Inspections/Audit** in the Agreement shall be amended and restated as follows: "Company Inspections/Monitoring/Audit. Company and its representatives shall have the right during reasonable business hours and after reasonable advanced notice to monitor and audit the activities of Site related to a Study. At no additional cost to Company, Site shall cooperate with any monitoring and audit conducted hereunder and make available to Company or its representatives for examination and duplication all documentation, data, and information relating to any Study. Site shall permit Company and its authorized representatives to inspect (i) the facilities where a Study is or will be performed; (ii) any equipment used or involved in the conduct of a Study; (iii) any records and source documents, including but not limited to

involved in the conduct of a Study; (iii) any records and source documents, including but not limited to medical records (whether in electronic or paper format); (iv) any related authorizations or patient informed consent forms; and (v) other relevant information necessary to determine whether a Study is being conducted in conformance with this Agreement and Applicable Laws. Further, direct access to electronic medical records for the purpose of monitoring/auditing source data is preferred, where possible, and in all cases, Site will provide the same level of access to source records to the monitor/auditor as provided to inspectors."

7.4 The parties agree that for this Order the Agreement shall be amended and supplemented by the following new provision: "Anti-Corruption. Site represents, warrants and covenants, as of the Effective Date to and through the expiration or termination of each Order or this Agreement, (i) that Site, and, to the best of its knowledge, Site Representatives, shall not, directly or indirectly, offer, pay, promise to pay, or authorize such offer, promise or payment, of anything of value, to any individual or entity for the purposes of obtaining or retaining business or any improper advantage in connection with this Agreement, or that would otherwise violate any Applicable Laws, rules and regulations concerning or relating to public or commercial bribery or corruption ("Anti-Corruption Laws"); (ii) that the books, accounts, records and invoices of Site related to this Agreement or related to any work conducted for or on behalf of Company are and will be complete and accurate; and (iii) that Company may terminate this Agreement (a) if Site or Site Representatives fails to comply with the Anti-Corruption Laws or with this provision, or (b) if Company has a good faith belief that Site or Site Representatives has violated, intends to violate, or has caused a violation of the Anti-Corruption Laws. If Company requires that Site complete a compliance certification, Company may also terminate this Agreement if Site (1) fails to complete a compliance certification, (2) fails to complete it truthfully and accurately, or (3) fails to comply with the terms of that certification. For the purposes of this Section, Site Representatives shall be deemed to further include owners, directors, officers, or other third party acting for or on behalf of Site.

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Order.

AMGEN TECHNOLOGY PVT. LTD.

(signature)

By: Dr. Veena Jaguste

Title: Director, Development Operations

Date: 07 Mar 2017

KLES DR. PRABHAKAR KORE HOSPITAL AND MEDICAL RESEARCH CENTER

(signature)

By: Dr. M.V. Jalli
(print or type name)

Title: MD and CE

Date: 17 MAR 2017

DR. ROHAN BHISE

(signature)

By: DR ROHAN BHISE
(print or type name)

Title: PRINCIPAL INVESTIGATOR

Date: 10 MAR 2017

ATTESTED

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

Planned Number of Subjects	25
Planned Number of Sites	1

Description	*Frequency/Detail*	*Unit Cost*	*Total*
Patient Milestones	In accordance with Table below	11,55,900.00	2,88,97,500.00
Radiology	In accordance with Table below	4,37,520.00	1,09,38,000.00
Additional Assessments	In accordance with Table below	22,752.00	5,68,800.00
Screen Failures	In accordance with Table below	28,800.00	5,18,400.00
Re-Screens	In accordance with Table below	10,140.00	5,07,000.00
Chemotherapy Costs	In accordance with Table below	3,73,600.00	93,40,000.00
Administrative Start-Up Costs	In accordance with Table below	40,000.00	40,000.00
Miscellaneous	In accordance with Table below	1,44,000.00	1,44,000.00
Maximum Study Cost:			**5,09,53,700.00**

Patient Milestones are inclusive of Hospital overhead fees, pharmacy costs, laboratory costs.

All Costs are denoted in: Rupees

Per Patient Fee (Overhead 20%)

Visit Type	Visit Description	Cost
Screening	Screening	28,800.00
	Week 1	14,940.00
	Week 4	12,780.00
	Week 7	12,780.00
	Week 10	25,440.00
	Week 13	12,780.00
	Week 16	12,780.00
	Week 19	25,440.00
	Week 22	12,780.00
	Week 25	12,780.00
	Week 28	25,440.00
	Week 31	12,780.00
	Week 34	12,780.00
	Week 37	25,440.00
	Week 40	12,780.00
	Week 43	7,860.00
	Week 46	20,520.00
	Week 49	7,860.00
	Week 52	7,860.00
	Week 55	20,520.00
	Week 58	7,860.00
	Week 61	7,860.00
	Week 64	20,520.00
	Week 67	7,860.00
	Week 70	7,860.00
	Week 73	20,520.00
	Week 76	7,860.00
	Week 79	7,860.00
	Week 82	20,520.00
	Week 85	7,860.00
	Week 88	7,860.00
	Week 91	20,520.00
	Week 94	7,860.00
	Week 97	7,860.00

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Treatment Phase	Week 100	20,520.00
	Week 103	7,860.00
	Week 106	7,860.00
	Week 109	20,520.00
	Week 112	7,860.00
	Week 115	7,860.00
	Week 118	20,520.00
	Week 121	7,860.00
	Week 124	7,860.00
	Week 127	20,520.00
	Week 130	7,860.00
	Week 133	7,860.00
	Week 136	20,520.00
	Week 139	7,860.00
	Week 142	7,860.00
	Week 145	20,520.00
	Week 148	7,860.00
	Week 151	7,860.00
	Week 154	20,520.00
	Week 157	7,860.00
	Week 160	7,860.00
	Week 163	20,520.00
	Week 166	7,860.00
	Week 169	7,860.00
	Week 172	20,520.00
	Week 175	7,860.00
	Week 178	7,860.00
	Week 181	20,520.00
	Week 184	7,860.00
	Week 187	7,860.00
	Week 190	20,520.00
	Week 193	7,860.00
	Week 196	7,860.00
	Week 199	20,520.00
	Week 202	7,860.00
	Week 205	7,860.00
	Week 208	20,520.00
	Week 211	7,860.00
	Week 214	7,860.00
	Week 217	20,520.00
	Week 220	7,860.00
	Week 223	7,860.00
	Week 226	20,520.00
	Week 229	7,860.00
	Week 232	7,860.00
	Week 235	20,520.00
	Week 238	7,860.00
	Week 241	7,860.00
	Week 244	20,520.00
	Week 247	7,860.00
	Week 250	7,860.00
	Last Dose of IP	22,440.00
	Next Q3W visit after disease progression	20,040.00

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Long Term Follow-Up	Month 4	480.00
	Month 7	480.00
	Month 10	480.00
	Month 13	480.00
	Month 16	480.00
	Month 19	480.00
	Month 22	480.00
	Month 25	480.00
	Month 28	480.00
	Month 31	480.00
	Month 34	480.00
	Month 37	480.00
	Month 40	480.00
	Month 43	480.00
	Month 46	480.00
	Month 49	480.00
	Month 52	480.00
	Month 55	480.00
	Month 58	480.00
	Month 61	480.00
	Month 64	480.00
	Month 67	480.00
	Month 70	480.00
	Month 73	480.00
Per Subject Totals		
Per Subject Total for Completers using CT Scans		11,55,900.00
Maximum Per Subject Total		**11,55,900.00**

Radiology Costs

Radiology procedures shall be paid at the rates below, if required. Amgen shall pay for either CT or MRI Scans and Scans per Patient.

Radiology Procedures (Payable on Invoice)	Cost	Frequency		Total per Patient
CT Chest & Interpretation	5,100.00	30	per Subject	N/A
CT Abdoman & Interpretation	5,400.00	30	per Subject	N/A
MRI Chest & Interpretation	6,780.00	30	per Subject	2,03,400.00
MRI Abdoman & Interpretation	7,680.00	30	per Subject	2,30,400.00
CT Brain	3,720.00	1	per Subject	3,720.00
Total Maximum Per Patient *Total maximum for additional costs assumes PET/CT costs*				4,37,520.00

Additional Assessments

Additional Procedures (Payable on Invoice)	Cost	Frequency		Total per Patient
Whole Body Bone Scan	10,800.00	2	per Subject	21,600.00
X-Ray Bone (max)	336.00	2	per Subject	672.00
Biopsy Sample process and handling	480.00	1	per Subject	480.00
Total Maximum Per Patient				22,752.00

Screen Failures

A max of 18 Screen Fails will be paid per Site at a rate in accordance with table below.

Visit Description	Cost
Screen Failure	28,800.00
Maximum Screen Failure Costs	28,800.00

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Re-Screens

A max of 2 Re-Screens will be paid per Subject at a rate in accordance with table below.

Visit Description	Cost
Re-Screen Labs & Procedures	10,140.00
Maximum Re-Screen Costs	10,140.00

Chemotherapy Costs (Payable only against original invoice)

Description	Cost	Frequency		Total per Patient
Pemetrexed	60,000.00	6	per Subject	3,60,000.00
Cisplatin	1,700.00	8	per Subject	13,600.00
Total Maximum Per Patient				3,73,600.00

****Inj. Pemetrexate will be reimbursed beyond 6 cycles only for the cases where it is used as first line chemotherapy, which immediately rolls into maintenance treatment with no break or change to the treatment administered and where study IP is continued.***
 # Inj. cisplatin will be reimbursed to the sites for maximum of 8 cycles/patient, with a reimbursement cost of no more than Rs 1,700/- per cycle and no more than Rs. 13,600/patient overall.

Administrative Start-Up Costs

Description	Cost	Frequency		Total
IRB Initial Review Fee	40,000.00	1	Total	40,000.00
Total Maximum				40,000.00

Miscellaneous

Description	Cost	Frequency		Total
Broadband charges for eCRF data entry	1,500.00	36	per Month	72,000.00
ISD phone line rent & monthly charges	1,500.00	36	per Month	72,000.00
Total Maximum				1,44,000.00

PAYMENT DISTRIBUTION

Initial Payment	**50,000.00** (Estimated advance for 1 cycle for 1 subject) *Amgen will pay Institution this initial payment upon execution of the Agreement. In order to receive further funds towards Subject related costs, the amount earned must exceed this initial payment In the event that the total amount earned for the Study is less than this initial payment, all unearned funds are fully refundable to Amgen.*
Progress Payment Frequency	Quarterly (based on calendar quarter), in accordance with Budget Worksheet attached hereto and incorporated herein by reference

The payment of the study will be made in the favor of '----------'
The EC for this study will be 'Ethics Committee of KLE University' and the payment of the EC fees will be made in the favor of 'Registrar, KLE University, Belagavi'.

Site represents and warrants that it shall not seek or accept reimbursement from any Subject or third party payors (including any "federal health care program" as defined at 42 U.S.C. section 1320a-7b(f)) for Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items or services that are funded by Company pursuant to the Agreement or provided without charge by Company for Study purposes.

In the event Site is not reimbursed for routine clinical services contemplated in the Protocol, Site may remit an invoice to Company. If Company is in agreement with the invoice, Company will reimburse Site for the invoiced amount subject to a fair market value assessment by Company.

Company shall pay for or provide those Study Drug(s), procedures, tests, treatments, drugs, reagents, materials, items, or services identified in the Protocol's Schedule of Assessments, except that the following are not paid for or provided without charge by Company:

N/A

Invoices

1) "Any additional activities/tests/procedures performed for the Study, which are not mentioned in this budget (schedule-A) may be reimbursed on confirmation of approval from the Amgen study team and receipt of an original invoice and rationale provided by the Site."
2) For all items that are payable upon invoice as indicated above, please send invoices to Company as follows:

Amgen Technology Pvt Ltd
Dynasty Business Park,
Level 4, A wing, A.K Road
Andheri (East) Mumbai 400059
Please submit invoices only for items indicated as payable upon invoice.

ATTESTED
Prof. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

100f

CONFIDENTIAL

CLINICAL STUDY AGREEMENT

This clinical study agreement ("Agreement") is executed as of the 11th day of July 2016 (Effective Date) by and between:

Sun Pharma Advanced Research Company Ltd. (CIN L73100GJ2006PLC047837), a company registered under the Companies Act, 1956 having its registered office at SPARC Ltd, Akota Road, Akota, Vadodara - 390020 India and having a business address at 17/B, Mahakali Caves Road, Andheri East, Mumbai 400093, India, which expression shall, where the context so permits include his successors in office and assigns (hereinafter referred to as the "**Sponsor**").

AND

KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, a hospital having its registered office at Nehrunagar, Belgaum - 590010, Karnataka, India, which expression shall, where the context so permits include his successors in office and permitted assigns (hereinafter referred to as the "**Institution**").

AND

Dr. Rohan Bhise, MBBS, MD (Oncology), Principal Investigator, at KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre, Nehrunagar, Belgaum - 590010, Karnataka, India. (hereinafter referred as the "**Investigator**")

AND

Global Drug Development (GDD) Experts India Pvt. Ltd. , Ground floor, Gulmohar Apartment, Opp. Hislop College, Civil Lines, Nagpur-440001, Maharashtra, India. Head Off.: 910 Seventeenth Street, NW Suite 312, Washington D.C. 20006 (hereinafter referred as the "**Site Management Organization**")

(each a "Party" and Sponsor, Investigator and Investigator collectively, the "Parties").

WHEREAS:

A. The Institution is a health care and research organization engaged in the diagnosis, treatment and prevention of disease and clinical research for the improvement of healthcare, and has the facilities and personnel necessary to conduct the clinical trial;

B. Sponsor is a pharmaceutical company involved, inter alia, in the research, development and manufacture of medicines for use in humans and has developed **Paclitaxel Injection Concentrate for Nano-dispersion (PICN)** which is intended to be used for treatment of **locally recurrent or metastatic breast cancer**. Sponsor represents that it has applied for the necessary permissions and licenses required under the provisions of relevant Acts and Rules which are required for use of the same on subjects/ healthy human volunteers etc.
Site Management Organization has agreed to provide a professionally trained and experienced Clinical Research Coordinator who will be responsible for delegated trial related activities and documentation from the start till close out of the trial

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
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at the Institute; a Project Manager to over-see & coordinate the progress & management of CRC activities and a Quality Control Associate to ensure adherence to the protocol, ICH-GCP, other applicable regulatory requirements and the relevant Standard Operating Procedures (SOPs). Hence GDD Experts will assist Investigator and institute for efficient Trial Management, Project Management and Quality Management.

C. Sponsor desires Institution to study the bioavailability and bioequivalence of PICN and Institution is willing to perform a clinical study of the Investigational Product (IP).

NOW THEREFORE in consideration of the promises and mutual covenants herein contained, Parties including Site Management Organization hereby agree as follows:

1. **SCOPE**

1.1 The Study is of mutual interest and benefit to Sponsor and Institution, and will further the Institution's instructional and research objectives in a manner consistent with the terms and conditions of this Agreement.

1.2 The Institution shall exercise its best efforts to carry out the research ("Study") set forth in the Protocol CLR_16_13: A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study Of Paclitaxel Injection Concentrate For Nano-Dispersion (PICN) And Abraxane® In Subjects With Locally Recurrent Or Metastatic Breast Cancer, which has been provided prior to signing of this Agreement. In the event of any inconsistency between this Agreement and the Protocol, the terms of this Agreement shall govern. Changes in the Protocol may be made only through prior written agreement between the Sponsor and the Institution. The Study shall be conducted under the direction of Investigator in accordance with this Agreement, subject to review and prior approval by the Institution's ethical committee.

2. **CONDUCT OF THE CLINICAL TRIAL**

2.1 The Investigator and the Institution shall conduct the Study in accordance with the Protocol. The Sponsor is responsible for obtaining and maintaining all applicable regulatory approvals for the Study in India. The Sponsor, Investigator and Institution shall perform the Clinical Study in accordance with all applicable laws, government regulations and guidelines including but not limited to the Drugs & Cosmetics Act 1940 and Rules 1945 : Schedule-Y (as amended from time to time), The Indian Council of Medical Research (ICMR) guidelines, Good Clinical Practices (GCP) and the standards conforming to the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH).

2.2 Site Management Organization will be ensure to follow the Study Management Responsibilities Matrix which is a detail agreement to define the terms and condition and obligation of each Party between PI, Institute and Site Management Organization

2.3 It is explicitly agreed and acknowledged by the Parties including Site Management Organization that the Protocol for clinical trial/Study be reviewed and approved by the Ethical Committee ("EC") registered with DCGI before the commencement of the Study.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

The Investigator shall obtain and deliver a copy of such approval to the Sponsor. The approval must indicate the date of issuance and bear the name and signature of the Chairperson or Secretary of the EC. If any such committee do not exist in the Institution, then the approval granted to a protocol by the ethics committee of another institution will be applicable to use of that protocol in the Institution.

2.4 The Institution and Investigator agree that the Sponsor or its designee as clinical monitor will conduct routine monitoring visits at mutually convenient times and upon reasonable advance notice to the Investigator. The clinical monitor will have direct access to all original records and documents pertaining to the study to ensure that the study is conducted in accordance with the Protocol and applicable regulatory requirements and in terms of this Agreement. Similarly, sponsor may conduct audit at mutually convenient times and upon reasonable advance notice to the Investigator. The auditor will have direct access to all records and documents pertaining to the study.

2.5 It is explicitly agreed and acknowledged by the Parties including Site Management Organization that in case Investigator is unable to perform the study in accordance with this agreement, the Institution shall appoint another Investigator in consultation with the Sponsor. The Institution shall take written consent from the Sponsor prior to such appointment. The Sponsor retains the right to suggest Investigator(s) for appointment to conduct and perform the Study.

2.6 If any biological samples are to be tested as part of the Study, these are to be tested in accordance with the Protocol and at a central laboratory approved by Sponsor and with the Clinical Trial Subject's signed written informed consent form. If study requires local lab, the investigator would share applicable documents (viz. lab head CV, accreditation, Lab normal values). It is explicitly agreed and acknowledged by the Parties including Site Management Organization that Collection, Retention, Use and Destruction of Biological Samples by Institution or Investigator or Sponsor or either of the parties including Site Management Organization shall be in accordance with the applicable Protocol, acceptable clinical trial practices, applicable subject privacy and informed consent laws and in compliance with all applicable laws and regulations.

For the investigations required to be conducted at the local laboratory, the expenses will be reimbursed as per actuals, subject to submission of the original invoices and corresponding receipts for the same obliterating subject's identity.

3. OBLIGATIONS, REPRESENTATIONS &WARRANTIES OF THE PARTIES INCLUDING SITE MANAGEMENT ORGANIZATION

3.1 The Investigator shall be responsible for obtaining and maintaining all approvals from the appropriate EC for the conduct of the clinical Study and from time to time the Investigator shall inform Sponsor about the progress of EC submissions, and provide Sponsor and the Institution with all correspondences relating to such submissions. The institution shall ensure the proper conduct of Study.

3.2 The Investigator shall be responsible for obtaining a signed informed consent form from each Clinical Study Subject prior to the Clinical Study Subject's participation in the Clinical Study. For clarity "Clinical Trial Subject" means a person recruited to participate in the Clinical Trial. The investigator shall comply with the applicable regulatory requirement(s), and should adhere to GCP and to the ethical principles in

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obtaining and documenting informed consent. The Parties including Site Management Organization agree that in addition to the requirement of obtaining written informed consent, , including the procedure of providing information to the subject and his/her understanding on such consent is required to be done while adhering to the principles of confidentiality. As per applicable regulatory requirement, it is agreed and acknowledged by the Parties including Site Management Organization that in case of certain clinical trials, audio-video recording of the informed consent process to be maintained by the investigator for certain subjects. In such event, the Parties including Site Management Organization will agree the necessary terms and conditions relating to the audio-video recording and incorporate the same in the informed consent form.

3.3 In addition, prior to the beginning of the Study, the Investigator must have the EC's written approval/favourable opinion of the written informed consent form and any other written information to be provided to Clinical Trial Subject. Neither the investigator, nor the trial staff, should coerce or unduly influence a Clinical Trial subject to participate or to continue to participate in a trial.

It is agreed and acknowledged by the Investigator and the Institution that when a clinical trial (therapeutic or non-therapeutic) includes Clinical Trial Subjects who can only be enrolled in the trial with the consent of the Clinical Trial Subject's legally acceptable representative (e.g., minors, or subjects with severe dementia), the Clinical Trial Subject should be informed about the trial to the extent compatible with the subject's understanding and, if capable, the subject should sign and personally date the written informed consent.

3.3 The Investigator shall take reasonable efforts to recruit the agreed number of Clinical Trial Subjects on a timely basis and the Parties including Site Management Organization shall take reasonable efforts to conduct the Clinical Study in accordance with the agreed time period.

Investigator shall target to enroll (randomize) at least **6-8 subjects** in the study.

3.4 The Institution and Investigator shall not permit the use of IP for any purpose (whether directly or indirectly) other than the conduct of the clinical Study and upon termination or completion of study, all used and unused IP shall, at Sponsor's instructions, either be returned to Sponsor or destroyed in accordance with the Protocol or Sponsor's written instructions.

3.5 It is explicitly agreed and acknowledged by the Parties including Site Management Organization that the Study may involve the participation of multiple sites and recruitment and in such event, when the enrolment goal for the clinical Study as a whole is reached, enrolment will be closed at all sites, including the trial Site, regardless of whether the Institution has reached its individual enrolment goal.

3.6 To the extent permitted by law, the Institution and the Investigator shall immediately inform Sponsor of:

3.6.1 Any intended or actual inspection, written inquiry or visit to the trial Site by any regulatory authority; or

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3.6.2 Any queries by State or Central Information Commission under Right to Information Act (amended up to date)

In connection with the clinical Study and forward promptly to Sponsor copies of any correspondence from any such authority.

The Institution or Investigator shall use its best efforts to obtain the approval of the regulatory authority (e.g. DCGI or state FDA personnel) to have a representative of Sponsor present during any such visit. If a representative of Sponsor is unable to be present during a visit, the Institution and the Investigator shall provide Sponsor with a prompt brief summary followed by a detailed written report following the visit.

3.7 The Institution and the Principal Investigator shall keep complete and accurate records of the conduct of the clinical Study and of all clinical Study data in accordance with generally accepted industry standards and practices and applicable Law. The Institution and the Investigator agree to retain all such records for a period of not less than fifteen (15) years from the date of completion of Study or termination of this Agreement, whichever is earlier, or any such period prescribed in the Sponsor's 'Document Retention & Destruction Policy'(the "Retention Period"). The Institution shall use reasonable efforts to give Sponsor written notice before destroying the Clinical trial documentation and clinical trial data. Any such destruction is subject to prior written consent of the Sponsor. In case, Institution and Principal Investigator do not have archival facility as per Sponsor's expectations, Institution and Principal Investigator agree to third party archival facilitated by the sponsor respecting confidentiality of subject's data.

For clinical/ therapeutic bioequivalence study, the investigator and institution agree to retention of Investigational Product (IP) as per regulatory requirements. In case, Institution and Principal Investigator do not have archival facility for IP as per Sponsor's expectations, Institution and Principal Investigator agree to third party archival by the sponsor respecting confidentiality of subject's data.

3.8 The Investigator undertakes to document all Adverse Events (AE) on adverse event page of Case Report Form (CRF). The investigator shall report all serious adverse events (SAE) to the licensing authority (DCGI), sponsor/ CRO (if applicable) and chairperson of ethics committee within 24 hour of SAE occurrence. The investigator shall report all SAE after due analysis to the licensing authority (DCGI), chairperson of ethics committee and head of the institution where the trial has been conducted within the timelines as per the applicable regulatory requirement. Subsequent follow-up information shall be reported to all stakeholders as mentioned above. In case, Investigator fails to report any SAE within stipulated period, the investigator shall have to furnish the reason for the delay to the satisfaction of licensing authority along with the report of SAE. Sponsor's safety physician/ CRO (if applicable) shall report all SAE after due analysis to licensing authority (DCGI), chairperson of ethics committee and head of the institution where the trial has been conducted within the timelines as per the applicable regulatory requirement. Subsequent follow-up information shall be reported to all stakeholders as mentioned above. Sponsor's safety physician/ CRO (if applicable) shall report all serious adverse events to other participating Investigators within the timelines as per the applicable regulatory

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requirement. (This shall be for multi centric studies). Sponsor's safety physician/ CRO (if applicable) shall notify SAE to other regulatory authorities as applicable.

As much information as possible shall be supplied by Investigator at the time of the initial report with at least the following information using SAE Report Form.

- Name, address, and telephone number of the reporting Investigator.
- Investigational product(s).
- Protocol number.
- Subject identification number, initials, sex and date of birth.
- Description of the AE, reason considered serious, measures taken and outcome (if resolved.
- Likelihood of drug causation of the adverse event assessed by the Investigator.

A SAE is any untoward medical occurrence that, at any dose:

- results in death;
- is life-threatening;
- requires in-subject hospitalization or prolongation of existing hospitalization; [For the avoidance of doubt, A planned hospitalization for pre-existing condition, or a procedure required by the Clinical Investigation Plan, without a serious deterioration in health or if the hospitalization is clearly not associated with an AE [(e.g., social hospitalization) are not to be considered as SAEs.]
- results in persistent or significant disability/incapacity;
- is a congenital anomaly/birth defect;
- important medical event.

For the sake of clarity, the term "life-threatening" in the definition of "serious" refers to an event in which the subject was at risk of death at the time of the event; it does not refer to an event, which, hypothetically, might have caused death if it were more severe.

To the maximum extent permissible under applicable laws and DCGI regulation, the Sponsor shall pay all medical expenses pertaining to Study subject in the event of any AE or SAE. In case of trial related injury or death, the financial compensation will be paid to the subject/ nominee subject to the terms and conditions of this Agreement.

3.9 The Sponsor shall pay all medical management pertaining to Study subject in the event of any SAE, and any IP or study participation related AE, unless it has arisen due to non-adherence to the terms of the Protocol or Sponsor's written instructions on IP as agreed by Investigator EC and/or the same has resulted from the negligence or willful malfeasance or malpractices by Investigator and /or any trial staff or the Institution.

If Subject has a medical emergency, illness or injury that was caused by the research drug or study procedures, Sponsor will provide subject medical management as per the applicable regulatory requirement.

In case of Study related injury or death, to the maximum extent permissible under applicable laws and DCGI regulation, Sponsor will provide complete medical care along

with compensation for the injury or death. In case of any SAEs (death and other than death) EC will evaluate and give its opinion regarding compensation to DCGI. Subject will get an additional compensation will be over and above any expenses incurred on subject's medical management from Sponsor if recommended by DCGI. Subject or his/her nominee(s) has the right to contact the Sponsor or his representative, for the purpose of making claim in the case of trial related injury or death.

3.10 Investigator warrants and represents that:

3.10.1 He is free to participate in the clinical trial/ Study and there are no rights, which may be exercised by, or obligations owed to any third party, which might prevent or restrict his performance of the obligations detailed in this Agreement;

3.10.2 Where the Institution is not the Investigator's principal employer, he has notified his principal employer of his proposed participation in the clinical trial/Study and, where relevant, his supervision of trial site team members. He has obtained all necessary consents from his principal employer relating to this;

3.10.3 He is not involved in any regulatory or misconduct litigation or investigation by the Drugs Controller General of India, Food and Drug Administration, the Ministry of Health, or other regulatory authorities;

3.10.4 He is qualified to provide clinical Study services based on the skills and experience and has reviewed information regarding the Sponsor's IP and the Protocol for the proposed clinical Study and wishes to conduct the trial and to supervise the team members at the trial site; and

3.10.5 During the Clinical Trial, he will not serve as an investigator or other significant participant in any clinical trial/study for another sponsor or any CRO companies if such activity might adversely affect his ability to perform his obligations under this Agreement.

3.11 Institution certifies that neither Institution nor any person (including Investigator) employed or engaged by Institution in the conduct of the Study has been debarred pursuant to applicable provisions of law (whether state or central) and that no debarred person will in the future be employed or engaged by Institution in connection with conduct of the Study. Institution further certifies that it will notify Sponsor immediately in the event of any debarment or threat of debarment of any person employed or engaged by Institution in the conduct of the Study occurring during the period of this Agreement.

3.12 Sponsor, Institution and the Investigator represent and warrant that it has the right to enter into and fully perform this Agreement and, by entering into this Agreement it is not in violation of any law, statute, agreement or any other statue.

4. FINANCIAL ARRANGEMENTS

4.1 SPARC, as Sponsor, has agreed to provide financial support for the project. The Sponsor shall pay fees for the services of the Investigator in accordance with the budget as per Exhibit-A.

4.2 Sponsor shall make payments to Institution in accordance with the payment schedule set forth in Exhibit A and incorporated herein. Cheque (s) shall be made payable and sent to the:

Payee Name: GDD Experts India Private Limited
PAN: AADCG0363Q

4.3 The Investigator agrees to make every effort to supervise and lead the study to completion as planned and in time. Should any circumstances beyond his control delay the project or make it impossible to complete it, the Investigator shall give due notice to the Sponsor so as to minimize the overall project delay or the loss, and return funds to the sponsor on pro rata basis as per Exhibit A. The Investigator and Institution should facilitate return of unused IP to sponsor or other site as per sponsor's instructions.

4.4 The Payee shall raise invoice on the Sponsor and separately specify Service Tax payable, if applicable, on the services rendered and shall also show other necessary details such as Service Tax registration no. etc. so as to enable Sponsor to claim credit for the same as per law. The Sponsor shall verify the invoice and make the payment within 30 days from the receipt of the invoice submitted by Payee. However, if, upon verification by Sponsor, the invoice is found to be incorrect or inappropriate, the same shall be returned by Sponsor to the Payee for correction and revision. No other costs, payments and expenses would be borne by Sponsor unless specifically mentioned in this agreement or mutually agreed in writing in advance. Notwithstanding the foregoing, any payment under this Agreement is subject to deduction of applicable Tax-deduction-at-source (TDS). Sponsor shall deduct the amount and pay balance amount to the Institution.

4.5The Parties including Site Management Organization hereby agree that Site Management Organization shall be responsible for payment of fees to Institution to performance of their obligation for conducting the clinical trial under this Agreement. The Parties including Institution further agree that SPARC shall not responsible for payment of any fees or cost to Institution. SPARC shall not be liable to pay any sum to Institution even in the event including the default of Site Management Organization in making payment to Institution SPARC shall not be liable to pay to Institution under this Agreement.

5. TERM AND TERMINATION

5.1 Unless otherwise terminated earlier, this Agreement shall commence upon Effective Date and will continue for a period of 5 years from the Effective Date or upon completion of the Clinical Study, whichever is earlier.

5.2 Parties may terminate this Agreement with immediate effect, at any time, if another Party is in breach of any of the defaulting Party's obligations hereunder (including a material failure without just cause to meet a timeline) and fails to remedy such breach, where it is capable of remedy, within thirty (30) days of a written notice from the terminating Party specifying the breach and requiring its remedy. Notwithstanding to the above, the Investigator may terminate the Study, if the Investigator suspects an adverse drug reaction / adverse drug event related to the Study related procedure and of serious nature to take its cognizance, after informing Institution, EC and Sponsor in writing. It is explicitly agreed and acknowledged by the Investigator and Institution that in case of termination of study, no further payment shall be made by Sponsor to Principal Investigator, Institution or any other person under this agreement.

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5.3 Sponsor may terminate this Agreement upon thirty (30) days prior written notice to the Institution and the Principal Investigator, or such shorter notice period as required by a Regulatory Authority (whether State or Central), for any reason whatsoever.

5.4 Without limiting the generality of the foregoing, Sponsor may terminate this Agreement:

5.4.1 if the Investigator is not performing the Study as required in the protocol;

5.4.2 in case of failure of the Investigator and/ or Institution to provide access by Sponsor representatives /Clinical monitor all original medical records necessary to verify entries on study case report forms;

5.4.3 in case of an unauthorized replacement of Investigator;

5.4.4 if Sponsor determine that business or scientific considerations require termination of this Agreement (either full or in part);

5.4.5 if Case report forms provided to Investigator by Sponsor for use in the study are not legibly and/or accurately completed and forwarded the same to Sponsor or its designated representative persistently within 1 week of each Subject's visit date; or

5.4.6 if any malpractices adopted either by Investigator or Institution or both.

5.5 Within thirty (30) days after the termination of this Agreement, the Investigator shall deliver to Sponsor completed CRF pages on RDC.

6. INDEMNIFICATION

6.1 To the maximum extent permitted by applicable laws, the Institution agrees to defend, indemnify and hold harmless the Sponsor and its respective directors, officers, employees and agents (the "Indemnities") and those of its affiliates against all claims, actions, suits, proceedings, liability, losses, damages, charges, orders, fines and expenses, including assessable legal fees and disbursements made or brought by a third party against an Indemnity for harm:

6.1.1 Arising out of or relating to the negligence or willful misconduct or malpractices of the Institution, its employees and agents in performing their obligations under this Agreement;

6.1.2 Arising out of errors or omissions by Institution;

6.1.3 arising out of or relating to the failure of the Institution, its employees and agents to comply with the provisions of this Agreement, the Protocol, or any written instructions of Sponsor concerning the Clinical Study; or

6.1.4 Arising out of the violation of applicable Law related to the conduct of the Clinical Study by the Institution, its employees or agents.

6.2 The Investigator agrees to defend, indemnify and hold harmless the Sponsor and its respective directors, officers, employees and agents (the "indemnities")and those of its

affiliates against all claims, actions, suits, proceedings, liability, losses, damages, charges, orders, fines and expenses, including assessable legal fees and disbursements made or brought by a third party against an indemnity for harm:

6.2.1 arising out of or relating to the negligence or willful misconduct or malpractices of the Investigator, his study team member/employee or any person for whom the Investigator is responsible at law in performing their obligations under this Agreement;

6.2.2 arising out of or relating to the failure of the Investigator, his or her study team members or employees and any person for whom the Investigator is responsible at law to comply with the provisions of this Agreement, the Protocol, or any written instructions of Sponsor concerning the Clinical Study ;

6.2.3 arising from a violation of applicable laws and regulations related to the conduct of the Clinical Trial by the Investigator, his or her study team members/ employees or any person for whom the Investigator is responsible at law; or

6.2.4 arising out of from or by reason of any breach or non-frivolous of alleged breach of representation, warranty or covenant herein.

6.3 To the maximum extent permitted by applicable laws, SPONSOR agrees to indemnify and hereby indemnifies, defend and hold the Site, its Principal Investigator, Sub-Investigators and study team, directors, officers and the support staff, agents, the trustees of the Institution harmless from and against any proven liability, loss, damage, costs, expenses, claims, demands and suits (including reasonable attorney's fees and expenses) including arising from and resulting out of (i) the breach of any of Sponsor representations, warranties or covenants set forth in this Agreement or (ii) the performance of the Study or any of its results / outcome including, adverse drug experiences or an injury, death to/of a Study subject directly or indirectly caused by or attributed to the Study , (iii) any injury or claim arising due to any defect / malfunction of the IP used during the Study in accordance with the provisions of the Protocol and this Agreement.

6.4 Each Party shall use reasonable efforts to inform the other Parties including Site Management Organization promptly of any circumstances of which it is aware that are reasonably likely to give rise to a claim or proceeding and shall keep the other Parties including Site Management Organization reasonably informed of developments in relation to any claim or proceeding, even where a Party decides not to make a claim for indemnification under this Section 5. The Parties including Site Management Organization further agree that they have a right to retain their own counsel to conduct a full defense of any such claim or proceeding.

6.5 The Institution, Investigator and Sponsor shall each give to the others such help as may reasonably be required for the efficient conduct and prompt handling of any claim or proceeding concerning the Clinical Study.

6.6 No settlement or compromise of a claim or proceeding subject to indemnification under this Section 6 shall be binding on a Party without the prior written consent of the other affected Party(s). A Party shall not unreasonably withhold such consent of a settlement or compromise. Without limiting the generality of the preceding, no Party shall admit fault on behalf of an indemnity or enter into a non-monetary settlement that places future obligations on an indemnity without the written approval of the indemnity.

7. CONFIDENTIALITY.

"Confidential Information" means all information (including, without limitation, subject identity, Study Protocol(s), Investigator Brochure, informed consent form, subject diaries, case report forms, clinical data, other data, reports, specifications, computer programs or models and related documentation, know-how, trade secrets, or business or research plans) of Sponsor or Sponsor's Affiliates that are: (1) provided to Institution or Investigator in connection with this Agreement or a Study; (2) cumulative Study data, results, and reports from all sites conducting the Study.

7.1 Sponsor Confidential Information and all tangible expressions, in any media, of Sponsor Confidential Information are the sole property of Sponsor. Each party shall endeavor to identify tangible Confidential Information provided to the other party as "Confidential" given the understanding that failure to do so does not constitute a designation of non-confidentiality when the confidential nature is apparent from context and subject matter. Institution and Investigator agree to treat Sponsor's Confidential Information as it would its own proprietary and confidential information. Institution and Investigator will only accept information from Sponsor which is required for conduct of the Study and which must be maintained for Institution's records.

7.2 Investigator agrees for a period of ten (10) years after the expiration or termination of the Study not to use and disclose Sponsor Confidential Information to any third party. Institution and Investigator agrees not to disclose Sponsor Confidential Information to third parties including Site Management Organization or use except as necessary to conduct a Study and under an agreement by the third party to be bound by the obligations of this Section. Institution and Investigator shall safeguard Sponsor Confidential Information with the same standard of care that is used with own Confidential Information, but in no event less than reasonable care. The parties including Site Management Organization understand and agree that information communicated to EC is "Confidential and Privileged".

7.3 The Parties including Site Management Organization agree to abide by applicable Law relating to the protection of Clinical Trial Subject Personal Information and where Confidential Information is also Personal Information, the obligations in this Section 7 shall remain in force for the period required under such law. The Party that received Personal Information hereunder shall only use or disclose the Personal Information as set out in the Clinical Trial Subject's consent form or as required by applicable Law. Each Party shall give prompt notice to the other Parties including Site Management Organization of any privacy or security breach it has experienced that affects Clinical Trial Subject Personal Information.

8. PUBLICATION

8.1 Institution and/or Investigator shall have the right to publish his own site patients' data generated during the Study. Upon receipt of written instruction from Sponsor, Institution and/or Investigator shall have the right to publish the results of the Study subject to the terms and conditions of this Section 8. Prior to submission for Publication purpose, the Institution and/or Investigator shall provide Sponsor thirty (30) days to review a Publication. If Sponsor requests in writing, the Institution and/or the Investigator shall withhold any publication or presentation an additional sixty (60) days solely to permit Sponsor to seek patent protection and to remove any Confidential Information from all publications. For the purpose of this Section, "Publication"

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means a paper, article, manuscript, report, poster, internet posting, presentation slides, abstract, outline, video, instructional material, presentation (in the form of a written summary), or other disclosure of Study Results, in printed, electronic, oral or other form.

8.2 Inclusion of the Institution and/or Investigator in the authorship of any multi-center publication will be based upon substantial contribution to the design, analysis, interpretation of data, drafting and/or critically revising any Publication derived from the Study. The Institution and the Investigator agree that if a Study is part of a multi-center study, any Publication by the Institution and/or Investigator of the results of the Study conducted at Institution shall not be made before the first multi-center publication. In the event there is no multi-center publication within twelve (12) months after a Study has been completed or terminated at all Study sites, and all data has been received, Institution shall have the right to publish its results from the Study, subject to the notice requirements described above.

8.3 Any publication or disclosure by the Investigator contrary to the provisions of this section or without prior written consent of Sponsor shall be void-ab -initio. It is agreed and acknowledged by the Parties including Site Management Organization that in the event of any breach of this Section, Section (7) & (8), in addition to other legal remedies that may be available, Sponsor shall have the right to seek specific performance and other injunctive and equitable relief, in any court having jurisdiction over the Parties and the subject matter hereof.

9. INTELLECTUAL PROPERTY RIGHTS

9.1 All Intellectual Property Rights owned by or licensed to Sponsor prior to and after the date of this Agreement are and shall remain the exclusive property of Sponsor.

9.2 All Intellectual Property Rights owned by or licensed to the Institution or the Investigator prior to and after the date of this Agreement, other than any Intellectual Property Rights arising from the clinical Study, are and shall remain the exclusive property of the Institution or the Investigator, as applicable.

9.3 All Intellectual Property Rights (including Clinical trial data and clinical trial documentation) arising from and relating to the Clinical Study/trial, the Investigational drug or the Protocol (the **"Clinical Trial Intellectual Property"**) shall be the exclusive property of Sponsor and for this purpose, the Institution and the Investigator hereby assign and transfer, and shall cause the trial site team members to assign and transfer, without additional consideration, to Sponsor (or its nominate designee), all their rights and title in and to the Clinical Trial Intellectual Property throughout the world on perpetual basis. The Institution and the Investigator shall execute and deliver, and shall cause the trial site team members to execute and deliver, all such documents and, at Sponsor's expense, do all such other acts as Sponsor may reasonably require in order to vest fully and effectively all Clinical Trial Intellectual Property in Sponsor or its nominate designee.

9.4 The Institution and the Investigator shall promptly disclose to Sponsor any Clinical Trial Intellectual Property generated pursuant to this Agreement and shall treat the Clinical Trial Intellectual Property as Confidential Information.

10. MISCELLANEOUS

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10 .1 All notices required to be given by one Party to the other shall be deemed to have been properly served when sent by a registered post or any other means of communication acceptable in law to the addresses mentioned in the first page of this Agreement or such appropriate addresses available in public domain.

10 .2 No forbearance or tolerance on the part of the either Party of any breach of this Agreement by the other shall constitute waiver of the requirements of this Agreement.

10 .3 Each Party acknowledges that it is entering into this Agreement solely on its own behalf, and will perform any and all of its obligations or work under this Agreement as an independent contractor. Nothing under this Agreement shall create any other relationship between the Parties including Site Management Organization including without limitation one of principal and agent, employer and employee, or partnership.

10 .4 The Institution and Investigator will be responsible for payment to its employees, study team members and/or agents of all salaries, wages, benefits, workman compensations reimbursable travel, lodging, and other expenses to which the study team members or employees or agents may be entitled to receive for performing services. Investigator will be solely responsible for withholding and paying all applicable taxes of whatsoever in nature, statutory contributions ,benefits, dues etc. that may be payable to its employees and/or agents.

10.5 This Agreement constitutes the entire Agreement between the Parties including Site Management Organization and supersedes all prior oral and written understandings between the Parties including Site Management Organization on the subject matter of this Agreement. Any Exhibit, Annexure or otherwise any documents, including but not limited amendment or modification made in reference with this Agreement shall be valid if the same is incorporated in writing on the terms that may be mutually agreed and signed by the authorized signatories of the respective parties including Site Management Organization.

10.6 The Parties including Site Management Organization hereby agree that any provision/s of this Agreement which is held to be invalid and unenforceable in law shall not by itself make this Agreement invalid nor effect the other provisions of this Agreement and the other terms shall remain fully enforceable and valid in law.

10.7 Neither the Investigator nor the Institution may assign this Agreement without the prior written consent of Sponsor. Sponsor may assign any or all of its rights and obligations under this Agreement at any time, provided that Sponsor ensures the assignee is bound by the terms hereof.

10.8 The Investigator and the Institution shall not subcontract the whole or any part of the performance of the clinical Study without the prior written consent of Sponsor. This Agreement ensures to the benefit of and binds the Parties including Site Management Organization and their respective administrators, successors and permitted assigns, and with respect to the investigator, heirs and executors.

10.9 This Agreement and the obligations of the Parties including Site Management Organization shall be governed by and construed in accordance with the laws of India .The Parties including Site Management Organization agree to submit to the exclusive jurisdiction of courts at Mumbai in connection with this Agreement.

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10.10 Neither Party to this Agreement shall be liable for breach of this Agreement to the extent caused by or arising from prohibition or restriction by law or regulation of any Government, fire, flood, storms, weather, strike, lock-out or other labour problems, accident, riots, acts of God, breakdown of communication facilities, breakdown of web host, breakdown of internet service provider or other events beyond that Party in breach. The Party affected by such circumstances shall promptly notify the other Parties including Site Management Organization in writing when such circumstances cause a delay or failure in performance and shall take whatever reasonable steps are necessary to relieve the effect of such cause as rapidly as reasonably possible. In the event of a delay lasting for four (4) weeks or more, the non-affected Parties shall have the right to terminate this Agreement in accordance the term of this Agreement.

10.11 The provisions of this Agreement which, by their terms, require performance after the termination or expiration of this Agreement, or have application to events that may occur after the termination or expiration of this Agreement, will survive the termination or expiration of this Agreement. All indemnity obligations and any applicable indemnification procedures will be deemed to survive the termination or expiration of this Agreement.

11. INTERPRETATION

11.1 Unless the context requires otherwise:

11.1.1. references to this Agreement are to this Agreement as it is from time to time amended;

11.1.2. headings are for convenience only and shall not affect interpretation;

11.1.3. references to the singular include the plural and vice versa, and references to one gender include all genders;

11.1.4. any phrase introduced by the expressions "including", "include" or any similar expression shall be construed as illustrative and shall not limit the sense of the words preceding those terms;

11.1.5. reference to any law: shall be deemed to include any bye-laws, licences, statutory instruments, rules, regulations, orders, notices, directions, consents or permissions made under that law; and shall be construed as referring to any law which replaces, re-enacts, amends or consolidates such law (with or without modification) at any time;

11.1.6. references to "writing" or "written" include any modes of reproducing words in a legible and non transitory form but do not include writing on the screen of a visual display unit or other similar device;

11.1.7. references to a numbered clause are references to the clause of or to this Agreement so numbered.

11.2 The parties hereto have participated jointly in the negotiation and drafting of this Agreement and, in the event an ambiguity or question of intent or interpretation arises, this Agreement shall be construed as jointly drafted by the parties hereto and no presumption or burden of proof shall arise favoring or disfavoring any party by virtue of

the authorship of any provision of this Agreement.

IN WITNESS WHEREOF the parties have executed this Agreement after carefully reading the contents of this Agreement out of their free will and consent without any kind of force or coercion on them.

- Signature page follows-

BY SPONSOR:

Sun Pharma Advanced Research Company Ltd.

Signature: Ajay Singh Solanki

Name: Mr. Ajay Singh Solanki

Designation: GM, Clinical Operations
(who by his signature hereto warrants his authority)

Date: 22.Aug.2016

Place: Mumbai.

BY INSTITUTION:

KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre

Signature:

Name: Dr. M. V. Jali

Designation: Medical Director
(who by his/her signature hereto warrants his/her authority)

Date:

Place:

BY INVESTIGATOR

KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre

Signature:

Name: Dr. Rohan Bhise

Designation: Principal Investigator
(who by his signature hereto warrants his authority)

Date:

Place:

BY SITE MANAGEMENT ORGANIZATION

GDD Experts India Pvt. Ltd.

Signature:

Name: Vinod Gyanchandani

Designation: Head-Clinical Operations
(who by his signature hereto warrants his authority)

Date: 29/Aug/2016

Place: Nagpur

APPROVED BY LEGAL
No.: R31.19.08.16
INITIALS

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

EXHIBIT-A

Financial Grant

Protocol No.: CLR_16_13

Protocol Title: "A Randomized, Open Label, Two Period, Single Dose, Crossover, Bioavailability Study of Paclitaxel Injection Concentrate for Nano-dispersion (PICN) and Abraxane® in Subjects with Locally Recurrent or Metastatic Breast Cancer."

Investigator's Name: Dr. Rohan Bhise

Institute Name: KLEs Dr. Prabhakar Kore Hospital & Medical Research Centre

Heads	Amount in INR with breakup		Schedule for Generating Invoice
Screen failure cost up to 5 subjects	8000/subject		Monthly
Investigator fee per completed subjects	Screening Visit	8000	Monthly
	Cycle 1 Day1	20500	
	Cycle 1 Day 8	4500	
	Cycle 1 Day 15	4500	
	Cycle 2 Day 1	20500	
	Cycle 2 Day 8	4500	
	Cycle 2 Day 15	4500	
	End of study visit	8000	
	Total	75000	
Study coordinator salary/month (From Site Initiation date till Site Close-out date)	15000		Monthly
Phlebotomist charges/ completed subject	Cycle 1	1250	Monthly
	Cycle 2	1250	
	Total	2500	
IP reconstitute or charges per reconstitute	1000		Monthly
Subject travel reimbursement/visit	1000		Monthly
Subject study participation in period 1 and period 2 *	Cycle 1	2500	Monthly
	Cycle 2	2500	
	Total	5000	
Administrative cost/ month (Internet, courier, stationary etc.) (From Site Initiation date till Site Close-out date)	2500		Monthly
Ethics committee charges	As per actual		Monthly
Hospitalization charges for cycle 1 & cycle 2	As per actual		Monthly
SAE management	As per actual		Monthly
Local lab charges	As per actual		Monthly
Institutional overheads charges	20 %		Monthly

ATTESTED

Prof. Dr. V.A KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

1) All invoices will be addressed to: Mr. Ashok Gupta, Sun Pharma Advanced Research Company Ltd., Clinical Research Dept., 17/B, Mahal Industrial Estate, Mahakali Caves Road, Andheri (E), Mumbai 400093, Maharashtra, India.

2) *As per Indian Council for Medical Research guidelines 2006 on "Ethical Guidelines for Biomedical Research on Human Participants"

Reliance Life Sciences Pvt. Ltd.
R-282, TTC Area of MIDC, Thane - Belapur Road,
Rabale, Navi Mumbai - 400 701, Maharashtra, INDIA.
Phone: +91-22-4067 8000 • Fax: +91-22-4067 8099

Reliance
Life Sciences

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the Agreement) is entered on the _ day of _ 2018 between **1) Dr. Sameer Haveri ("Investigator"), Consultant Orthopedics** at **KLE's Dr. Prabhakar Kore Hospital** and **2) KLE's Dr. Prabhakar Kore Hospital ("Institution")** both having its address at **KLE's Dr. Prabhakar Kore Hospital & M.R.C, OPD No 18, First Floor, NH 4, Nehru Nagar, Belagavi, Karnataka 590010, India 3) Genesis Research ("SMO") Site Management Organization** having its address at **4/22 , E Ward, Jadhavwadi, Kolhapur (M Corp), Karveer, Kolhapur- 416005, Maharashtra, India** and **4) Reliance Life Sciences Pvt. Ltd.**; **("Reliance")**, with a registered office at Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701, India.

"Investigator", "Institution", "SMO" and "Reliance" are hereinafter collectively referred to as 'Parties" and individually as a 'Party".

PROTOCOL NUMBER:	RLS/OST/2016/05
PROTOCOL TITLE:	Prospective, multi-center, randomized, double-blind, two-arm, parallel group, active control, comparative clinical study to evaluate efficacy and safety of R-TPR-045 / Prolia® in post-menopausal women with osteoporosis.
STUDY PRODUCT:	R-TPR-045 / Prolia®
Sponsor	**Reliance Life Sciences Pvt. Ltd.**
INVESTIGATOR:	**Dr. Sameer Haveri**
INSTITUTION/SITE:	**KLE's Dr. Prabhakar Kore Hospital & M.R.C, OPD No 18, First Floor, NH 4, Nehru Nagar, Belagavi, Karnataka 590010, India**

WHEREAS, Reliance wishes to engage the Investigator, SMO & Institute to carry out Sponsor designated clinical study set out and described in protocol **RLS/OST/2016/05** and the Investigator, SMO & Institute is able and willing to conduct a clinical trial (the "Study"), in accordance with the above-referenced Protocol (the "Protocol" and any subsequent amendments thereto) on the terms and conditions set forth in this Agreement. Reliance wishes to contract with the Investigator & Institute for conducting the Study at the Institution.

WHEREAS, the Investigator, SMO & Institute is willing to conduct the Study in accordance with the above-referenced Protocol and any subsequent amendments thereto and Reliance requests the Investigator to undertake such Study;

ATTESTED

Regd. Office: Dhirubhai Ambani Life Sciences Centre, R-282, TTC Area of MIDC, Thane - Belapur Road, Rabale, Navi Mumbai - 400 701, INDIA. • Phone: +91-22-4067 8000 • Fax: +91-22-4067 8099. • Website: www.rellife.com
CIN : U24239MH2001PTC130654

Prof. Dr. V.A.KOTHIWALE
Registrar
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WHEREAS the Institution has engaged **Genesis Research** a Site Management Organization of **KLE's Dr. Prabhakar Kore Hospital & M.R.C.**, authorized to facilitate the clinical trial study, on behalf of the Institution.

NOW THEREFORE, the parties have agreed as follows:

A. Reliance hereby appoints the Investigator as principal investigator to conduct the portion of the Multi-Center Clinical Study (referred to hereinafter as the "Study) that is to be conducted at the Institution under the supervision and direction of the Investigator pursuant to this Agreement". The Investigator, SMO and Institution agree to ensure that all associates, employees assisting in the conduct of the Study and other study team members will be bound by the terms of this Agreement. The Investigator , SMO and Institution shall conduct the Study in accordance with: (a) the Protocol; (b) the terms of this Agreement, (c) the Financial Agreement attached as Appendix A; and any other the attachments hereto, which are all incorporated by reference herein (the "Agreement"), (d) the International Conference on Harmonization ('ICH') guidelines for Good Clinical Practices ('GCP'), Ethical Guidelines for Biomedical Research on Human Subjects as prescribed by the Indian Council of Medical Research 2000 and all applicable laws and regulations and approval of the Ethics Committee ('EC') of the Institution. The Investigator hereby warrants that he has the experience, capability and resources, including, but not limited to, sufficient personnel and equipment to perform the Study in a professional and competent manner, and in strict adherence to the Protocol.

B. The Study will be conducted at the Institution under the direction of the Investigator identified above. The Investigator, SMO and Institution will be responsible for performing the Study and for direct supervision of any individual performing any portion of the Study at the Institution. In the event the Investigator becomes unwilling or unable to perform the duties required for the Study conducted under this Agreement, the Institution, SMO and Reliance shall attempt to agree on a mutually agreeable replacement. In the event a mutually acceptable replacement is not available, then the Agreement may be terminated by Reliance hereto in accordance with Section 10 of this Agreement.

C. In consideration of conducting the Study hereunder, Reliance shall pay the Payee for the conduct of the Study, in accordance with the budget and payment schedule attached as Appendix A to this Agreement, with the last payment being made after the Investigator, SMO and Institution complete all obligations hereunder, including the return of any Confidential Information as defined herein, and after Reliance receives verification that all completed case report forms (CRF's) have been completed and data queries have been entered and resolved.

D. In the event that the Study does not start or is terminated prematurely by Reliance, Investigator/Institution shall be entitled reimbursement for all reasonable fees and expenses incurred by the Investigator/Institution/SMO up to the effective date of termination of the Study on the production of bills to Reliance. The Investigator/Institution/SMO will not be paid for Study subjects who do not complete the Study unless the Study is terminated in accordance with Section 10

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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E. Reliance shall execute an agreement with Central Laboratory, to perform certain Study-related investigations for the Study. The Investigator agrees to cooperate with Central Laboratory and their designated representatives in performing Study-related investigations as specified in the Protocol.

F. This Agreement will become effective on the date on which it is signed by the parties.

G. Investigator's signature below evidences Investigator's agreement that, prior to commencement of the Study, he/she shall read and ensure that he/she understands all information in the Protocol and the Investigator's Brochure, including the potential risks and side effects of the Study Product, and understands the Applicable Laws and Requirements.

TERMS AND CONDITIONS

1. Conduct of the Study.

1.1 Before Commencement of Study. Before the Study commences, the Investigator shall make necessary filings and obtain all necessary authorizations, approvals, favourable opinions and other regulatory documentation required by the Protocol and "Applicable Laws and Requirements" (defined below), including:

a. Written approval or favourable opinion from all relevant Institutional Ethics Committees or institutional review boards (the "Institutional Ethics Committee") regarding the conduct of the Study, the terms of the Protocol (including the informed consent template), recruitment procedures, and the other matters designated for their opinion under the Protocol or Applicable Laws and Requirements. Reliance will assist the Investigator in making applications to the Institutional Ethics Committee by providing relevant information and documentation

b. In addition, before participating in the Study, the Investigator shall sign and deliver to Reliance an Investigator's Study Undertaking in accordance with Appendix VII to Schedule Y to Drugs and Cosmetics Rules, 1945,, and such other applicable documents as may be required from Investigator pursuant to Applicable Laws and Requirements, and Institution, Investigator and shall cause any co-investigators or sub-investigators to timely submit such documentation to Reliance.

c. The Investigator shall also, prior to commencement of the Study, provide to Reliance a copy of all (i) requests for review, requests for authorization, and requests for opinion, (ii) approvals, authorizations, favourable opinions and any other opinions given by any of the Institutional Ethics Committee, and (iii) any other documentation filed with and/or received from any Institutional Ethics Committee or Regulatory Authority related to the Study.

d. After the conditions precedent set forth in this Section 1.1 are satisfied, the Institution, and Investigator shall commence the Study, and shall comply with the conditions attached to the authorizations/approvals.

e. The Investigator will review and understand the information in the Investigator's Brochure, shall ensure that all informed consent requirements as well as the procedures described in the Protocol in relation to each Study patient are met. Investigator will complete a CRF for each Study patient in accordance with the procedure set out in the Protocol. Investigator will review and sign each of the CRF's to confirm that they accurately reflect the data collected during the Study.

f. Upon completion of the Study, investigator shall inform the Institution, Institutional Ethics Committee and provide a summary of the Study report.

1.2 Site Visits. The Institution , SMO and the Investigator shall permit Reliance and their representatives to visit the Study Site during normal business hours, with reasonable advance notice, to review personnel, procedures, and facilities; to discuss with Investigator the general obligations regarding the Study; to review Investigator's Study file and the forms used for data collection for completeness and adherence to the Protocol; and to ensure compliance with this Agreement and all Applicable Laws and Requirements. The Investigator will promptly and fully produce all data, records and information relating to the Study, to Reliance and their representatives and shall assist them in resolving any questions and in performing audits or reviews of original subject records, reports or data sources.

1.3 Study Product.

a. Upon the receipt by Reliance of the written approval of the Institution's Ethic Committee Reliance shall provide the Investigator, at no charge, with such quantities of the Study Drug as may be required for the Study. The Investigator, SMO and Institution shall have no liability for any failure to fulfill its obligations as a result of unavailability of the Study Drug. Upon completion or termination of the Study, Reliance may retrieve all unused Study Drug and Study materials (such as unused laboratory kits) and all Confidential Information (as defined below). The Investigator, SMO and Institution will keep full and accurate records of who dispenses the Study Drugs, the quantity dispensed and the quantity returned. The Investigator and Institution shall use the Study Drug being tested in connection with the Study, solely for the purpose of properly completing the Study and shall maintain all Study Drug and Study materials provided by Reliance in a locked, secured area at all times.

b. The Investigator shall be primarily responsible for the Study Product's accountability and will keep full and accurate records of the use and disposition of the Study Product, including the delivery of the Study Product to the Investigator's Site, the inventory at the Site, who dispenses the Study Product, the quantity dispensed, and the quantity returned to the Sponsor or disposed.

c. Institution, SMO and Investigator shall comply with all Applicable Laws and Requirements governing the disposition or destruction of Study Product and with instructions from the Reliance. If in case site is not destructing the IP, all used and unused IP shall be return to sponsor along with copies of accountability documents at the time of close out or earlier as per sponsor's intimation.

1.4 Adverse Events. The Investigator shall report all adverse events, adverse reactions, product problems and any other reportable events or product use errors to the Reliance immediately and within the timelines defined in the Protocol, and to report the same to the Institutional Ethics Committee in accordance with the Protocol and Applicable Laws and Requirements, and shall otherwise comply with all Applicable Laws and Requirements in connection therewith. Reliance shall ensure that an up-to-date Investigator's Brochure on the Study Product is available for dissemination to the Institutional Ethics Committee, as well as subsequent modifications, if any, to the Subject Information Sheet and informed consent template.

1.5 New findings. Reliance will promptly report to the investigator any new findings that could affect the safety of participants and the willingness of participants to continue participation influence the conduct of the study or alter the IRB's approval to continue the study. Those findings that could affect the safety or medical care of the participants will be communicated to the participants by the investigator. The investigator will also inform the participant when medical care is needed for an illness of which the investigator becomes aware.

2. **Recruitment.** Subject to all necessary approvals being obtained, the Investigator shall be responsible for the recruitment of Research Subjects in the Study. The Investigator shall use the Investigator's best efforts to ensure that Research Subjects fulfilling the Protocol criteria are recruited. Investigator shall ensure the unbiased selection of an adequate number of suitable subjects according to the Protocol, and shall use best efforts to enrol at least **10 suitable subjects** and shall limit enrolment of subjects to the maximum number specified by the Reliance from time to time. Investigator acknowledges that Reliance reserve the right to limit entry or enrolment of subjects at any time on written notice to Investigator. Investigator shall obtain the written approval of the Institutional Ethics Committee and Reliance to the text of any communication soliciting subjects for the Study before placement, including, but not limited to, newspaper and radio advertisements, direct mail pieces, Internet advertisements or communications, and newsletters, which communications must comply with Applicable Laws and Regulations.

3. **Enrolment; Notices; Informed Consent; Authorization:**

3.1 Prior to enrolling a Research Subject in the Study, Investigator shall obtain (a) the Research Subject's informed consent, as evidenced by a signed informed consent document evidencing the informed consent of Research Subjects for participation in the Study, in the form approved by the relevant Institutional Ethics Committee; (b) an Authorization (as defined and described below); and (c) such other consents as may be required by the Protocol or Applicable Laws and Requirements.

3.2 Institution, SMO and Investigator shall adhere to the principles of medical confidentiality and shall comply with all Applicable Laws and Requirements related to the personal data of Research Subjects,

including data privacy or data protection laws of the country in which the data originated. Investigator shall obtain from each Research Subject and provide to Reliance a written consent and authorization valid under Applicable Laws and Requirements (each, an "Authorization") for the access, use, processing, storing, disclosure and transfer of the Research Subject's personal data by and to (a) Institution, SMO, Investigator, and their study team, (b) persons monitoring the Study and/or the Multi-Center Clinical Study or conducting an independent valuation of the Study and/or the Multi-Center Clinical Study, (c) the representatives of the Institutional Ethics Committee, (d) the Regulatory Authorities, and (e) Reliance and Central Lab and their representatives and agents, including third parties directly or indirectly performing services for Sponsor related to the Study and/or the Multi-Center Clinical Study.

4. **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 Study Product), provided to the Investigator, SMO and Institution by Reliance or Sponsor or their agents (whether verbal, written or electronic), and all data, reports and information relating to the Study Product, the Study or its progress (hereinafter, the "Confidential Information") shall be the property of Sponsor. The Investigator, SMO and Institution will undertake to keep in strict confidence and not at any time to use other than in the Study or to disclose or permit to be disclosed to any third party the data and results of the Study and any information provided directly or indirectly by the Sponsor or Sponsors Representatives under this Agreement. The Investigator, SMO and Institution shall keep the Confidential Information strictly confidential and shall disclose it only to its employees involved in conducting the Study on a need-to-know basis. The Investigator, SMO and Institution shall ensure that the immediate members of the staff and any co-investigator who have access to Confidential Information are informed of its confidential nature and agree in writing to keep it strictly Confidential in accordance with the provisions of this Section 4. The obligations of non-disclosure stated in this Section shall be for a minimum period of ten (10) years after disclosure of said Confidential Information to Investigator and /or Institution and /or SMO under consideration for the provisions of sub-section 4 (a) – (f) inclusive, and these confidentiality obligations shall continue 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 Investigator, SMO and Institution ; b) is disclosed to the Investigator by a third party not subject to any obligation of confidence; c) must be disclosed to ECs or applicable Regulatory Authorities; d) must be included in any Study subject's ICF; e) is published in accordance with Section 7 herein; or, f) is required to be disclosed by applicable law.

5. **Intellectual Property Rights -** All intellectual property rights existing prior to the date of this Agreement will belong to the Party that owned such rights immediately prior to the date of this Agreement. Neither Party will gain by virtue of this Agreement any rights in or ownership of copyrights, patents, trade secrets, trademarks or any other intellectual property rights owned by the other party. The Investigator, SMO and Institution hereby agree that the Sponsor shall own all intellectual property rights arising out of the Study and related to the Study Drug, including any rights with respect to any discoveries, inventions, whether patentable or otherwise and which relates to the materials and arising as a result of the Study. The Investigator, SMO and Institution will, at Sponsor's expense, execute any documents and give any testimony necessary for Sponsor to effect the

time to time, for inspection/audit by representatives of Reliance and/or national or international Regulatory Authorities, all such report forms and further documentation and information used and/or generated in the Study. The Investigator, SMO and Institution shall immediately notify Reliance of, and provide Reliance 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 Institution's facilities, and the Investigator, SMO and Institution shall permit Reliance to attend any such inspections. The Investigator, SMO and Institution will make reasonable efforts to separate, and not disclose, all confidential materials that are not required to be disclosed during such inspections, except as required by law. The Investigator, SMO and Institution shall also arrange for access by such individuals to source data and shall be responsible for obtaining the informed consent of Study subjects to such disclosure of personal medical data and records, if required by law, and if not expressly granted by the subject in the signed ICF.

9.2 The Investigator and/or Institution and/or SMO shall permit the representatives of Reliance to visit the premises on which the Study is being conducted and arrange/ grant access to laboratories and facilities used in connection with the Study, at periodic intervals at a mutually agreeable time.

9.3 The Investigator, SMO and Institution shall permit the Reliance to inspect and audit the study. The Investigator, SMO and Institution shall be responsible for maintaining essential Study documents for the time and in the manner specified by current ICH-GCP guidelines, local laws, and Sponsor requirements and shall take measures to prevent accidental or premature destruction of these documents. In the event the Investigator leaves an Institution or otherwise changes addresses, the Investigator, SMO and Institution shall promptly notify the same to Reliance.

9.4 The Investigator, SMO and Institution represents and warrant that neither the Investigator nor the Institution nor any of the employees, agents or other persons performing the Study under the Investigator's 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 Investigator or Institution shall notify Reliance immediately if any such investigation, disqualification, debarment or ban occurs.

10. Study Term and Termination.

10.1 This Agreement shall be effective upon the date it is signed by all the parties and shall continue in effect till the completion of the Study as mentioned in the Protocol, unless terminated earlier by the parties as given below:

a. Reliance may terminate this Agreement with prior written notice of 30 days to the Investigator/ Institution for reasons including but not limited to any of the following occurrences:

i) If no subjects are recruited by the Investigator within 30 days of the site initiation; or

ii) No recruitment is done by the Investigator for a period of 45 consecutive days; or

iii) If, no patients have been enrolled or the Investigator recruits no patients or recruits such a low number (less than 2 in number) of patients that it can be assumed that the agreed number of patients will not be reached during the planned recruitment phase;

iv) Sponsor terminates the Study or the Study Drug or the indication is discontinued;

v) It is proved that the dosage used for the Study no longer seems to be justified;

vi) A regulatory authority or other pertinent institution decides to terminate the Study in this Institution or as a whole;

vii) The Investigator/ Institution/SMO fail to adhere to the conditions of the Protocol and the requirement to complete CRF data according to the Guidelines for Good Clinical Practice.

b. Should the Investigator/Institution/SMO recognize, with reasonable discretion, that continuation of the Study is no longer medically justified, due to (i) unexpected results (ii) the severity or prevalence of serious adverse effects or (iii) the efficacy of the treatment with Study Drug appears to be insufficient; then he/ she will promptly notify Sponsor as well as the Institutional Ethics Committee in writing. Should Reliance or the Institutional Ethics Committee agree that continuation is not justifiable; the Investigator/Institution/SMO may arrange immediate termination of the Study.

c. Whichever party terminates the Study early shall provide the other parties with a written statement of its reasons for doing so. Reliance will notify Regulatory authorities as appropriate of early termination, except that the Investigator will notify the Institutional Ethics Committee.

10.2 **Effect of Termination** Upon receipt of notice of termination, the Investigator shall immediately cease any patient recruitment, complete all outstanding Case Report Forms and return to Reliance all documents/equipment (if any) provided by the Reliance under this Agreement and following the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs. In the event of early termination Reliance shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in the Payment Schedule (Annexure A); provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all completed CRFs and all data clarifications issued and satisfaction of all other applicable conditions set forth in the Agreement.

10.3 Reliance shall not be responsible to the Investigator, SMO or the Institution or for any lost profits, lost opportunities, or other consequential damages arising out of this Agreement. If a material breach of this Agreement appears to have occurred and termination may be required, then, subject to subject safety, Reliance may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

11. Indemnification; Claims and Disclaimers.

11.1 Reliance agrees to indemnify, defend or cover costs of defense for, and hold harmless ("Indemnify") the, Principal Investigator; the Institution, SMO its officers, agents, and employees; and the IEC that approved the Trial (collectively, "Indemnified Parties") against any claim filed by a third party for damages, costs, liabilities, expenses to the extent that it relates to the death of a Subject caused by: a) the administration of the Sponsor Drug and/or Comparator Drug; (b) by a properly-performed Protocol-required procedure;, provided, however, that Reliance will not indemnify or hold harmless the **Indemnified Parties** for any Liabilities arising from any injuries or damages that are a result of:

(i) the negligence or intentional misconduct of any of the **Indemnified Parties** and/or
(ii) any activities conducted contrary to the provisions of the Protocol or outside the scope of the Protocol; or information supplied by Sponsor and/or generally accepted medical standards and the applicable SOPs; and/or
(iii) any negligence, omission, or willful misconduct by any **Indemnified Parties** in the performance of their obligations under this Agreement and/or,
(iv) failure to have complied with all dosage and other specifications, directives and recommendations furnished by the Sponsor for the use and administration of the Study Drug and/or
(v) failure to have complied with all applicable laws, rules, and regulations.

However, Reliance's indemnification obligations are subject to the following conditions:

a. The Research Subjects involved gave an adequate written informed consent and was provided prompt diagnosis and appropriate medical care following the occurrence of the injury;
b. The Reliance receives notice of the applicable, diagnosis, care initiated and care anticipated to be necessary and all appropriate follow-up reports; and Reliance are promptly notified in writing of any such claim or suit;.
c. Indemnified Parties reasonably cooperates with Sponsor and its legal representatives in the defense of any claim, suit, demand, action or other proceeding covered by this Agreement; and
d. permits Sponsor to select and retain the right to defend any claim or suit in any manner it deems appropriate, including retaining a counsel to represent the Institution Indemnities and
e.. The indemnification obligations above shall not apply to amounts paid in settlement of any claim, demand, action or other proceeding if such settlement is effected without the consent of the Sponsor.

Reliance's indemnification obligations do not apply to any complication of an underlying illness or any other injury that any Research Subjects may experience during the course of the studies that is not directly related to the Study Drug.

ATTESTED
Prof. Dr. V.A.KOTHIWALE
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11.2 Investigator Institution and SMO shall indemnify, defend, and hold harmless Reliance and each of their respective affiliates, directors, officers, employees, contractors, and agents from and against any loss claim or demand arising from the following: (i) injuries or damages resulting from the negligent or willful misconduct of the Investigator, SMO and Institution or any of their respective affiliates, directors, officers, employees, contractors, and agents, including any co-investigators or sub-investigators performing the Study; or the failure of Institution and/or Investigator or any of their employees, contractors, and agents, including any co-investigators or sub-investigators, (i) to comply with the Protocol or written instructions of Reliance or any Applicable Laws and Requirements; or (ii) any breach by Institution, SMO or Investigator of any of their respective obligations under this Agreement, including but not limited to any failure to comply with the Protocol or any Applicable Laws and Requirements or (iii) any case in which the Investigator fails to obtain an informed consent form in compliance with the terms of this Agreement or otherwise fails to comply with local or national laws or regulations provided:

a. Investigator, SMO and Institution promptly notified in writing of any such claim or suit;
b. Sponsor cooperate fully in the investigation and defense of any such claim or suit;
c. Investigator, SMO and Institution retain the right to defend any claim or suit in any manner it deems appropriate, including the right to retain counsel of its choice; and
d. Investigator, SMO and Institution shall have the sole right to settle the claim; provided, however, that Investigator shall not admit fault on Sponsor's behalf without Sponsor's advance written permission.

11.3 The Investigator, SMO and Institution shall promptly notify Reliance in writing of any claim of illness or injury actually or allegedly due to an adverse reaction to the Study Product and allow Reliance to handle such claim (including settlements) as per the guidelines of regulatory authorities, and shall cooperate fully with Sponsor in its handling of the claim.

11.4 Institution, SMO and Investigator acknowledge that the study product is experimental in nature, is not for commercial use, and is provided "as is" without any warranty, representation or undertaking whatsoever, express or implied, including, without limitation, any warranty of merchantability, fitness for a particular purpose, or non-infringement. Reliance shall not under any circumstances be responsible or liable under this agreement for any indirect, incidental, or consequential damages (including without limitation damages for loss of profit, revenue, business, or data), even if the party has been informed of the possibility of such damages.

12. **Financial Disclosure**. Reliance may withhold payments if it does not receive a completed form from each such Investigator and sub-Investigator. The Investigator shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one year after its completion. The Investigator, SMO and Institution agree that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, Reliance and their agents and Institutional Ethics Committee.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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Whenever the investigator discloses a financial interest, the nature of financial disclosure will be reviewed by the Project Manager of Reliance and the same shall be reported to the sponsor.

13. **Insurance**: Each party shall maintain types and levels of insurance or other adequate forms of protection consistent with industry standard and sufficient to satisfy its respective obligations under this Agreement. Each party shall provide the other party with a certificate of insurance upon request.

14. **Shipping of Dangerous Goods and Infectious Materials.** The handling, packaging and shipment of dangerous goods and infectious materials (including infectious specimens) are subject to local and national laws and regulations.

15. **Publicity.**

15.1 **Solicitation of subject:** Reliance and Institution Institutional Ethics Committee shall approve in writing, the text of any communication soliciting subjects for the Study before placement, including, but not limited to newspaper or radio advertisements, direct mail, internet advertisements or communications, and newsletters. Such communication must comply with applicable laws and guidelines.

15.2 **Press Releases:** Reliance shall approve, in writing, press statements by Investigator and Institution regarding the Study or the Study Drug before the statements is released.

15.3 **Enquiries from media and financial analysts**: During and after the Study, the Investigator, SMO and Institution may receive enquiries from reporters or financial analysts. Investigator and Institution confer with Sponsor and the Reliance authorised signatory to this Agreement named below or other named person in the same position of employment at that time at Reliance Life Sciences Pvt. Ltd. Dhirubhai Ambani Life Sciences Centre, Plot no. R - 282, TTC Area of MIDC, Thane Belapur Road, Rabale, Navi Mumbai 400 701 before responding to such enquiries.

15.4 **Use of Name**: Investigator, SMO and /or Institution or any of the Investigator and Institution's trained staff/employees, agents or other persons performing the Study under the Investigator's direction will not use Reliance's ' name or the names of Reliance employees in any advertising or sales promotional material or in any publication without the prior written permission of Reliance. The Sponsor and Reliance shall not use the name of the Investigator, SMO or Institution and their employees in any sales promotional material or in any publication without written permission from the Investigator, SMO and Institution.

16.0 **Additional Contractual Provisions.**

16.1 In conducting the Study, the Investigator, SMO and Institution shall be an independent contractor and shall not be considered the partner, agent, employee, or representative of Reliance and the Investigator and /or Institution and/or SMO has no authority to bind Reliance to any contract or commitment unless specifically

authorized to do so in writing. 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.

16.2 The following provisions shall survive the termination or expiration of this Agreement; Section 4 (Confidential and Proprietary Information); Section 6 (Study Records); Section 7 (/Publication); Section 8 (Subject Injury Reimbursement); Section 11 (Indemnification; Claims and Disclaimers) and Section 15 (Publicity/Use of Names)

16.3 Amendments 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.

16.4 During the term of this Agreement, neither Investigator, nor Institution or SMO shall directly or indirectly conduct study related clinical trials as set out in the protocol no. RLS/RES/2016/01 and any subsequent amendments thereto or participate in the study which is same or similar to the sponsor designated study of Reliance mentioned in this CTA, without prior written approval of the Reliance.

16.5 Restrictions on Assignment. Neither Party will assign or transfer any rights or obligations under this Agreement without the prior written consent of the other Parties, which consent shall not be unreasonably withheld.

16.6 Conflict of interest. Investigator, SMO and Institution warrant and represent that the Investigator has no obligations, contractual or otherwise, that would conflict with its entering into this Agreement. Investigator, SMO and Institution further agree that subsequent to execution of this Agreement, the Investigator and /or Institution and/or SMO will undertake no obligations that would conflict or interfere with its performance hereunder.

16.7 Notice: Any notices that either Party may be required to give the other shall be deemed to be duly given when mailed by certified or registered mail, postage prepaid, to the other Party at the addresses first given above or to such other addresses as the Parties may direct in writing. Any notice or other communication required or permitted under the Agreement shall be in writing and will be deemed given as of the date it is received by the receiving party.

16.8 Governing Language: The controlling language of this Agreement and all related documents, correspondence and notices shall be in English. This Agreement shall be governed by and construed in accordance with the laws of India without conflict of laws and principles.

16.9 Arbitration. Any dispute, controversy or misunderstanding between the Parties arising out of or related to this Agreement or any breach thereof shall be mutually settled by the Parties between their authorized representatives within a period of thirty days. In case, the dispute is not settled within a period of thirty days by the authorized representatives, the same shall be submitted to arbitration in accordance with Arbitration and Conciliation Act, 1996. Parties shall appoint a sole arbitrator, mutually agreed by the Parties or panel of arbitrator as required thereto. The place of Arbitration shall be at Mumbai and the language shall be in English. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs. Any award rendered by the arbitrators shall be in writing, shall be the final binding disposition on the merits, and shall not be appealable to any court in any jurisdiction. Judgment on an award rendered may be entered in any court of competent jurisdiction, or application may be made to any such court for a judicial acceptance of the award and an order of enforcement, as appropriate.

16.10 The Parties waive any right they may enjoy under the law of any nation to apply to the courts of such nation for relief from the provisions of this Item or from any decision of the arbitrators. In the event a court of competent jurisdiction determines that this Agreement is invalid or unenforceable for any reason, this provision shall not be affected thereby and shall be given full effect without regard to the invalidity or unenforceability of the remainder of this Agreement. Notwithstanding anything herein seemingly to the contrary, any party may seek injunctive relief from a court of competent jurisdiction to prevent or limit damage to that party's intellectual property.

16.11 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original and all of which shall constitute the same instrument. This Agreement shall be effective upon full execution by facsimile or original, and a facsimile signature shall be deemed to be and shall be as effective as an original signature.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

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ACKNOWLEDGED AND AGREED BY RELIANCE LIFE SCIENCES PVT. LTD:

By: _____

Name: Ms. Jamila Joseph

Title: SVP, Reliance Products Clinical Research Group

Date: 19 March 18

ACKNOWLEDGED AND AGREED BY INVESTIGATOR:

By: _____

Name: Dr. Sameer Haveri

Title: Consultant Orthopedics

Date: _____

ACKNOWLEDGED AND AGREED BY THE INSTITUTION:

By: _____

Name: Dr. M. V. Jali.

Title: KLE's Dr. Prabhakar Kore Hospital & M.R.C.

Date: _____

ACKNOWLEDGED AND AGREED BY SMO:

By: _____

Name: Genesis Research

Date: 26 Mar 2018

Appendix A to Clinical Trial Agreement

Payee:

Investigator and Institution have designated "**Genesis Research**" as a Payee to receive all the payments under this Agreement. The details of the Payee designated to receive all of the payments for the services performed under this Agreement

PAYEE NAME:	**Genesis Research**
PAYEE ADDRESS:	**4/22 , E Ward, Jadhavwadi, Kolhapur (M Corp), Karveer, Kolhapur- 416005, Maharashtra, India**
TAX ID NUMBER (PAN Number)	**CQJPP0528D**
GSTIN	**27CQJPP0528D1ZX**

The payments will be made by account payee Cheque in favor of the Payee **Genesis Research** in Indian Rupees.

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

Agreement Clauses

1) For the amount designated as per-patient budget, the Payee will receive payment only for the actual number of visits and procedures performed in accordance with agreed upon procedure fees outlined in the financial agreement; such compensation is limited to payment for the number of patients who have completed these visits as per the Protocol, unless Reliance has given the Payee written approval to enroll additional Study subjects or extend the enrollment period.

2) To be eligible for payment, the procedures must be performed in full compliance with the Protocol and the Agreement, and the data submitted must be complete and correct. For data to be complete and correct each Study subject must have signed an EC-approved ICF document, and all procedures designated in the Protocol must be carried out on a best effort basis; omissions must be satisfactorily explained.

3) Reliance will reimburse the Payee, in accordance with the attached budget and payment schedule. The final payment will be made by Reliance to the Payee upon final acceptance by Reliance of all completed CRFs, all data clarifications issued, the receipt and approval of any outstanding regulatory documents as required by Reliance, the return of all unused supplies to Reliance, and upon satisfaction of all other applicable conditions set forth in the Agreement.

4) Other than the final payment, Reliance shall not issue any payment for a total amount less than Rs.1000/- If the amount due in any given period is less than Rs.1000/-, such amount shall carry over without payment to the next payment period.

5) Major, disqualifying Protocol violations are not payable under this Agreement.

6) Matters in dispute shall be payable upon mutual resolution of dispute.

7) Start-up fee of Rs. 60000/- will be released by Reliance at the time of site initiation before screening first patient in the study.

If Reliance requests the Investigator's attendance at a Study-start up meeting or other meeting necessary to provide the Investigator with information regarding the Study or Study Drug, Reliance shall reimburse the amount of reasonable and necessary travel and lodging expenses that may be incurred to attend such meeting(s) and that have been specifically approved in advance by Reliance. Reliance shall make such reimbursements within thirty (30) days of receiving acceptable detailed documentation of such expenses provided that Reliance receives such documentation within sixty (60) days of the date that the expenses were incurred.

Payments shall be made as described in Appendix A and the rates agreed to between the Parties, as per the milestones described in the budget and payment schedule. Original invoices must be submitted to Reliance at the following address for reimbursement:

Reliance Life Sciences Pvt. Ltd.,
Dhirubhai Ambani Life Sciences Centre,
Plot no. R-282, TTC Area of MIDC,
Thane Belapur Road,
Rabale, Navi Mumbai 400 701
Attn: Kamlesh Londhe , Tel: 022- 6767 8213, Fax: 022-6767 8099

The Payee will have 15 days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

Taxes

All payments shall be made net of income tax as per the Income tax act applicable at the time of payment. The TDS certificates for the income tax deducted will be provided in accordance with Income Tax Act 1961.

Appendix A - Budget & Payment Schedule

A.1. FINANCIAL SUMMARY (Unit Cost/Visit)

Protocol: **RLS/OST/2016/05**

Investigational Product: R-TPR-045

Clinical Trial Budget		
	Project Name:	Denosumab
	Project Code	K069
	Name of PI	Dr. Sameer Haveri
		Unit Cost/Visit
Investigator fees		5,750
1	Principal Investigator	4,000
2	Clinical Research Coordinator	1,500
4	Phlebotomist (for PK and PD samples)	250
Patient related expenses		3,000
1	Travel reimbursement	500
2	Hospitalization charges	2,500
Administrative overhead-20% of Investigator Fee		800
Laboratory Testing Charges		
	Name	Cost
	Investigation	
1	Dexa Scan (BMD)	3,000
2	Spinal X-ray	500
3	12 lead ECG	300
4	Chest X Ray	500
5	X-ray (Maxillofacial region-Jaw)	500
	Study Start-up fee	60,000

- Reliance will pay for screening fees at the rate of one Screen Failure for every 2 patients enrolled in the study
- Hospitalization charges mentioned are for 24 hrs. Patient participating in PK will be hospitalized for 2 days.

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Registrar
KLE Academy of Higher Education
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A.2 Per Visit Payment schedule:

Total study Budget/patient						
Visit	Sub visit	Investigator fees	Laboratory Test	Patient related expenses	Administrative Overheads	TOTAL
Screening		5500	4800	500	800	11600
Day 1	0 hrs	5750	300	3000	800	9850
Day 3	48 hrs	250	0	3000	0	3250
Day 5		250	0	500	0	750
Day 7		250	0	500	0	750
Day 9		250	0	500	0	750
Day 11		250	0	500	0	750
Day 13		250	0	500	0	750
Day 15		250	0	500	0	750
Day 22		250	0	500	0	750
Day 29 (1M)		5750	0	500	800	7050
Day 43		250	0	500	0	750
Day 57		250	0	500	0	750
Day 85 (3M)		5750	0	500	800	7050
Day 113		250	0	500	0	750
Day 141		250	0	500	0	750
Day 183 (6M)		5750	4300	500	800	11350
9 Month		5750	0	500	800	7050
12 Month		5750	4300	0	800	10850
TOTAL		43000	13700	14000	5600	76300
					Total budget per subject excluding GST	76300
					cGST(9%) sGST(9%) iGST(18%)	90034

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Note:

* Patient related expenses (investigation, travel expense etc will be released as per actual number of visits completed by patients after monitor's verification and as per the statement provided by the investigator on the letterhead of the Investigator/Institute (not exceeding the cost specified above for each patient per visit).

- # In addition to the above Reliance shall make the following payments:
- It is expected that the site will enroll 10 patients.
- Reliance will pay for screening fees at the rate of one Screen Failure for every 2 patients enrolled in the study as per A.2 Payment schedule, However site need to send pre-screen report to the sponsor before performing actual screening.
- EC protocol review fee will be paid as per actuals.
- Procedure and Non-procedure cost for unscheduled visit and SAE or conditional procedures will be reimbursed upon receipt of invoices as per A.2 Payment schedule under this Agreement. However, sponsor's prior approval should be taken for such visits and procedures (on case to case basis).

Please note the following:

- Payments are calculated according to the above schedules payable on confirmation by Reliance.
- Early Discontinuations will be paid through last completed "visit".
- The investigator has to present statement on letterhead for claiming any above mentioned payment under section A.1.
- If the study is prematurely terminated, the total payment to you will be made for those evaluable subjects enrolled by you in accordance with study visits completed at the time of the termination notice and upon receipt by Reliance of completed Case Report Form. You agree to refund any excess amount previously paid, and we agree to promptly pay any amount owing based to the receipt of acceptable case report forms at Reliance and the resolution of all queries/questions relating to the data.
- Permission to enroll additional subjects must be obtained from the sponsor. The grant total will increase according to the per subject cost for the increased number of subjects.
- Reliance will reserve the right to re-allocate subjects budget to other sites originally reserved for your site if site is having difficulty in enrolling and qualifying subjects.
- Site is responsible to archive the documents as per regulatory requirements and no separate cost for the same will be paid by Reliance.
- GST will be paid as per prevailing rates. All other taxes are included in the budget cost. TDS shall be deducted as applicable.

ATTESTED

Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education
and Research, BELAGAVI

CLINICAL TRIAL AGREEMENT

THIS CLINICAL TRIAL AGREEMENT is made on this 04 Day of Apr 2018 by and between,

Veeda Clinical Research Pvt. Ltd, an Indian Company having its principal place of business at Shivalik Plaza–B, Nr. I.I.M., Ambawadi, Ahmedabad – 380 015 Gujarat (hereinafter referred to as the "Veeda") which shall include its successors, assigns, representatives, affiliates, and subsidiaries,

And

Dr. Mahesh Kalloli ("Principal Investigator"), having its place of work at KLES Dr.Prabhakar Kore Hospital and MRC, Second Floor, Nehru Nagar, Belagavi – 590010, Karnataka, India.

And

KLES Dr.Prabhakar Kore Hospital and MRC ("Institution") having its principal place of business at Second Floor, Nehru Nagar, Belagavi – 590010, Karnataka, India.

(Hereinafter referred to as the "Institution") which shall include its successors, assigns, representatives, affiliates, and subsidiaries.

WHEREAS, Veeda is a contract research organization contracted by Qilu Pharmaceutical Co., Ltd, No. 243 Gong Ye Bei Road, Jinan, Shandong Province, P.R., China - 250100 (herein after referred to as "Sponsor") to perform one or more of sponsor study related duties and functions for the Project No. 17-VIN-0855 entitled " A multicenter, open label, randomized, balanced, two treatment, three period, three sequence, reference replicate crossover, single dose, bioequivalence study of Capecitabine Tablets 500 mg of Qilu Pharmaceutical Co., Ltd, China in comparison with XELODA® (Capecitabine) Tablets 500 mg, Distributed by Genentech USA, Inc. following a single oral dose administration in adult cancer patients under fed condition."; and

WHEREAS, Principal Investigator is properly qualified and experienced and working at Institution and Principal Investigator has the authority and desire to conduct the Study at the Institution; and

WHEREAS, Institution has adequate infrastructure to conduct the Study and allowed Principal Investigator and Veeda to conduct the Study;

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

ATTESTED
Prof. Dr. V.A.KOTHIWALE
Registrar
KLE Academy of Higher Education and Research, BELAGAVI

1. DEFINITIONS

1.1 Definitions. As used in this Agreement, each capitalized term listed below shall have the meaning that is given after it:

- "Budget" means the detailed budget established for the Study, as detailed in Exhibit B, which is incorporated herein by reference.
- "CRF" or "Case Report Form" means a printed, optical, or electronic document designed to record all of the Protocol required information to be reported to Sponsor on each Subject.
- "Data" shall mean all information, reports, records, and documents generated under this Agreement, excluding subject medical records. Data shall be the sole and exclusive property of Sponsor and may be freely utilized by Sponsor and their representatives. Sponsor may freely assign its rights to and interests in any Data to a party of the Sponsor's choice.
- "Financial Disclosure Certification Form" means the financial disclosure certification attached as Exhibit B, to record compliance with 21 CFR Part 54 (U.S.).
- "ICH Guidelines" means the International Council for Harmonization, Harmonized Tripartite Guideline for Good Clinical Practice E6, 1996, or such successor provisions in force at the time of performance of the services.
- "IEC" means the Independent Ethics Committee/Institutional Ethics Committee ("IEC"), as the term is defined in ICH Guidelines and any other review board required by applicable law or ICH Guidelines.
- "Informed Consent" means a consent signed by or on behalf of a Subject which consent shall comply with the applicable local law and the regulations of the U.S. Department of Health and Human Services, its supporting agencies, the FDA and any other applicable regulatory agency governing informed consents including without limitation, Schedule Y, Section 4.8 of the ICH Guideline, 45 CFR §46.116(a), 21 CFR Part 50 and 21 CFR Part 812.
- "Protocol" means the document that specifies the clinical trial procedures, as developed by Sponsor applicable for the performance of a Study and any amendments thereto. Protocol shall be attached to this Agreement as Exhibit A.
- "Study Product" means Capecitabine tablets, 500 mg of Qilu Pharmaceutical Co., Ltd, No. 243 Gong Ye Bei Road, Jinan, Shandong Province, P.R., China - 250100 an investigational drug.
- "Subject" means an individual who meets all eligibility criteria, is properly consented and enrolled in the Study.

2. Scope

2.1 This Agreement allows the parties to specify distinct clinical study activities to be performed by Principal Investigator and Institution for the Study.

2.2 Conduct of Study Principal Investigator and Institution shall conduct the Study pursuant to the terms of this Agreement and in strict adherence to the Protocol, as the same may be amended from time to time in writing by Sponsor, and any other written instructions that may be provided from time to time to Principal Investigator by Sponsor. Prior to conducting the Study, the Principal Investigator shall review and understand the Protocol, as evidenced by the Principal Investigator's signature on the "Investigator Agreement(s)" contained within the applicable Protocol, all of which are incorporated herein by reference.

2.3 Principal Investigator.

2.3.1 Principal Investigator shall be personally responsible for the conduct of the Study. If such personal services are not available for any reason, Veeda or Sponsor may terminate this Agreement immediately without any further financial obligation to Principal Investigator and / or Institution.

2.3.2 Principal Investigator agrees to return to Veeda any unearned or unaccounted for amounts paid by Veeda that exceed the amount to which Principal Investigator are entitled hereunder.

2.3.3 During the performance of the Clinical Trial and / or for a period of 15 years after termination of the agreement, the Principal Investigator is responsible for, but not be limited to, the following aspects:

a) Provision of required study documents (e.g. curriculum vitae(s), medical registration certificates and/or other relevant documents evidencing qualifications of Investigator(s) and sub-Investigator(s), confirmation of adequate site facilities, etc.);

b) Progress reporting (including recruitment figures) to Ethics Committee and Veeda on a regular basis;

c) Ensuring reasonable access by monitors, auditors and regulatory authorities to Principal Investigator and other project personnel, project facilities, original study materials, drug records, subject records, case reports, and other records; subject to applicable laws and regulations; and providing appropriate working conditions for monitors, auditors and regulatory authorities to perform study-related monitoring, audit and inspection;

d) To allow any regulatory audit by DCGI or any applicable regulatory authorities within 15 years of submission of report and ensure compliance of any regulatory deficiency raised by such authorities in reasonable period of time; If Principal Investigator is to submit any information to such regulatory authorities agencies, such submissions shall not be made without Veeda's prior review and written approval, and any changes (other than entry of required information) also shall be subject to such prior written approval.

e) Safe handling, storage, transportation and disposal of infectious materials and wastes involved in the Clinical Trial;

f) Inform the Ethics Committee of study closure;

g) Maintenance of drug accountability records, study documents including study drug acknowledgment receipts, study supply receipts, payment receipts, EC approvals etc.;

h) Handling and storage of compound according to protocol; and

i) Storage of site file and all the trial related data for a period of 15 years after completion of the study without any additional cost / compensation / grants. At their discretion the Institution / Investigator at their own cost will make arrangements to store the site file and all the trial related data at the authorized third party location.

j) The Principal Investigator is responsible for training and supervision of sub-Investigators and other site study team member on the procedures specified in the Protocol to ensure scientific, technical, and ethical conduct of the Clinical Trial. In case of any personnel changes, the Principal Investigator is responsible for notifying Veeda of such change in a timely manner.

2.3.4 The review of serious adverse events shall be undertaken by Veeda in close coordination with Principal Investigator. "Serious" as used in this section, refers to an experience which results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect. "Unexpected" as used in this section, refers to conditions or developments not previously submitted to governmental agencies or encountered during clinical studies of the Product, and conditions or developments occurring at a rate higher than shown by information previously submitted to an agency or other governmental agencies or encountered during clinical studies of the Product or, if applicable, conditions or developments not identified in the approved Product information circular, and includes any other meaning under applicable law.

2.3.5 Veeda shall have the right, to monitor or visit the Principle Investigator and audit the Trial with respect to the services provided hereunder with / without the Sponsor. Principal Investigator will cooperate with Veeda and the Sponsor and provide a current status of the trial.

2.3.6 The Principle Investigator is responsible for reporting, and shall report, all such findings in the manner and within the time limits as set out in the applicable provisions of ICH GCP and the applicable legislation. The Principle Investigator shall strictly adhere to the SAE reporting timeline as per the current regulations of licensing authority (DCGI), requirement of ICH GCP, current Schedule Y.

The investigator will be responsible to report any SAE to the licensing authority, Sponsor's representative, CRO representative and chairman of Ethics Committee within 24 hours of identifying the event as SAE.

In case of SAE other than death the investigator will send the detailed report within 14 calendar days of SAE to the licensing authority, chairman of Ethics Committee where the SAE has occurred, and the head of the institution where the trial is being conducted.

In case of SAE of death the investigator will send the detailed report within 14 calendar days of SAE to the chairman of Ethics Committee, chairman of the expert committee constituted by the licensing authority with a copy to licensing authority and the head of the institution where the trial is being conducted.

Notwithstanding anything in this Agreement to the contrary, the Principal Investigator and the Institution shall have the right to disclose findings that could adversely affect the safety of Clinical Trial subjects to the Ethics Committees of participating sites, and appropriate regulatory authorities if they deem it necessary to protect the health of study participants, provided that Veeda is copied on such reports.

2.3.7 The Principle Investigator shall participate in teleconferences required by Veeda to update the study product information and resolve issues, if any.

2.3.8 The Principle Investigator and/or the Institution, Veeda and Sponsor shall comply with all regulatory requirements relating to the retention of records and shall maintain all such records, and make them available for inspection, and shall allow Sponsor and all applicable authorities in charge of the Clinical Trial to inspect such records, including the patient's medical records. The Site Investigator File containing the essential documents and source data must be archived for at least fifteen (15) years following completion of the study at the Site or such other authorized facilities as agreed between Veeda, the Principle Investigator and the site. The Principle Investigator and /or the Institution shall inform Sponsor in the event of relocation or transfer of archiving responsibilities. At their discretion the Institution / Investigator at their own cost will make arrangements to store the site file and all the trial related data at the authorized third party location.

2.3.9 In the event that the Principle Investigator is to destroy the Investigator Site File or source data, the Principle Investigator should inform Veeda prior to destruction to confirm it is acceptable for them to be destroyed.

2.3.10 Investigational Medicinal Product i.e. both unused and retention samples will be retained at the site after completion of the study for a desired period, as per USFDA/sponsor requirement and also as per the written instruction given by Veeda/Sponsor at free of cost. The samples will be retained for a period of at-least 5 years following the date on which the application or supplemental application is approved, or, if such application or supplemental application is not approved, at-least 5 years following the date of completion of bioavailability study in which the sample from which the reserve sample was obtained was used. Investigational Medicinal Product i.e. both unused and retention samples will continue to remain at the site unless further information is received from Veeda/Sponsor.

2.3.11 Principal Investigator/ Institute will intimate to CRO and Sponsor about any inspection/s from any regulatory authorities for the study , within 48 business hours of their notification.

2.4 Compliance with Law. Principal Investigator and Institution represent that they shall comply with all applicable laws in performing its obligations under this Agreement. Principal Investigator will assume all those responsibilities assigned to principal investigators under all applicable laws, rules, regulations, guidelines and standards including, without limitation, all relevant ICH Guidelines and standards, and all applicable laws relating to the confidentiality, privacy and security of patient information. In furtherance of the foregoing obligation, Principal Investigator shall ensure that timely report is sent to the IEC for the progress and conduct of Study. Principal Investigator and Institution, as applicable, shall comply with the directives of the IEC respecting the conduct of the Study, and shall immediately notify Veeda and Sponsor to the extent any such directives vary from the Protocol. Principal Investigator shall obtain from each Subject, prior to the Subject's participation in the Study, a signed Informed Consent and necessary authorization to disclose health information to Sponsor in a form approved in writing by the IEC and in conformity with local regulations and Sponsor's requirements therefore set forth in the Protocol.

2.5 Study Supplies. Veeda shall provide Principal Investigator with a sufficient quantity of Study Product to conduct the Study, as well as any other compounds, materials and information which the Protocol specifies. All such Study Product, compounds, materials and other information are and shall remain the sole property of Sponsor/Veeda. Principal Investigator and Institution, as applicable, shall ensure that the Study Product is stored and handled in accordance with protocol, all applicable laws in addition to any specific instructions from Sponsor and/or Veeda. Principal Investigator and Institution shall not use the Study Product past the labeled expiration date and shall not use the Study Product for any purpose other than the performance of the Protocol. In addition, upon completion or premature termination of the Study, Study Product shall be returned or destroyed pursuant to the procedures to be provided by Veeda and/or Sponsor.

Veeda on behalf of sponsor will provide the study-specific documents, e.g. Investigator Site File, Case Report Form, etc. to the Investigator before commencement of the Clinical Trial.

2.6 Delivery of Essential Documents and Reports. Principal Investigator shall provide to Veeda all Essential Documents (to be designated as such by Veeda) within two (2) weeks of Principal Investigator's receipt of IEC's written approval. If all Essential Documents have not been timely executed and received by Veeda, Veeda may terminate this Agreement immediately upon written notice. Principal Investigator shall submit written reports, as directed *by* Veeda and/or Sponsor, on the progress of the Study. Within thirty (30) days following the completion or premature termination of the Study, Principal Investigator shall furnish Veeda with the IEC report, notification as required by IEC on the Study prepared by the Principal Investigator, as well as all completed, used and unused CRFs not already delivered to Veeda, and all Data, reports and other information generated in relation to the Study, as well as all other materials and information

provided by Veeda and/or Sponsor, unless Veeda and/or Sponsor directs otherwise in writing.

2.7 Monitoring of Study. Principal Investigator and Institution shall permit Veeda and/or Veeda designee(s) including but not limited to Sponsor access to Institution, during regular business hours with reasonable prior notice, to monitor the conduct of the Study as well as to audit records, CRFs, Data and other information and documents relating to the Study, in order to verify Principal Investigator's compliance with their obligations herein. If any governmental entity should audit or inspect the Institution with respect to the Study, Principal Investigator and/or Institution shall provide Veeda and Sponsor with immediate notice and shall provide an opportunity for Sponsor or its designee to be present during such governmental audit.

2.8 Contract Research Organizations/vendors. Subject to Sponsor's approval, Veeda may retain one or more contract research organizations ("CRO")/vendor to assist them in managing and monitoring the Study. Principal Investigator and Institution acknowledge Veeda's right to assign or transfer, in whole or in part, without the consent of the Principal Investigator and Institution, any of its rights or obligations under this Agreement to any such CRO or vendors. The Principal Investigator and Institution shall permit such CROs/vendors to perform any or all of Veeda's obligations, or to exercise any or all of Veeda's rights, under this Agreement.

2.9 No Reimbursement for Sponsor Paid Drug or Services. Principal Investigator and Institution agrees that, if Study Product and/or other services are paid for or provided without charge by Sponsor or Veeda, Principal Investigator, Institution and/or any other vendor subcontracted or engaged by Principal Investigator or Institution shall not separately bill or seek reimbursement for such Study Product and/or services from any third party including, without limitation, the Subject, any private provider of Insurance or state program. Principal Investigator and Institution further agree that they shall accurately report receipt of such Study Product to any government or private insurance program, as may be required by law.

2.10 Financial Disclosure Certification. Principal Investigator or Institution, as applicable, shall ensure that any sub investigators connected with the Study, complete and return to Veeda and/or Sponsor the Financial Disclosure Certification Form prior to the initiation of the Study. Principal Investigator or Institution, as applicable, shall require any sub investigators to promptly notify Veeda and/or Sponsor of any change in the accuracy of the Financial Disclosure Certification Form during the term of Study and for one (1) year following completion of the Study. In addition, Principal Investigator or Institution, as applicable, shall comply with all applicable requirements of the National Institutes of Health and the Public Health Service regarding reporting and management of conflicts of interest.

3. COMPENSATION

3.1 Payment. Veeda shall pay Principal Investigator/Institution the amounts set forth in Exhibit B for Subjects properly enrolled, completed visits and CRFs completely and accurately returned to Veeda and/or Sponsor. All payments shall be payable in Indian Rupees and made within forty five

(45) days of receipt and approval of an invoice for Institution /Principal Investigator's services.

The parties hereto agree as follows:

a) Veeda will pay a sum for every complete and evaluable patient as defined in the payment schedule for "Per Patient Fee".

The "Per Subject Fee" is a fixed fee per patient which includes all costs and honoraria, including, but not limited to:

- all study related activities such as conduct of visits and Source & CRF completion
- time and effort of Principle Investigator and other site staff
- study coordinator salary
- all diagnostic tests and other investigations (ECG,Echo, X-ray Chest etc)
- housing or hospital stay for patients including meals
- Patient conveyance/compensation
- miscellaneous (telephone, fax, courier, etc)
- all overhead costs

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

- all procedures must be performed according to the protocol
- a patient will only be included according to the inclusion/exclusion criteria
- all data are documented accurately, completely

c) All payments will be on a *pro rata* basis. For patients who do not complete (early termination, drop-out, etc), the payment schedule will be evaluated according to the number of days completed.

d) Invoice will be generated / requested for payment on monthly basis according to the actual work performed (after source data verification and CRFs retrieval for completed visits). Invoice will be generated / requested according to milestone specified above. The final payment (20%) will be made at the time of site closeout visit or immediately after site close-out visit.

e) Any third parties designated by you (including Radiology, Local Laboratory, etc) will be managed and paid by you.

f) The Ethics Committee fee will be paid by Veeda, and is separate from the per-patient grant. Details of the payment are as mentioned below.

- Name of Ethics Committee: **Institutional Ethics Committee, KLE University**
- Relationship between the site/institution and Ethics committee: **Institutional Ethics Committee**

- Ethics committee payee name: **Registrar KLE University.**
- Relationship between the Ethics committee and the Ethics committee payee name, if it is different from Ethics committee as mentioned in the SOP: **NA**
- PAN no. of the payee: **AABTK0881E**
- Ethics Committee Fees: **Rs. 88500/- (Excluding TDS)**

g) Screen failure patient's visit will be paid ONLY if the patient is screen failure based on results or reports of laboratory investigations, ECG,ECHO, X-ray Chest, and SAE or in case patient withdraw consent.

h) If patient was randomized in the study deviating from protocol inclusion and exclusion criteria (without waiver, if applicable) then payment will not be made for such wrong randomization and subsequent visits, however screening visit can be paid, if performed according to protocol.

i) Patient conveyance will pay by Veeda, and is not included in per patient fees.

j) Veeda will manage SAE reimbursement for medical management expenses towards AE/SAE directly to the patient or LAR and SAE compensation payment directly to the patient / LAR with prior written approval from the sponsor and will get for reimbursement for those expenses.

k) Veeda will pay the Institution an upfront amount of INR 20,000/- once 1st patient is enrolled / randomized. This upfront amount will be adjusted form subsequent payment(s). In case site is not able to enroll any patients then Principle Investigator / Institute is liable and must return upfront amount immediately without any delay.

Details of Payee are:

Name of Payee: Genesis Research

PAN No. : CQJPP0528D

GSTIN No. : 27CQJPP0528D1ZX

Note: All the payments made to the payee are subject to Withholding Tax (Tax Deducted at Source (TDS)) as applicable from time to time and Veeda will deduct the tax at the time of making payments.

3.2 Disputed Payment. Principal Investigator/Institution agrees that in the event of a dispute regarding Sponsor's approval of documentation of supporting costs incurred under this Agreement, data and information resulting from Institution's (including Principal Investigator) participation in Study cannot be withheld by Institution's (including Principal Investigator) pending resolution of the dispute. Veeda and Principal Investigator/Institution agree to use reasonable efforts to resolve any disputes in a timely manner.

3.3 Overpayment/Underpayment. If, at the date of Study termination, the total amount paid to Principal Investigator/Institution exceeds the amount to which Principal Investigator/Institution is entitled, Principal Investigator/Institution shall return the overpayment to Veeda within forty-five (45) days from the termination date. If, at the date of termination, the total amount paid to Principal Investigator/Institution is less than the amount to which Principal Investigator/Institution is entitled, Veeda shall pay the amount due to Principal Investigator/Institution within forty-five (45) days following termination of the Study, delivery to Veeda and/or Sponsor of the remaining CRFs, final reconciliation of any remaining amounts due, and the return to Veeda of all items described in Section 2.7 above.

3.4 Commercially Reasonable Efforts. The Principle Investigator and/or the Institution shall use all reasonable endeavors to enroll maximum Eligible Cases as soon as possible. The parties may agree in writing to extend the time for recruitment of eligible patients if so desired. Recruitment period will be of 10 months however recruitment will be competitive among participating sites hence the site may have recruitment period even less or more then specified.

Principal Investigator/Institution shall use reasonable efforts to complete enrollment of study subjects within two months (2) months after receiving a go ahead from the sponsor/veeda to enroll patients in the study. Veeda may terminate this Agreement upon written notice, if Principal Investigator/Institution is not able to enroll any patient for a month following Study initiation at their site and in that case, the Principal Investigator / Institution is responsible to refund the all amount paid till the date of termination of the agreement within 7 days from the date of intimation of termination of the agreement.

Allowed screen failure rate in the study is 20 %, hence the investigator should put in reasonable efforts to recruit eligible cases in the study.

3.5 Remittance of Payment. All payments to Principal Investigator/Institution and any other party as defined in this agreement made pursuant to this Agreement shall be made by Veeda and all study related payments will be made by cheque and sent to:

Trial Payee Address: KLES Dr. Prabhakar Kore Hospital and MRC, Second Floor, Nehru Nagar, Belagavi – 590010, Karnataka, India.

3.6 Relationship of Parties. Veeda shall be responsible for all payments to Principal Investigator/Institution pursuant to this Agreement but such responsibility is subject to receipt of funds from Sponsor. Upon receipt of such funds by Veeda from Sponsor, Principal Investigator / Institution shall have no recourse against Sponsor or any of its subsidiaries or affiliates for Veeda's breach of its payment obligations to Investigator pursuant to this Agreement.

4. CONFIDENTIALITY

4.1 Confidentiality & Non-Use Obligation. During the Study's performance and for Five years (5) years thereafter, Institution, its employees, agents, and subcontractors (if any) and Principal

Investigator shall not disclose Confidential Information (hereinafter defined) for any purpose other than as indicated in this Agreement without Sponsor's prior written consent.

4.2 Definition of Confidential Information. Subject to Principal Investigator's publication rights as set forth in Sections 6.1 and 6.2, " Confidential Information" shall include the Protocol, CRFs, Data, Study Product, and all materials and information in whatever form or medium (whether now known or in the future developed) and however communicated, be it by written, verbal, visual, machine readable form, or in the form of biological materials or samples, or in any other form, relating, directly or indirectly, to Sponsor and the Study disclosed to Principal Investigator and/or Institution by Sponsor or Veeda or developed by Principal Investigator or Institution as a result of conducting the Study. Confidential Information shall also include any confidential information obtained under a confidentiality agreement with a third party, which Sponsor is permitted to disclose to Principal Investigator and/or Institution.

4.3 Exceptions to Obligation of Confidentiality and Non-Use. Principal Investigator and Institution's obligation of confidentiality and non-use described in Section 4.1 applies to all Confidential Information, except any portion thereof which:

(i) Is known to Principal Investigator and Institution, its employees, agents, or subcontractors before receipt thereof under this Agreement, as evidenced by written records;

(ii) is disclosed to Principal Investigator and/or Institution, their employees, agents, or subcontractors after acceptance of this Agreement by a third party who has a right to make such disclosure in a non-confidential manner;

(iii) is or becomes part of the public domain through no fault of Principal Investigator or Institution , their employees, agents, or subcontractors; or

(iv) is independently developed by Principal Investigator or Institution, their employees, agents, or subcontractors, without reference to, use of, or disclosure of Confidential Information, as evidenced by written records.

4.4 Disclosure Required by Law. Nothing in this Agreement shall be construed to restrict Principal Investigator or Institution from disclosing Confidential Information as required by law or court order or other governmental order or request, provided in each case Institution and/or Principal Investigator shall timely inform Veeda and Sponsor and use all reasonable efforts to limit the disclosure and maintain the confidentiality of such Confidential Information to the extent possible. In addition, Institution and Principal Investigator shall permit Veeda and/or Sponsor to attempt to limit such disclosure by appropriate legal means.

4.5 Subject Confidentiality. The parties agree to abide by all applicable laws and regulations regarding Subject confidentiality. Principal Investigator is responsible for obtaining from each Subject, prior to the Subject's participation in the Study, a signed Informed Consent in a form approved in writing by the IEC and in conformity with Sponsor's guidelines. Before requesting an

individual's consent to participate in clinical trial the Principal Investigator must provide the individual with the trial information in a language that is non- technical and understandable by the study subjects and the same shall be recorded as per local regulatory requirement.

This is in case requirement of Audio visual recording. During the audio-visual recording of informed consent process, the identity and records of the trial subjects are as far as possible kept confidential; and that no details about identity of said subjects, which would result in the disclosure of their identity, are disclosed without valid scientific and legal reasons which may be essential for the purposes of therapeutics or other interventions, without the specific consent in writing of the subject concerned, or someone authorized on their behalf, and after ensuring that the said subject does not suffer from any form of hardship, discrimination or stigmatisation as a consequence of having participated in the trial. Prior consent of the subject should be taken for audio-visual recording of informed consent process and the same should be documented by the Investigator. Such consent may be taken orally. Only those subjects who give the consent for the AV recording shall be included in the clinical trial.

The Investigator must safeguard the confidentiality of trial data, which might lead to the identification of the individual subjects. Data of individual subjects can be disclosed only in a court of law under the orders of the presiding judge or in some cases may be required to communicate to Drug regulatory/ Health authority.

5. INTELLECTUAL PROPERTY

5.1 Inventions. All inventions whether or not patentable, discoveries, techniques, ideas, trade secrets, new uses, improvements, processes, compounds, products, and all other works that are conceived or reduced to practice during the course of performing the Clinical Trial by Principal Investigator and Institution (including but not limited to their employees, agents and/or any other vendor subcontracted or engaged by Principal Investigator or Institution) ("Intellectual Property") shall be promptly disclosed to Veeda and Sponsor and shall be the sole property of Sponsor; provided however, that Principal Investigator and Institution will have a fully-paid-up, royalty-free, perpetual, nonexclusive right without the right to sublicense, to make, have made, and use any Intellectual Property created here under for its own internal, noncommercial research, noncommercial patient care, and academic purposes. Principal Investigator and Institution agree, upon Sponsor's written request and at Sponsor's expense, to execute such documents and to take such other reasonable actions as Sponsor deems necessary or appropriate to obtain patent or other proprietary protection in Sponsor's name covering any Intellectual Property. Sponsor may freely assign its rights to and interests in any Intellectual Property to a party of the Sponsor's choice.

6. PUBLICATIONS

6.1 General procedures. If Principal Investigator prepares any presentation or publication, Principal Investigator is to provide Sponsor with a draft of the same for Sponsor's review and comment at least sixty (60) days prior to publication or presentation so that Sponsor may ascertain whether any Intellectual Property or other patentable Subject matter or Confidential Information

are disclosed therein. Sponsor shall return comments to Principal Investigator within thirty (30) days after receipt of the draft presentation or publication ("Review Period"). In addition, Principal Investigator shall delay any proposed publication/presentation an additional sixty (60) days in addition to the Review Period in the event Sponsor so requests to enable Sponsor to secure patent or other proprietary protection ("Delay Period"). The Principal Investigator shall keep the proposed publication confidential until the Review Period concludes and, if elected by Sponsor, the Delay Period has expired. The Principal Investigator understands that, with respect to any proposed publication or presentation, good faith consideration will be given to Sponsor's comments with due regard for Sponsor's commercial and proprietary interests and at Sponsor's request, any Confidential Information will be deleted from such article or presentation. Notwithstanding the foregoing, unless otherwise permitted in writing by Sponsor / Veeda, the Principal Investigator shall not be permitted to publish Confidential Information. For the purposes of this provision, Confidential Information shall not include the results of the Study. Institution shall have no right to publish or present pursuant to this Agreement.

6.2 Multi-Center Studies. It is agreed and understood by Principal Investigator that Study is a multi-center study and an independent, joint publication is anticipated to be authored by investigators in the multi-center study, including Principal Investigator. Therefore, Principal Investigator agrees not to publish or present the results or any information derived from the study without prior approval from the sponsor.

7. Term & Termination

7.1 Termination by Sponsor/Veeda. Veeda or Sponsor may terminate this Agreement (i) immediately if the Study is terminated by regulatory authorities or in the interest of public health; or (ii) without cause at any time during the Term of this agreement on thirty (30) days prior written notice to Institution and Principal Investigator.

7.2 Effect of Termination. Termination or expiration of this Agreement shall not affect any rights or obligations which have accrued prior thereto. In the event of termination of this Agreement, Principal Investigator and Institution shall complete the Study for then-enrolled Subjects where required by accepted medical practice.

8. Indemnification

8.1 Sponsor Indemnification. Sponsor shall indemnify Principal Investigator and Institution, (including Principal Investigator's and Institution's affiliates, contractors, agents, fellows, employees and servants) (collectively "Investigator Indemnitees") for any damages and liabilities, including reasonable attorney's fees incurred by Investigator Indemnitees as a result of any claim or lawsuit against them arising directly out of the performance of the Study drug pursuant to the Protocol ("Claims"); provided however Sponsor will not be responsible for and assumes no liability for any loss, claims, and/or demands to the extent arising from any of the following: the negligence or willful misconduct of an Investigator Indemnitees or any Investigator Indemnitees failure to adhere to (i) the terms of the Protocol and/or this Agreement including any amendments

thereto; or (ii) applicable federal, provincial, or local laws; or (iii) the written instructions relative to the use of the Study Product.

8.2 Institution Indemnification. Institution shall indemnify, defend and hold harmless Sponsor and Veeda (including Sponsor's and Veeda's affiliates, contractors, agents, fellows, employees and servants) (collectively "Sponsor Indemnitees") from any and all losses, injuries, harm, costs or expenses, including without limitation, reasonable attorney's fees, incurred by Sponsor Indemnitees that arise from the negligence or willful misconduct by Investigator Indemnitees (as defined above in clause 8.1). Principal Investigator and Institution shall carry professional Indemnity Insurance and such other insurance required to indemnify under this clause, for the duration of this Agreement and for a reasonable period (which is not less than 1 year) after termination or expiration thereof. Principal Investigator and Institution shall provide the copy of insurance as and when required by Veeda or Sponsor.

8.3 Obligation to Notify. The foregoing agreement to indemnify is conditioned upon the obligation of the Indemnitee to:

(i) advise indemnifying party of any claim or lawsuit, in writing, within fifteen (15) days after Indemnitee has received notice of said claim or lawsuit, or within such other time frame so that indemnifying party's ability and rights to defend or settle such claim or lawsuit, as determined in Sponsor's sole discretion, are not prejudiced;

(ii) Assist indemnifying party and its representatives in the investigation and defense of any lawsuit and/or claim for which indemnification is provided; and

(iii) Not compromise or otherwise settle any such claim or lawsuit on behalf of indemnifying party without indemnifying party prior written consent.

8.4 Serious Adverse Event Reimbursement. Notwithstanding any other terms contained in this Agreement, Sponsor will reimburse the Institution for any reasonable, necessary and properly documented medical expenses directly related to a Subject's Serious Adverse Event (as the term is defined in the Protocol, also referred to as an "SAE") that is because of the administration of the Study drug in accordance with the Protocol. Sponsor shall not be responsible for the reimbursement of SAE costs that are the result of a) the negligence, misconduct, lack of adherence to applicable law or breach of this Agreement by any agent/vendor or employee of the Principal Investigator or Institution

9. DEBARMENT

9.1 Debarment and Exclusion. Institution and Principal Investigator certify that they are not debarred or restricted from conducting clinical research and will not use in any capacity the services of any person debarred or restricted from conducting clinical research under applicable law with respect to services to be performed under this Agreement. Institution and Principal Investigator also certify that they are not excluded from any governmental health care program.

Institution and Principal Investigator further certify that they are not subject to a government mandated corporate integrity agreement and has not violated any applicable anti-kickback or false claims laws or regulations. During the term of this Agreement and for three years after its termination, Principal Investigator and Institution will notify Veeda promptly in writing to the extent possible within two (2) business days if either of these certifications needs to be amended in light of new information or if Institution and/or Principal Investigator becomes aware of any material issues related to the medical licensure of any associated researchers. Institution and Principal Investigator will cooperate with Veeda and/or Sponsor regarding any responsive action necessary.

10. NOTICE

10.1 Notices. Except as otherwise provided herein, all notices, consents, or approvals required under this Agreement will be in writing delivered personally or delivered by facsimile, electronic mail, first class mail, or by a commercial overnight courier that guarantees next day delivery when possible (in the case of notice by facsimile or electronic mail, a confirmation shall thereafter be transmitted to the addressee by first class mail or by a commercial overnight courier that guarantees next day delivery), addressed as follows:

If to Veeda:

Veeda Clinical Research Pvt. Ltd.

Address: Shivalik Plaza –A, 2nd floor, Nr. I.I.M., Ambawadi, Ahmedabad 380 015.

Attention: Dr. E. Venu Madhav

Phone: +91 79 30013000
Fax: +91 79 30013010

If to Principal Investigator:

Name: Dr. Mahesh Kalloli

Address: KLES Dr.Prabhakar Kore Hospital and MRC, Second Floor, Nehru Nagar, Belagavi – 590010, Karnataka, India.

Attention:

Phone : +918312470400
Fax: +918312493099

If to Institution:

Name: Dr M.V. Jali

Designation: MD and CE

Address: KLES Dr.Prabhakar Kore Hospital and MRC, Second Floor, Nehru Nagar, Belagavi – 590010, Karnataka, India.

Attention:

Phone: +918312470400
Fax: +918312493099

11. Miscellaneous

11.1 Binding Obligations. Principal Investigator and Institution represent and certify that the terms of this Agreement are valid and binding obligations are not inconsistent with any other contractual and/or legal obligations they may have, or with the policies of company with which it is associated.

11.2 Publicity. To the extent permitted by law or regulation, no party shall disclose the existence or terms of this Agreement nor use the name of any other party, nor the names of other party's employees, in any publicity, advertising or announcement without the consenting party's prior written approval.

11.3 Independent Contractor. Principal Investigator's and Institution's relationship to Veeda and Sponsor under this Agreement is that of an independent contractor, Principal Investigator and Institution have no authority to bind or act on behalf of Veeda or Sponsor.

11.4 Assignment. Principal Investigator and Institution may not assign this Agreement to any other party, nor may it subcontract any of its services here under, without Veeda's and Sponsor's prior written consent. Any attempted assignment without Veeda's and Sponsor's prior written consent shall be null and void and shall, for the avoidance of doubt, constitute a material breach of this Agreement.

11.5 Sub-investigators. Principal Investigator and Institution hereby agree that as to any individuals identified on the applicable FDA Form 1572 or Investigator information and Agreement Form as sub-investigators for the Study, Principal Investigator and Institution shall ensure such individuals' compliance with the terms and conditions hereof.

11.6 Entire Agreement. This Agreement contains the entire understanding of the parties with respect to the subject matter herein and supersedes all previous agreements and undertakings with respect thereto. This Agreement may be modified only by written agreement signed by the parties.

11.7 Governing Law. This agreement shall be governed by and interpreted in accordance with the Indian laws. Any disputes arising in connection with this Agreement shall be resolved through arbitration. The arbitrator shall be mutually decided among the parties. The arbitration shall be conducted under the Arbitration and Conciliation Act of 1996. The place of arbitration shall be

Ahmedabad. Each party shall bear its own costs of the arbitration unless the arbitrator otherwise directs.

11.8 Survival. Notwithstanding termination of this Agreement for any reason, rights and obligations which by the terms of this Agreement survive termination thereof, shall remain in full force and effect including but not limited to Section 4 (Confidential Information), Section 5 (Intellectual Property) and Section 6 (Publication).

11.9 Severability. If any of the provisions or a portion of any provision, of this Agreement is held unenforceable or invalid by a court of competent jurisdiction, the validity and enforceability of the other portions of any such provision and/or the remaining provisions shall not be affected thereby.

11.10 Conflict with Protocol. In the event of a conflict between the terms and conditions of this Agreement and those of the Protocol, the Protocol shall control in matters of science and the Agreement shall control in all other matters.

11.11 Headings: Any headings, titles and captions used in this Agreement are for convenience and reference only. They do not purport to, and shall not be deemed to, limit or extend the scope or intent of the sections to which they pertain.

11.12 PI/Institute will be responsible for facilitating the availability of site level Phlebotomist dedicated for this study throughout the study duration.

IN WITNESS WHEREOF, the parties have executed this Agreement as of the date written above.

For, Veeda Clinical Research Pvt. Ltd.

Name: Dr. E. Venu Madhav
Title: COO

Date: 05 Apr 2018

For, Principal Investigator

Name: Dr. Mahesh Kalloli
Title: Principle Investigator

Date: 14 Apr 2018

For, Institute

Name : Dr. M. V. Jali
Title: MD and CE

Date: 28 Apr 2018

Witness:

Name: Snehal Wandre

Contact Details: 9657279369