YENEPOYA
(DEEMED TO BE UNIVERSITY)
Recognized under Sec 3(A) of the UGC Act 1956
Accredited by NAAC with 'A' Grade

3.2.1 Grants for research projects/clinical trials sponsored by the non-governmental sources such as industry, corporate houses, international bodies, endowments, professional associations, endowment-Chairs etc. in the Institution during the year.

E-copies of the grant award letters for research projects sponsored by non-government organizations

8.	Measuring tumor-specific genetic alterations in cerebrospinal fluid (CSF) as a biomarker of tumor burden in malignant brain tumor patients	Strand Life Science Private Limited, Bangalore	63 – 70
9.	A prospective , Interventional, Open label, Randomized, Parallel Group, Multi-centric, Comparative Clinical Study to Evaluate the efficacy and safety of test drug, Potassium Chloride (K-Lyte) 600mg Immediate Release Tablet in comparison to reference drug, Potassium Chloride (Klor-Con)600 mg Extended Release Tablet in the treatment of the patients with Hypokalemia	ICBio Clinical Research Pvt Ltd, Bangalore	71 - 82
10.	A Randomized, Double Blind, Multicentric, Parallel-group, Phase III Clinical Trial to evaluate the Efficacy & Safety of 5% Spironolactone Topical Cream versus Placebo in Patients with Acne Vulgaris.	Alkem Laboratories Limited, Mumbai	83 - 93
11.	A single- centre, open label study to establish the efficacy of mechanical ventilation device (RespirAID R20) designed for the purpose of providing breathing support for those patients who face difficulty in breathing.	Remidio Innovative Solutions Pvt Ltd, Bangalore & Biodesign Innovation Labs Pvt. Ltd, Bangalore	94 - 102

1

INDIAN ASSOCIATION OF PUBLIC HEALTH DENTISTRY

REGISTERED UNDER THE REGISTER OF SOCIETIES, BANGLORE, NO.777/93-94

Award Certificate

This is to certify that Dr. Krishnaprakash.G Postgraduate student of Yenepoya Dental College,Mangalore has been awarded IAPHD FINANCIAL ASSISTANCE under PG research category under the guidance of Dr.Praveen Jodalli for the research project entitled "Effectiveness Of Oral Moisturizers in Xerostomia in Institutionalized Type II Diabetes Patients - A Randomised Controlled Trial".

Dr. Pushpanjali K
President

Dr. Vamsi Krishna Reddy.L
Secretary

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

KCK Dental Pvt.Ltd.
2nd Floor, 11/532, PK Commercial Complex,
Red Cross Road, Calicut-673032, Kerala (INDIA)
Tel : +91 495 4050896, 6577558, Mob: +91 9072666319.
Email: equipments@kckdentals.com, Web : www.kckdentals.com

KODEN

Dear Dr. Subramanya shetty and Dr. Salwa Bm

As per our discussion I am forwarding the proposal,

KODEN DUPLOST is a double slot bracket design; its innovating design allows incorporating two different arch wires (0.018 and 0.022) for correction of dental malocclusion.

We offer this treatment to young and old,

Our Aim is to make beautiful smiles with better accuracy

The cost is INR 5500 per patient kit.

As you are doing thesis on this appliance we are happy to provide you the bracket set free of cost.

We will be providing you bracket sets for 10 patients with the total coming up to INR 55000/-.

Once the thesis is completed, you have to share the details of your study to us and we shall use it in our presentation with due acknowledgement to you.

Looking forward to support you

For KCK Dental Pvt.Ltd.

Authorised Signatory

KCK Dental Pvt. Ltd. Ph: 0495 4050896 Kozhikode-32

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

derm ymch <derm@yenepoya.edu.in>

Fwd: IADVL Postgraduate Thesis Grant 2020

2 messages

Vedanth L <laddhavedant48@gmail.com> Wed, Nov 10, 2021 at 11:03 AM
To: derm ymch <derm@yenepoya.edu.in>

Thanking You and Regards
Dr.Vedant Laddha
Postgraduate
Department of Dermatology
Yenepoya Medical College
Mangalore 575018
Mob-9922947291
Whatsapp-7020061451

---------- Forwarded message ---------
From: **IADVL Academy** <academy@iadvl.org>
Date: Wed, 7 Apr 2021, 19:31
Subject: Re: IADVL Postgraduate Thesis Grant 2020
To: iadvl pgthesisgrant <iadvlpgthesisgrant@gmail.com>
Cc: Vedanth L <laddhavedant48@gmail.com>

Please refer to the email below.
The documents are complete and the first instalment will be transferred when the two conditions in the trailing email are met.

IADVL Academy

On Thu, Mar 11, 2021 at 7:21 PM IADVL Academy <academy@iadvl.org> wrote:

> Dear Dr Vedanth L,
> Thank you for sending the required documents in another email.
> Kindly use this thread for all future communication related to the grant.
> Hence, do send all documents as attachment in response to this email.
> As mentioned at the end of point 2 above, do keep your guide in the loop for all communications related to this grant.
>
> Best wishes
> Dr Dipankar De
> Convener, IADVL Academy

On Mon, Feb 22, 2021 at 1:52 PM iadvl pgthesisgrant <iadvlpgthesisgrant@gmail.com> wrote:

> Dear Dr Vedant Laddha
>
> We are pleased to inform you that your thesis titled A Case-control study on the evaluation of cardiovascular morbidity in Psoriasis guided by Dr Malcolm Pinto has been selected for PG thesis grant 2020. Kindly go through the following instructions and send the required documents for further processing.
>
> 1. Budget sanctioned is Rs 50000. As mentioned in the announcement, this could be used only to cover costs incurred for consumables, private laboratory investigations and contingencies as mentioned in your final revised protocol. No remittance for instruments, patient allowance, manpower requirement, shall be permitted. Please note if any change in the fund requirement under

ATTESTED
Dr. G. Gopinatha Shenoi, M.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

different heads is required, you will have to take approval of the Academy stating (with proof) the reasons thereof.

2. In a single email- please send final complete protocol with all scanned signed undertaking (undertaking signed by you, your guide and all co-guides that the proposed thesis is their original study plan and there are no conflicts of interest. State other sources for financial assistance, if any, for the same); ethical clearance certificate and CTRI registration proof. Please note that the funds (1st instalment) shall be disbursed only after a copy of these have been received by us. It is mandatory to keep your guide in the loop for every communication pertaining to the grant.

3. The grant will be directly remitted to you with intimation to your guide.

4. Fifty percent of the sanctioned grant shall be released when we receive all documents, and 50% after completion and submission of report with copy of bills (counter-signed by guide), utilization certificate and synopsis of thesis. It is imperative that all bills have to be counter-signed by the guide.

5. Please also note that in case the completion report is not submitted, the pending amount of 50% shall not be released. And the guide will have to submit report in lieu of post graduate in case the post graduate fails to do so. If the latter is not done, the guide will not be eligible to apply for the thesis grant again.

6.Publication of the thesis as a research paper is mandatory and should be sent for publication within 1.5 years after thesis completion. Please note the certificate will be disbursed only after proof of submission is sent.

7. The grant rules mandate, that If you are unable to complete the thesis, the post graduate has to refund the 50% amount. This is the liability of the postgraduate alone.

8.If the postgraduate fails to refund the grant money in case of non-completion of thesis a penalty shall be levied when he/she applies for becoming a life member of the IADVL association.

9. To increase the scope of the grant, the Guide will not be eligible for 3 years after receiving the grant.

10. Please send in a mail confirming your acceptance of the grant and furnish Bank details: **Name of the bank, Account No, Name of account holder, Branch address, IFSC code and send them along with** required documents (as stated in point 2 above) to iadvlpgthesisgrant@gmail.com and academy@iadvl.org.

Please feel free to contact us for any clarification at iadvlpgthesisgrant@gmail.com and academy@iadvl.org.

Congratulations for getting the grant.

Dr Sumit Sen

Postgraduates Activities Coordinator

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

LetzDream
Foundation
Dream to Change

01.02.2021

Dr.Gangadhara Somayaji K.S
Registrar,
Yenepoya (Deemed to be University)
Deralakatte, Mangalore-575018

LDF/2021/Yenepoya/01

Subject — Grant approval for project — Nutrition and Tuberculosis: Center for Nutrition Studies activities in Karnataka and Jharkhand.

Dear Sir,

We are in receipt of your proposal for project titled 'Nutrition and Tuberculosis: Center for Nutrition Studies' activities in Karnataka and Jharkhand' vide document dated15/01/2021.

We note that the applicants for this project are Dr Anurag Bhargava, Professor, Dept of Medicine, Yenepoya Medical College, Mangaluru and Head, Center for Nutrition Studies, Yenepoya (Deemed to be University) and Dr Madhavi, Assistant Professor, Dept of Community Medicine, Deputy Head, Center for Nutrition Studies, Yenepoya (Deemed to be University), Mangaluru, Karnataka-575018.

After going through the project proposal thoroughly, we are happy to support the budget of INR 40,00,000/- through a grant towards the extension of food support to severely undernourished patients in the RATIONS trial in Jharkhand as well as other mentioned activities in the area of Tuberculosis and Nutrition in Karnataka and Jharkhand.

The total grant amount will be paid in 4 equal instalments of INR 10,00,000 per month beginning February 2021.

We would appreciate receiving, from your end, an annual statement of expenditure and activities approved by the competent authorities of the University.

LETZ DREAM FOUNDATION

(Vaishali Samanta)
Chief Operating Officer
Letz Dream Foundation

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

5

From: IADVL Research Grants <iadvlresearchgrants@gmail.com>
Sent: Wednesday, October 14, 2020 9:22 AM
To: sunil dogra <sundogra@hotmail.com>; manjunath shenoy <manjunath576117@yahoo.co.in>; renmadhu08@gmail.com <renmadhu08@gmail.com>; shital poojary <spoojary2004@gmail.com>; drshyamanta@gmail.com <drshyamanta@gmail.com>
Cc: Academy IADVL <academy@iadvl.org>
Subject: IADVL Glowderma Research Grant 2020_provisionally selected proposals

Dear Dr. Sunil Dogra, Dr. Shivaprakash M, Dr. Tarun Narang, Dr. Manjunath Shenoy, Dr. R Madhu, Dr. Shital Poojary, Dr. Shymanta Barua

We are pleased to inform you that your proposal has been provisionally selected for IADVL Glowderma Research Grant 2020 as detailed below.

Project title- Effect of corticosteroids in the pathophysiology of dermatophytosis and antifungal susceptibility testing of isolates from patients with steroid modified tinea

Provisionally Approved Budget: INR. 6,72,000/-

Tenure of the project- 12 months (as per proposal of the applicant). The tenure will start from the date of release of the first instalment of the grant.

We extend our congratulations to you and your co-investigators for the selection of your project.

Kindly send us a zipped folder with all of your documents (Form 1, Form 2, incorporating final changes suggested (Budgetary details), separate detailed budget sheet with detailed break up-including approximate price of kits/ reagents etc & budget allocated for each participating centre, and investigators undertaking in the attached format.

If you have got the undertaking in the previous format already signed by your Institution head, you need to send the undertaking in the previous format signed by all investigators and the institution head, in addition to the last two points in the revised format signed by all the investigators only. If the undertaking is not yet signed by the institution head, kindly get all the signatures in the new format that is attached herewith.- (pending for your application)

In addition to these documents, to enable us disbursal of funds, kindly send us a copy of the Institute Ethics Committee approval (of all centers, in case of multicentric studies), CTRI registration number, and the bank account details where the funds should be transferred, along with a signed and scanned voucher (attached). Where trial insurance is required, we need the trial insurance certificate before disbursal of the first instalment of the grant.

Kindly acknowledge the receipt of this mail and send your response mail with all required documents to iadvlresearchgrants@gmail.com and academy@iadvl.org . The successful applicants get 6 months to send required documents from the date of receipt of this mail.

Sincere regards,

Professor & H.O.D.
Department of DVL (Dermatology)
Yenepoya Medical College
Yenepoya (Deemed to be University)
Deralakatte, Mangalore-575 018, India

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Dr.Gangadhara Somayaji K.S.
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Dr. Raghunatha S/ Dr Santoshdev P Rathod
IADVL Research Grant Coordinators

Dr. Deepika Pandhi
Chairperson, IADVL Academy

Dr Dipankar De
Convener, IADVL Academy

Professor & H.O.D.
Department of DVL (Dermatology)
Yenepoya Medical College
Yenepoya (Deemed to be University)
Deralakatte, Mangalore-575018, India

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Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

SIG Recalcitrant dermatophytosis scientific project proposal submitted to IADVL Academy for intramural grant

Investigators:

1. **Dr Sunil Dogra (Principal investigator),**

Department of Dermatology, Venereology and Leprosy, Mail: sundogra@hotmail.com

2. **Dr Shivaprakash M Rudramurthy (Co-investigator),**

Department of Midical Microbiology (Mycology), Mail: mrshivaprakash@gmail.com

3. **Dr Tarun Narang (Sub-investigator)**

Department of Dermatology, Venereology and Leprosy,

[1,2,3]Postgraduate Institute of Medical Education and Research, Chandigarh. India

(Lead Centre)

4. **Dr Manjunath Shenoy M, (Sub-investigator)**

Department of Dermatology, Venereology and Leprosy, Yenepoya Medical College, Deralakatte, Mangalore. Mail: manjunath576117@yahoo.co.in

5. **Dr Madhu R, (Sub-investigator)**

Department of Dermatology, Venereology and Leprosy, Madras Medical College, Chennai, India.Mail: renmadhu08@gmail.com

6. **Dr Shital A Poojary, (Sub-investigator)**

Department of Dermatology, Venereology and Leprosy, KJ Somaiya Medical College, Sion, Mumbai.Mail: spoojary2004@gmail.com

7. **Dr ShyamantaBarua, (Sub-investigator)**

Department of Dermatology, Venereology and Leprosy, Assam Medical College, Dibrugarh.Mail: drshyamanta@gmail.com

Professor & H.O.D.
Department of DVL (Dermatology)
Yenepoya Medical College
Yenepoya (D... University)
Deralakatte, Mangaluru-575018, India

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Dr.Gangadhara Somayaji K.S.
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Mangalore- 575 018, Karnataka

2,74,300 per patient (15 patients) - 41,14,500; Archival and Start-up - 1,45,000; Approximate grant total = 42,59,500

भारतीय गैर न्यायिक

भारत INDIA

रु. 500 FIVE HUNDRED RUPEES

पाँच सौ रुपये Rs. 500

सत्यमेव जयते

INDIA NON JUDICIAL

महाराष्ट्र MAHARASHTRA ◐ 2020 ◐ BB 479804

SUB TREASURY OFFICE KALYAN

Sub Treasury Officer
Kalyan
- 4 JUN 2021

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

DocuSigned by:
DKGS
Signer Name: Dr. K.S Gangadhara Somayaji
Signing Reason: I have reviewed this document
Signing Time: 28-Aug-2021 | 05:07:17 GMT
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DocuSigned by:
DPR
Signer Name: Dr. Prashanth RM
Signing Reason: I have reviewed this document
Signing Time: 26-Aug-2021 | 11:41:45 GMT
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DocuSigned by:
SM
Signer Name: saumya mathew
Signing Reason: I approve this document
Signing Time: 31-Aug-2021 | 06:00:32 GM
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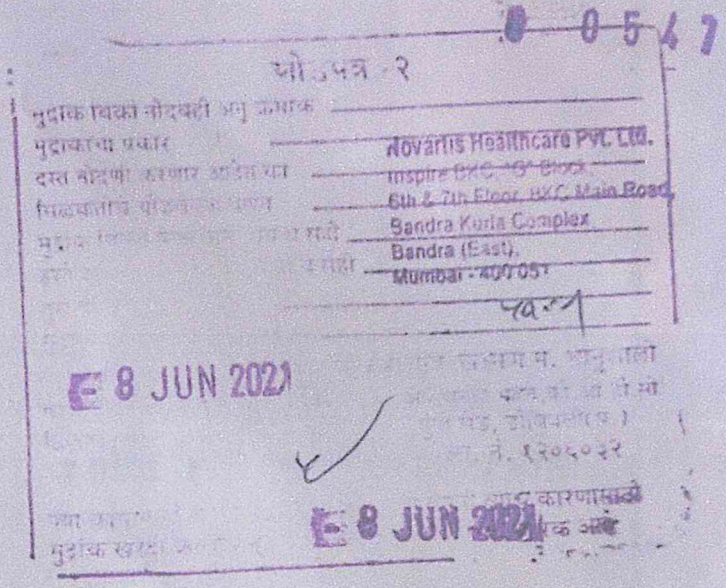

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

DocuSigned by:
DKGS
Signer Name: Dr. K.S Gangadhara Somayaji
Signing Reason: I have reviewed this document
Signing Time: 28-Aug-2021 | 05:07:32 GMT
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DocuSigned by:
DPR
Signer Name: Dr. Prashanth RM
Signing Reason: I have reviewed this document
Signing Time: 26-Aug-2021 | 11:41:58 GMT
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DocuSigned by:
SM
Signer Name: saumya mathew
Signing Reason: I approve this document
Signing Time: 31-Aug-2021 | 06:00:47 GM
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CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("**Agreement**") is entered into as of ***[__ _____ 20_]*** ("**Effective Date**") between **Novartis Healthcare Private Limited,** a company incorporated under the provisions of the Companies Act, 1956, and having its registered office at Inspire BKC, Part of 601 & 701, Bandra Kurla Complex, Bandra (East), Mumbai – 400 051, Maharashtra, India (hereinafter referred to as "**Novartis**" which expression shall unless repugnant to meaning or context mean and include its successors and assigns) of the FIRST PART;

AND

Yenepoya Medical College Hospital , Constituent College of Yenepoya (Deemed to be University) located University Road, at ***Deralakatte ,Mangalore-575018*** ("**Institution**") Recognised under Sec3 (A) of the UCG Act,1956) and having its address at University Road, Mangalore- 575018 which expression shall mean and include its successors and assigns of the SECOND PART;

AND

Dr. Prashanth R.M as clinical practitioner in the field of ***Cardiology Department of Yenepoya Medical College Hospital, Constituent College of Yenepoya (Deemed to be University) University Road, Deralakatte Mangalore-575018*** acting in the role of principal investigator ("**Principal Investigator**") which expression shall mean and include his/her heirs, executors, administrators and assigns of the THIRD PART;

Novartis, Institution and Principal Investigator are hereinafter individually referred to as the "**Party**" and jointly as the "**Parties**". For the purposes of this Agreement, "**Affiliate(s)**" shall mean any entity which directly or indirectly controls, is controlled by or is under common control of Novartis.

RECITALS:

WHEREAS, Novartis is to perform a clinical trial (hereinafter the "Trial) to evaluate the following drug: ***TQJ230/ Pelacarsen*** *(hereafter the "Trial Drug") in accordance with a protocol entitled* ***"A randomized double-blind, placebo-controlled, multicenter trial assessing the impact of lipoprotein(a) lowering with pelacarsen (TQJ230) on major cardiovascular events in patients with established cardiovascular disease and its potential subsequent amendments" [Protocol No. CTQJ230A12301]*** (hereinafter collectively the "Protocol").

WHEREAS, the Institution and the Principal Investigator having each reviewed the Protocol for the Trial and sufficient information regarding the Trial Drug to evaluate their interest in participating in the Trial, wish to conduct in the Trial and assure that they have sufficient authority, competence and experience in clinical trials, along with the necessary infrastructure and technical means to perform the Trial,

WHEREAS the Principal Investigator is an employee of the Institution,

WHEREAS, the Parties wish to set forth certain legal and commercial terms and conditions under which the Trial shall be conducted;

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

1. CONFORMANCE WITH LAW AND ACCEPTED PRACTICE

The Institution and Principal Investigator shall carry out the Trial in accordance with:

(a) the Protocol;

(b) Good Clinical Practice (GCP) including the International Conference for Harmonization (ICH) GCP;

ATTESTED

Dr.Gangadhara Somavaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

DocuSigned by: DKGS — Signer Name: Dr. K.S Ga...

DocuSigned by: DPR — Signer Name: Dr. Prashanth RM

DocuSigned by: SM — Signer Name: saumya mathew

(c) the Declaration of Helsinki of the World Medical Association, "Ethical Principles for Medical Research Involving Human Subjects";

(d) any applicable direction received from a Regulatory Authority (like Drug Controller General of India) or Ethics Committee with jurisdiction over the Trial;

(e) any "**Applicable Law(s)**" being hereinafter defined as: all regional, federal, state, and local directives, laws rules including but not limited to New Drugs and Clinical Trials Rules 2019, any data protection laws and rules relating to the privacy, security, confidentiality and/or integrity of Personal Data that are applicable to the operations, services or products of Institution, Principal Investigator and Novartis, regulations, orders, published guidelines, operating procedures applicable to the Trial and/or the Parties including but not limited to, legislation applicable to clinical studies, the Parties, medical treatment, disclosures of transfers of value and the processing of personal and medical data;

(f) Comply with all guidelines provided to it by Novartis from time to time including but not limited to the Applicable Anti-Corruption Legislations (as set out in Annex 3) and Novartis Professional Practice Policy.

and all written instructions given by Novartis.

all, as amended from time to time.

The Institution shall ensure that the Principal Investigator and the Institution's employees and other persons involved in the Trial will 1) adhere to all Applicable Laws, 2) comply with all obligations set forth in this Agreement, 3) fully understand and adhere to the Protocol.

2. PROTOCOL

2.1 A copy of the Protocol has previously been furnished to the Institution and the Principal Investigator and receipt thereof is hereby acknowledged by the Institution and the Principal Investigator. The Parties agree that the Protocol, including any subsequent amendments and the Annexes form an integral part of this Agreement.

2.2 Institution and Principal Investigator shall perform the Trial in accordance with the Protocol, all Applicable Laws, the identified timelines and the terms and conditions of this Agreement. Institution and Principal Investigator shall not start the Trial without prior approval of the appropriate Ethics Committee and/or Regulatory Authority.

2.3 Novartis may at any time amend the Protocol by written notice to Principal Investigator and Institution. Such amendments, whether or not substantial, may require the approval of the Ethics Committee and/or the Regulatory Authority before implementation.

2.4 No financial adjustments shall be made due to such amendments unless the Parties hereto amend this Agreement accordingly.

3. APPROVALS

The Trial shall not start until:

(a) all the necessary approvals of the relevant Regulatory Authority and the competent Ethics Committee have been obtained in writing by the Principal Investigator/or Novartis. Relevant approvals from the Ethics Committees shall be forwarded to Novartis as they are obtained;

(b) the written approval of relevant authority or organisation that owns or is responsible for the administration of the facility in which the Trial is to be performed has been obtained if such authority or organisation is not the Institution.

(c) the Informed Consent Form as defined in Section 5.3 (d)provided by Novartis, has been approved by the Principal Investigator and/or, as applicable, by the Ethics Committee.

4. TERM OF THIS AGREEMENT

4.1 This Agreement shall be effective upon signature by both Parties and shall expire upon receipt and acceptance by Novartis of the work product specified in the Protocol.

ATTESTED
Dr.Gangadhara Somavaji K.S.
Registrar
Yenepoya(Deemed to be University)
Yenepoya Road, Deralakatte
Mangalore- 575 018, Karnataka

DocuSigned by: DLGS — Signer Name: Dr. K.S Ganadhara Somavaji
DocuSigned by: DPR — Signer Name: Dr. Prashanth PM
DocuSigned by: SM — Signer Name: saumya mathew

4.2 The following provisions shall survive the termination or expiry of this Agreement: Section 11 (Intellectual Property), Section 13 (Publication), Section 14 (Confidentiality) and Section 15 (Data Privacy), as well as any other provisions which by their terms are understood to survive the termination or expiry of this Agreement, including compliance with Applicable Laws.

The Institution shall not be able to replace the Principal Investigator with another Principal Investigator without the prior written consent of Novartis. The Institution shall inform Novartis in writing within five (5) business days if the Principal Investigator is unable or unwilling to continue to perform its duties as Principal Investigator and shall provide reasonable assistance in finding a replacement acceptable to Novartis. Enrolment of new trial subjects (hereinafter "Trial Subjects"), shall be put on hold until the new Principal Investigator has been appointed. The Institution acknowledges that Novartis will continue to make payments for Trial Subjects already enrolled by the prior Principal Investigator, but shall not make payments for new Trial Subjects.

During the selection process of the new Principal Investigator, Novartis shall agree immediately with the Institution to appoint an ad interim Principal Investigator in order to continue to perform the Trial Subjects visits according to Protocol.

If a replacement is unable to be found within thirty (30) days after notification, Novartis may terminate this Agreement. If the Principal Investigator ceases to be affiliated with the Institution, Novartis shall have the right to transfer the conduct of the Trial from the Institution to the Principal Investigator's new practice, and the Institution agrees to fully cooperate with Novartis and the Principal Investigator in the transition of such responsibilities, including assisting with the transfer of any subject medical records.

5. PERFORMANCE OF THE TRIAL

Principal Investigator shall be responsible for the performance of the Trial, in particular for the following:

The Principal Investigator may appoint individuals and investigational staff as they may deem appropriate as sub-investigator (the "Sub-Investigators") to assist in the conduct of the Trial, (collectively " the Trial Staff").

All Sub-Investigators and investigational staff will be adequately qualified, timely appointed and an updated list will be maintained by the Principal Investigator. Principal Investigator shall be responsible for leading such team of Sub-Investigators and investigational staff, who, in all respects, shall be bound by the same terms and conditions as the Principal Investigator under this Agreement. The Principal Investigator shall provide Novartis with an up-to-date signed CV of him/her and of all key investigational staff members as well as all other relevant document establishing qualification, experience. He/ She shall document and oversee the duties delegated to the staff, ensuring only qualified and trained staff members are involved in the Trial. The Principal Investigator shall be responsible for the conduct of the Trial in its entirety and for the rights, safety and well-being of the Trial Subjects.

5.1 Trial Site

The Trial shall be conducted at the premises of Institution: ***Yenepoya Medical College Hospital*** (hereinafter the "**Trial Site**").

5.2 Use of Trial Drug:

Novartis shall provide the Trial Drug in sufficient quantity to conduct the Trial. For purposes of this Agreement only, the Trial Drug shall be supplied to Institution free of charge. In all events, the Trial Drug shall remain the sole property of Novartis.

The Principal Investigator shall

(a) ensure the safe receipt, handling, storage, use and administration of the Trial Drug and take all reasonable measures to ensure that it is kept secure, in agreement with GCP, the Protocol and any applicable guidelines;

(b) make a written declaration revealing whether or not the Principal Investigator has any possible economic or other interests in connection with the conduct of the Trial and the Trial Drug and – if so – what his/her interests are and shall submit such written declaration to Novartis.

(c) not permit Trial Drug to be used for any purpose other than the conduct of the Trial in compliance with the Protocol;

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

(d) shall not make the Trial Drug available to any third party other than as specified in the Protocol without Novartis' prior written consent;

(e) keep full and accurate records of who dispenses the Trial Drug, the quantity dispensed, and the quantity returned which shall be available for review and /or collection by Novartis and/or designated monitor entrusted with the oversight of the Trial("Novartis Monitor") at any scheduled monitoring visit;

(f) cooperate with the Novartis Monitors and observe the instructions given by them;

(g) upon any earlier expiration or termination of this Agreement, at Novartis's expense, return any remaining quantities of the Trial Drugs to Novartis.

5.3 **Trial Subject consent and entry into Trial:**

Before entering a Trial Subject into the Trial, the Principal Investigator shall:

(a) Exercise independent medical judgement as to the qualification of each prospective Trial Subject with the requirements of the Protocol;

(b) advise Novartis of all instances in which, in the Principal Investigator's judgement, there is any question as to any prospective Trial Subject's suitability for participation in the Trial, and abide by Novartis's decision as to whether or not to enrol that Trial Subject;

(c) ensure that, before their participation in the Trial, the Trial Subject, and/or as the case may be, her/his legal representative, are duly informed in language understandable to them, about all aspects of the Trial that are relevant to them, including: (i) the purpose, duration, nature, significance, implications, potential benefits and/or risks of the Trial; and (ii) the collection, processing, auditing, and monitoring of data (including personal data) under this Agreement;

(d) ensure that, before his /her participation in the Trial, each Trial Subject and/or as the case may be her/his legal representative has given his or her Informed Consent by signing a consent form ("Informed Consent Form" or "ICF")in the form provided by Novartis, in accordance with the Protocol and without the undue influence or coercion of any person directly involved in the Trial, and in accordance with Applicable Laws.;

(e) ensure that a copy of the signed Informed Consent Form be provided to the Trial Subject, and/or as the case may be, his/her legal representative;

(f) acknowledge that the use of the Informed Consent Form does not release the Principal Investigator from his or her legal, regulatory and contractual obligations relating to Informed Consent, and that it remains the Principal Investigator's responsibility to ensure that those obligations are complied with; and

(g) comply with the procedures described in the Protocol in relation to that Trial Subject.

5.4 **Trial Subject Recruitment**

Principal Investigator has estimated that he/she can recruit the number of Trial Subjects as specified in Annex 1. This target of recruitment can be increased only upon written agreement of Novartis. In addition, Novartis may establish a threshold number of Trial Subjects and rate of accrual of Trial Subjects (1 Subjects per month) to allow for appropriate monitoring of the Trial, and will communicate this information to the Principal Investigator. The Principal Investigator undertakes to comply with these limitations and conditions for further recruitment at the Trial Site as required by Novartis.

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

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

5.5 **Recordkeeping**

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

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(a) Preparation and maintenance of complete, accurately written and electronic records, including accounts, notes, reports, Case Reports Forms, records of Trial Subject identifications, medical notes, clinical observations, laboratory tests, and the receipt and disposition of the Trial Drug and all supportive documentation and data for each Trial Subject of this Trial (hereinafter "Records");

(b) Preparation and maintenance of the Investigator Site File (hereinafter "the ISF") and, in particular, ongoing filing of all relevant Trial-related original documents in the ISF;

(c) Maintenance of a copy of all documents related to this Trial for the longer of at least a) fifteen (15) years after the Trial is completed or discontinued by Novartis, b) or longer as required by Applicable Laws. Maintenance of all documents and other Records generated in the Trial in safe keeping for such period as is required by any applicable regulations, and in any event for 15 years following termination of the Trial. If Novartis has any legal reasons to wish to access the documents for a longer period than described above, Novartis shall notify the Institution accordingly before the end of such period. In the event of the insolvency or bankruptcy of Institution, Institution agrees to promptly transmit all copies of such records to Novartis in accordance with Novartis' written instructions at Novartis' expense.

(d) Meet with a representative of Novartis to discuss the progress of the Trial; and notification to Novartis immediately upon discovering any significant violations of the Protocol.

(e) Safely keeping the hospital records of Trial Subjects in a known and accessible location during the period defined here-above.

(f) Make available all Records to Novartis, its nominee or Health Authorities promptly upon request for monitoring and/or auditing purposes;

(g) Be responsible for making any necessary applications for registration under the data protection legislation in connection with data obtained under this Agreement.

5.6 **Reporting**:

The Principal Investigator shall, and shall ensure that any co-investigator involved in the conduct of the Trial shall, on reasonable notice

(a) Meet with a representative of Novartis to discuss the progress of the Trial; and

(b) Make the hospital notes and Case Report Forms for each Trial Subject available for source data verification or auditing purposes by representatives of Novartis and the officers of any competent regulatory authority.

(c) In accordance with the procedure set out in the Protocol: Completion of a Case Report Form for each Trial Subject; review and signing of each of the Case Report Forms to ensure and confirm their accuracy and completeness, ensuring errors are corrected upon identification; and prompt submission of the Case Report Forms to Novartis following their completion,

(d) Cooperation with Novartis in all their efforts to monitor the Trial and to support Novartis in all matters of data collection, verification and discrepancy resolution

(e) Immediately or at latest within two (2) days of the occurrence, inform Novartis upon discovering any violations of the Protocol, or breaches or potential breaches of the Applicable Laws.

5.7 **Reporting of Safety Information**:

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

The Institution and the Principal Investigator shall also ensure that any person involved in the conduct of the Trial shall:

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(a) Immediately and not later than within 24 hours report to Novartis according to the procedure set out in the Protocol, any new safety findings on the Trial Drug, including Serious Adverse Event or Serious Adverse Reaction affecting or which could have an impact on the safety of the Trial Subject or which could result in a re-assessment of the risk-benefit ratio of the Trial Drug. The Principal Investigator shall follow up such immediate reports and provide the additional information in a detailed, written manner to Novartis in accordance with the Protocol;

(b) Report to Novartis all Adverse Events (refer definition of adverse event as per current ICH E6 guidelines for Good Clinical Practice and/or as mentioned in the Protocol)in accordance with the trial Protocol, applicable trial procedures for safety data reporting;

(c) Cooperate with and supply any further information required by Novartis and/or any relevant Ethics Committee or Regulatory Authority with jurisdiction over the Trial; and

(d) Report to Novartis any emergency that requires to that requires to unblind the patient in the event of double-blind studies and to document and notify Novartis of the date and reason for the emergency situation.

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

During the Trial Novartis shall further report the adverse events to the competent Regulatory Authorities, in accordance with the current Applicable Laws. Novartis will furthermore provide the Principal Investigator with safety-related information from other investigational sites in order to inform the ethics committees IRB/IEC, as required.

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

5.8 Items supplied by Novartis

Novartis shall provide directly or indirectly the Principal Investigator and/or the Institution with all necessary information, documents, study equipments (as set out in Annexure 1)and materials, including but not limited to:

(a) the Investigator Brochure (IB)

(b) the Protocol,

(c) the CRF/e-CRF

(d) The Trial Drug

6. LIABILITY-INDEMNIFICATION

Novartis shall assume responsibility for injuries to third parties caused in the course of carrying out the Trial according to the Applicable Laws, this Agreement and the Protocol, provided that:

(a) The Institution, the Principal Investigator, the Institution's employees and collaborators (hereinafter collectively "the Indemnitees" or each an "Indemnitee") shall have been free of wrongful conduct or omission, negligence, and wilful misconduct in the conduct of the Trial and in their obligations under this Agreement and the Protocol, and shall not have failed to follow the instructions or recommendations of Novartis;

(b) The Indemnitee refrains from making any admission of liability or any attempt to settle any claim without Novartis' consent;

(c) The Trial Drug causing the injury was given by the Principal Investigator in accordance with the Protocol;

(d) an adequate causal relationship is proven between the use of the Trial Drug and the appearance of injury;

(e) Novartis is immediately informed of the claim and all pertinent information relating thereto (but in any case, within ten (10) days after the Indemnitee shall have received notice thereof);

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(f) The Indemnitee provide such information and assistance to Novartis in connection with such claim as is reasonably requested by Novartis and its representatives;

(g) Novartis is permitted to handle and control such claim in its sole discretion.

(h) An Indemnitee seeking indemnification shall take all reasonable steps to mitigate the amount of any claim for indemnification; and

(i) The indemnity will not inure to the benefit of any Indemnitee's insurer, by subrogation or otherwise. The provisions of this Section constitute the Indemnitees' sole and exclusive remedy against Novartis in respect of all claims.

7. INSURANCE

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

Novartis warrants that it has insurance for the Trial Subjects included in the Trial in place at Trial start as per the Applicable Laws.

8. COMPENSATION

8.1 In consideration for the Institution's satisfactory performance of the Trial according to this Agreement and the Protocol, the Institution and Investigator agrees to Payment Schedule attached hereto as Annex 1.

8.2 Novartis reserves the right to terminate the Agreement immediately if no Trial Subjects have been recruited at the Trial Site within 90 days after the Site Initiation Visit (SIV).

8.3 Fees for the Trial Subjects not completing the Trial will be paid to the Institution on a prorated basis according to the number of completed Trial assessment as per Protocol. All payment will be made for subject visits according to the Payment Schedule referred in Annex 1. Reimbursement for expenses related to screening failures will be made according to the Payment Schedule in Annex 1.

8.4 The Institution shall send the invoices to:

Novartis Healthcare Private Limited

GDO Trial Monitoring, India

6 & 7 floor, Inspire BKC, G Block,

BKC Main Road,

Bandra Kurla Complex , Bandra (East),

Mumbai – 400051

8.5 Each invoice shall specify the Trial Code. Novartis shall make payments into the account indicated by the Institution within 60 (sixty) days of receipt of an invoice from the Institution.

8.6 Novartis shall give its prior express written approval regarding any additional costs or expenses not foreseen in the Payment Schedule or Annex 1. Any costs or expenses incurred without this prior written approval shall be borne by the Institution.

8.7 Each Party represents and warrants to the others that the payment of the fees related to the conduct of the Trial (including payments to subcontractors, consultants, or other agents working on behalf of the Institution/the Principal Investigator or as part of the Institution's and/or Principal Investigator's services to Novartis, as applicable) (i) represents the fair market value for the conduct of the Trial, (ii) has not been determined in any manner that takes into account the volume or value of any referrals, reimbursements or business between the Institution and/or the Principal Investigator and Novartis, and (iii) is not offered or provided, in whole or in part, with the intent of, directly or indirectly, implicitly or explicitly, influencing or encouraging the recipient to

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purchase, prescribe, refer, sell, arrange for the purchase or sale, or recommend favorable formulary placement of a Novartis product or as a reward for past behaviour.

9. EQUIPMENT

9.1 If necessary and based upon Novartis' assessment of Institution existing equipment, Novartis may provide equipment (the "Equipment") to the Institution and/or Investigator as detailed in Annex 1. The Equipment shall remain the sole and exclusive property of Novartis. It shall be used exclusively by the Institution, the Investigator and/or the designated Trial Staff: The Equipment shall only be used for the conduct of the Trial in accordance with the Protocol, Novartis instructions and until the Trial is completed or discontinued.

9.2 If Novartis, or its designee, provides the Institution and/or Investigator with Equipment for the purpose of this Trial, the Institution and Investigator agree that neither Novartis nor its designee shall be responsible to (i) insure the Equipment against any damages caused to or by the Equipment, and (ii) do the maintenance of the Equipment during the term of the Trial. The Institution and/or Investigator agree that the Equipment shall remain in the same condition during the Trial, with the exception of ordinary depreciation.

9.3 During the term of the Trial, Institution and/or Investigator shall be responsible for immediately notifying Novartis of any malfunctioning Equipment.

9.4 Following completion of the Trial or upon discontinuation of the Trial for any reason, the Institution and/or Investigator, as the case may be, shall return the Equipment to Novartis or alternatively, in the event the Equipment remains with the Institution and/or Investigator, the cost of such Equipment will be deducted from the last payment(s) to be made to either the Institution or Investigator, as the case may be.

10. TERMINATION

(a) Termination by Novartis. Novartis, in its sole discretion, shall have the right to terminate with immediate effect the conduct of the Trial at any time and give notice to the Institution accordingly. Upon receipt of the notice to terminate the Trial, the Institution and the Principal Investigator shall immediately take all reasonable steps to cease conduct of the Trial at the Institution as soon as reasonably possible and to protect the wellbeing of Trial Subjects.

(b) Termination by the Institution. The Institution shall have the right to terminate the conduct of the Trial upon a thirty (30) days prior written notice if necessary, to protect the wellbeing of Trial Subjects.

(c) Termination due to unavailability of the Principal Investigator. In addition, either Party may terminate this Agreement with immediate effect by written notice to the respective other Party if the Principal Investigator is no longer available or terminates his or her relationship with the Institution, and a suitable replacement cannot, after reasonable efforts by the Institution, be found that is agreeable to Novartis as described in Section 5.

(d) Termination for Breach etc. Either Party may terminate this Agreement with immediate effect by written notice to the other in the event that (i) the other Party commits a material breach of this Agreement which (if remediable) is not remedied within thirty (30) days of a written notice from the non-defaulting party; or (ii) the other party becomes insolvent.

Any violation of the good clinical practices, the Applicable Anti-Corruption Legislations (as set out in Annex 3), or data protection provisions under the Applicable Laws shall be deemed to be a material breach of this Agreement.

(e) Respective Obligations in the Event of Early Termination. In the event that the conduct of the Trial at the Institution is terminated prior to its completion other than by Novartis under Section 10 Novartis shall pay to the Institution the remuneration detailed in this Agreement for the milestones which have been duly achieved to the date of termination and all non-cancellable expenses previously approved by Novartis. In the event of early termination for any reason, the Institution shall provide all such assistance as Novartis shall reasonably require in order to ensure an efficient handover of the conduct of the Trial to a third party and with due regard for the welfare of the Trial Subjects.

(f) Return of Documents and Material. Upon termination of this Agreement for any reason the Institution shall and shall procure that the Principal Investigator shall return to Novartis all documents, Trial results and material used, generated or referred to in the course of

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the Trial, and the Institution and the Principal Investigator hereby irrevocably waive any ownership interest or intellectual rights worthy of protection of any of the above.

The Agreement shall be terminated in writing by registered mail with acknowledgement of receipt. The termination of this Agreement by e-mail communication shall be excluded.

11. INTELLECTUAL PROPERTY

11.1 All data, information and documents provided to the Institution and/or Principal Investigator by or on behalf of Novartis, whether in paper, oral, electronic or other form, shall remain the sole property of Novartis.

11.2 All data, information, documents, inventions and discoveries, resulting from or developed in the performance of the Trial or this Agreement shall be the sole property of Novartis and may be used and/or transferred by Novartis in its sole discretion to any of its Affiliate or such third parties with no further payment or other obligation to the Institution and/or Principal Investigator. The Institution and/or Principal Investigator shall have no rights whatsoever therein

11.3 The Institution also agrees to, and to cause its employees and collaborators and the Principal Investigator to, execute promptly all documents and take all such other action as may reasonably be requested by Novartis to permit Novartis to obtain the benefit of its rights under this Agreement. This includes without limitation taking all necessary steps for the transfer of ownership of all data, information, documents, inventions and discoveries to Novartis in accordance with this Agreement, and assisting Novartis in the preparation and prosecution of patent applications. The Institution shall be solely responsible for all payments due to the Principal Investigator and/or the Institution's employees and/or collaborators according to the applicable law for any inventions transferred to Novartis. The fees under Section 8 and Annex 1shall be deemed to include consideration for such payments by the Institution.

12. TAXES AND SOCIAL SECURITY CONTRIBUTIONS

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

13. PUBLICATION

13.1 Novartis recognizes the Institution's interest in making publications and presentations relating to the Trial in journals, at meetings or otherwise, and Novartis shall therefore permit such publications and presentations, provided however that the Institution shall provide to Novartis any proposed presentation (oral or written) at least 15 (fifteen) working days and any other proposed publication at least 45 (forty-five) working days, for its review prior to being disclosed or submitted to anyone who is not employed by the Institution and not under an obligation of non-disclosure and non-use at least substantially identical to that imposed on the Principal Investigator by this Agreement, and provided that Novartis shall have the right to require amendments to any such proposed presentation or publication on reasonable grounds including without limitation:

(a) to ensure the accuracy of the presentation or publication;

(b) to ensure that proprietary or confidential information is not inadvertently divulged;

(c) to enable intellectual property rights to be secured;

(d) to enable relevant supplementary information to be provided.

13.2 The list of persons to be designated as primary or secondary author of any publication relating to the Trial shall be determined by mutual agreement.

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

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

13.5 Any such publication or disclosure must comply with all Applicable Laws and must be limited to scientific findings. Such publications or disclosures must, in particular, not constitute promotion under the Applicable Laws.

13.6 Subject to any copyright rights owned by the applicable publisher, Novartis and its agents may use, refer to and disseminate reprints of scientific, medical and other published articles which disclose the name of the Institution and/or the Principal Investigator.

13.7 Novartis and its agents may use the Institution and the Principal Investigator contact details and Trial status in Trial specific newsletters and on the worldwide web for the purpose of conducting this Trial. Newsletters may be distributed to all participating sites and postings to the worldwide web are for the purpose of providing information to potential Trial Subjects regarding the Trial giving them the ability to contact participating sites.

13.8 Neither the Institution nor the Principal Investigator shall disclose the existence of this Agreement or its association with Novartis, or use the name of Novartis or its agents in any press release, article or other method of communication, without the express prior written approval of the party whose name is the subject of the potential disclosure. Provided, however, that in order for the Institution to satisfy its reporting obligations, they may identify Novartis as the Trial sponsor and disclose the amount of funding received for the Trial, but it shall not include in any such report any information that identifies any product by name or the therapeutic area(s) involved in the Trial, except as otherwise required by the Applicable Laws. The Institution, the Principal Investigator and investigational staff shall not use the name of Novartis or its agents or any information that identifies the Trial Drug or Trial in any social media.

14. CONFIDENTIALITY

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

14.2 All email communication with Novartis, especially those involving trial related information should happen via secure 'Institutional email Ids'. Exceptions (i.e. use of non-institutional email Ids), if any, must be discussed with Novartis and a secure communication solution, as mutually agreed and in line with Novartis' security standards, is implemented.

14.3 Upon termination or expiry of this Agreement, the Institution shall destroy or return to Novartis, as per Novartis' request, all documents, samples and material containing or relating to Information, except for one copy of Information which is to be retained in the confidential files of the Institution for record purposes only. If requested by Novartis, such destruction shall be promptly confirmed in writing by the Institution to Novartis.

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

(a) Information which is, at the time of disclosure, in the public domain or thereafter becomes part of the public domain otherwise than by the act or omission of the Institution, the Principal Investigator, or the Institution's employees and/or collaborators;

(b) Information that the Institution can demonstrate by written evidence was in its possession prior to its disclosure by Novartis or that said Information, its collection or creation did not occur during or in connection with the Trial;

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(c) Information which the Institution received from any third party not engaged in the activities which are the subject of this Agreement, where such information is not subject to an obligation of confidentiality in favour of Novartis or any of its affiliates.

15. DATA PRIVACY

15.1 Provisions on the collection and processing of data by the Institution and the Principal Investigator.

(a) The collection and processing of Research Data (meaning any data, including personal data concerning the Trial Subjects(such as gender, age, health status, etc) and the Trial Staff shall be performed in compliance with this Agreement and as indicated in the Protocol, the Informed Consent Form and any written instructions issued by Novartis. Research Data collected by the Institution in the Case Report Form shall be processed by the Institution only for the purpose of the performance of this Agreement. However, the Institution may use the data collected in the course of the Trial for the Trial Subject's treatment purposes.

(b) Processing of Research Data shall be performed by the Principal Investigator, Trial Staff and other authorized persons on the need to know basis. The Institution shall be responsible for managing access to the Research Data provided the details in the Institution's possession or control.

(c) The Institution shall ensure Trial Staff processing Research Data have appropriate skills and training to handle personal data and maintain its confidentiality.

(d) Research Data must be kept confidential. It shall not be disclosed or transferred to any third party without prior written approval of Novartis. In case such disclosure includes personal data, the third party receiving the data must have a valid ground under Applicable Law to receive and process such data. Research Data may be disclosed where required by Applicable Law or when requested by a data protection authority.

(e) The Institution shall implement appropriate administrative, technical and physical security measures to protect personal data using current industry best practices taking into consideration the state of the art of applicable technologies.

(f) The Institution shall comply with any instructions regarding the coding of Research Data issued at any time by Novartis in accordance with Applicable Laws and best practice.

(g) The Institution shall maintain procedures to detect and respond to a personal data breach, as defined under Applicable Law, including breach of security leading to the accidental or unlawful destruction, loss, alteration, unauthorised disclosure of, or access to, personal data transmitted, stored or otherwise processed. The Institution shall notify Novartis of any personal data breach, related to the processing of the Research Data, without undue delay, but no later than twenty-four (24) hours of discovery of such breach. The Institution and Novartis shall reasonably cooperate to remediate a personal data breach and liaise with each other before reporting a personal data breach to the relevant authority.

15.2 Information to Data Subjects. The Institution and the Principal Investigator shall provide Trial Subjects, in accordance with the Applicable Laws, with an Informed Consent to participate in the Trial approved by the sponsor Novartis and the relevant Ethics Committee. Such Informed Consent shall be signed prior to Trial Subject's participation in the Trial. The Institution and/or the Principal Investigator shall timely inform Novartis when a Subject withdraws consent or opposes the use of his/her personal data, as per Applicable Law. The parties agree to collaborate in the context of Trial Subjects' individual requests.

15.3 Trial Staff Personal Data. Prior to and during the course of the Trial, the Principal Investigator and Trial Staff may be required to provide personal data which falls within the scope of the Applicable Laws and/or is needed for the implementation of the Agreement. The Institution and the Principal Investigator agree to inform Trial Staff that their personal data will be processed by Novartis and are responsible for sharing an appropriate privacy notice with such staff members following the framework attached as Annex 5.

15.4 Transfer of data. Novartis may transfer personal data to other affiliates of the Novartis group of companies and their respective agents worldwide. Novartis and its affiliates and respective agents will apply adequate privacy safeguards to protect such personal data. Personal data may also be disclosed as required by individual competent authorities or

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Applicable Laws, for example to report serious adverse events and comply with drug safety laws and regulations.

15.5 Retention of data. Personal data will be kept only for the period necessary to fulfil the purposes of the collection unless a longer retention period is required or permitted by Applicable Laws.

16. **NOTICES**

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

17. **ASSIGNMENT**

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

18. **SUBCONTRACTING**

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

Whenever a subcontractor is appointed and approved by Novartis, the Principal Investigator shall be responsible for the oversight of the subcontractor's personnel as part of the Trial Staff.

19. **SEVERABILITY**

The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision hereof.

20. **WAIVER**

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of any such term, provision or condition, or of any other term, provision or condition of this Agreement.

21. **ENTIRE AGREEMENT**

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

22. **DEBARMENT OF INSTITUTION/PRINCIPAL INVESTIGATOR OR OTHER RESTRICTIONS FROM THE COMPETENT AUTHORITIES**

(a) **Debarment.** The Institution and the Principal Investigator certify that they are not debarred or more generally under a prohibition under the relevant Applicable Laws to perform their activities. They certify that they will not use in any capacity the services of any person debarred (or otherwise under a prohibition to perform their activity) with respect to services to be performed under this Agreement. During the term of this Agreement and for three (3) years after its termination, the Institution and the Principal Investigator will notify Novartis promptly if this certification needs to be amended in light of new information. Principal Investigator also certifies that he/she does not have a revoked or suspended medical license or applicable certification.

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(b) **Investigations, Inquiries, Warnings or Enforcement Actions Related to Conduct of Clinical Research.** The Institution and the Principal Investigator certify that they are not the subject of any past or pending governmental or regulatory investigation, inquiry, warning, or enforcement action (collectively, "**Competent Authority Action**") related to

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DocuSigned by: DPR
Signer Name: Dr. Prashanth RM
DocuSigned by: SM
Signer Name: saumya mathew

its conduct of clinical research that has not been disclosed to Novartis. The Institution and the Principal Investigator will notify Novartis promptly if it receives notice of or becomes the subject of any Competent Authority Action regarding its compliance with ethical, scientific, or regulatory standards for the conduct of clinical research, if the Competent Authority Action relates to events or activities that occurred prior to or during the period in which the Trial was conducted.

23. CONFLICT OF INTEREST AND FINANCIAL DISCLOSURE

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

23.2 As the case may be, the Institution and the Principal Investigator shall ensure that the Principal Investigator and all Sub-Investigators involved in the Trial provide Novartis or its designee with the appropriate financial disclosures required by the U.S. Food and Drug Administration under 21 CFR Part 54, on such forms as Novartis or its designee may supply or approve. During the term of this Agreement and one (1) year following its expiration or earlier termination, the Institution and the Principal Investigator agree to assist the Sponsor or its designee in obtaining updated forms.

24. TRANSPARENCY/DISCLOSURE

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

(a) that Novartis has retained Principal Investigator for professional services in relation to the conduct of the Trial; and

(b) any other relationships that Novartis has with Principal Investigator which a reasonable and ethical person would expect to be disclosed.

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

24.3 It shall be assessed locally if the Provision 24.3 below is required and that it does not contradict with Local Regulations on Data Privacy. The provisions shall be adapted as needed to ensure consistency with Local Regulations on Data Privacy. This term is mandatory for clinical studies that have sites in China as they have to be registered in the "Drug Clinical Trial Registry", and this registration includes investigator's personal data. Please inform clinicaltrial.cn@novartis.com if this term could not be included due to Local Regulations on Data Privacy so that individual consent request could be administered.

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

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar
(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018

DocuSigned by: DEGS
DocuSigned by: DPR
DocuSigned by: SM

25. AUDITS AND INSPECTIONS

(a) Audit by Novartis and Records. The Institution shall grant access to its premises periodically as frequently as required for the proper performance and oversight of the Trial site in order to proceed with any and all monitoring activities required for the Trial. In addition, the Institution shall permit Novartis and its agents, during normal business hours and at mutually agreeable times, to inspect and make abstracts of records and reports collected and generated by the Institution and the Principal Investigator in the course of conducting the Trial and to inspect the facilities at which the Trial is conducted to verify compliance with this Agreement, the Protocol, Applicable Laws and the accuracy of information provided in connection with the Trial. The Institution shall ensure that the Principal Investigator and other relevant staff is available for Novartis and its agents during an audit in order to discuss such records and reports and to resolve any questions relating to such records and reports. At the request of Novartis or its agents, the Institution and the Principal Investigator shall immediately correct any errors or omissions in such records and reports.

(b) Cooperation during Audit by Novartis. The Institution shall cooperate, and shall cause the Principal Investigator and the staff to cooperate, with Novartis and its contractors and agents in the event of any internal audits, upon reasonable notice and during normal business hours. The Institution shall furthermore make available to Novartis and its contractors and agents (for examination and duplication) all documentation, data and information relating to the Trial. Trial Subject medical records will be made available where appropriate for the purpose of source document verification procedures as part of the audit. The Institution also shall make the Principal Investigator and staff available to Novartis and its contractors and agents to explain and discuss such documentation, data and information. For the avoidance of doubt audits shall be supported at no cost by the Principal Investigator and investigational staff.

(c) Inspection by Competent Authority. The Institution and the Principal Investigator acknowledge that the Trial is subject to inspections by regulatory agencies worldwide, and that such inspections may also occur after completion of the Trial. In the event the Institution or the Principal Investigator receives notice that the Institution shall be the subject of an investigation or audit by any competent authority or Ethics Committee, as applicable, in relation to the Trial, it shall notify Novartis immediately within twenty four (24) hours the latest and shall obtain approval for Novartis or its agents to be present at the inspection or otherwise keep Novartis timely and constantly informed of the progress. In the event the Institution or the Principal Investigator does not receive prior notice of said inspection, it shall notify Novartis as soon as practicable after receiving knowledge of said inspection. Institution shall provide Novartis with copies of any reports or information issued by the authority and Institution's proposed and final response. The Institution will promptly forward to Novartis copies of any inspection findings that the Institution receives from a competent authority or Ethics Committee, as applicable, in relation to the Trial. The Institution will provide Novartis with an opportunity to prospectively review any Institution responses to competent authority inspections in regard to the Trial.

(d) The Institution, the Principal Investigator and the staff shall cooperate with the relevant competent authorities or Ethics Committee, as applicable and comply with the legitimate requirements of an inspection. This also includes the making available (for examination and duplication) of documentation, data and information relating to the Trial. Subject medical records shall be made available where required for source document verification procedures as part of the inspection. The Institution also shall make the Principal Investigator and other staff available to the relevant competent authority to explain and discuss such documentation, data and information.

26. JURISDICTION AND APPLICABLE LAW

This Agreement shall be governed by and construed in accordance with the laws of India. The Parties hereby submit to the exclusive jurisdiction of Mumbai, India, without restricting any right of appeal.

27. PRECEDENCE

To the extent that there may be any inconsistency between this Agreement and the Protocol, the Protocol shall take precedence in relation with trial procedures.

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

DocuSigned by: DKGS
DocuSigned by: DPR
DocuSigned by: SM

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

NOVARTIS HEALTHCARE Pvt Ltd.

By: DocuSigned by: saumya mathew

Signer Name: saumya mathew
Signing Reason: I approve this document
Signing Time: 31-Aug-2021 | 06:34:08 GMT
CF4836A964FD4F6B9D61377852A11E5D

Name: Saumya Mathew

Title: Country Trial Operations Lead

Date: 31-Aug-2021 | 06:35:38 GMT

YENEPOYA MEDICAL COLLEGE HOSPITAL, YENEPOYA (DEEMED TO BE UNIVERSITY)

By: DocuSigned by: Dr. K.S Gangadhara Somayaji

Signer Name: Dr. K.S Gangadhara Somayaji
Signing Reason: I have reviewed this document
Signing Time: 28-Aug-2021 | 05:11:26 GMT
AF9CF0D5EDF347E6B706AB224BBE064B

Name: Dr. K.S Gangadhara Somayaji

Title: Registrar

Date: 28-Aug-2021 | 05:16:35 GMT

PRINCIPAL INVESTIGATOR

By: DocuSigned by: Dr. Prashanth RM

Signer Name: Dr. Prashanth RM
Signing Reason: I have reviewed this document
Signing Time: 26-Aug-2021 | 11:45:50 GMT
1A24E9D22CB4D4F9E998E28E3489E54

Name : Dr. Prashanth R.M.

Title: Principal Investigator

Date : 26-Aug-2021 | 11:47:54 GMT

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Annex1: Payment (and Equipment) Schedule

STUDY NUMBER: CTQJ230A12301

STUDY NAME: A RANDOMIZED DOUBLE-BLIND ,PLACEBO-CONTROLLED, MULTICENTER TRIAL ASSESSING THE IMPACT OF LIPOPROTEIN (A) LOWERING WITH TQJ230 ON MAJOR CARDIOVASCULAR EVENTS IN PATIENTS WITH ESTABLISHED CARDIOVASCULAR DISEASE

Investigator's Name: Dr. Prashanth R.M

Institute Name: Yenepoya Medical Collage Hospital, Constituent Collage of Yenepoya (Deemed to be University)

Payee Name: Yenepoya (Deemed to be University)

Pan Card Number: AAATY1645F

GSTIN: 29AAATY1645F1ZC

Committed Number of Study Subjects:15

List of Equipments provided to Institution / Principal Investigator:

Thermohygrometer: To be retrieved post DBL

1. Payment shall be made directly by Novartis
2. Payments to the Institution shall be subject to the following:

- "Evaluable" subjects shall be all subjects correctly entered into the Trial in accordance with the Protocol, i.e. those who satisfy all of the inclusion and exclusion criteria specified in the Protocol, commence the dosing regimen and complete the Trial.
- The final payment will not be due and payable until the entirely and duly completed Case Report Forms (CRFs) were sent to and have been accepted by Novartis and any potential queries have been resolved;
- Pharmacy dispensing costs are not included in the "per subject costs" and will be paid additionally upon receipt of a respective invoice along with supporting receipt.
- The amount of payment due to the Institution/Investigator will be calculated in respect of each patient visit according to the attached budget schedule.
- For patients who are not randomized into the study based on Screening results (Screen Failures) Institution/Investigator will receive remuneration in the amount of a screening visit cost
- Any other third parties designated by the Institution/Investigator that would receive remuneration, will be managed by & paid by the Institution/Investigator.
- The work performed by the hospital laboratory in addition to budget schedule shall be paid based on actuals. It is the Investigators responsibility to liaise with the hospital laboratory and provide invoice along with supporting receipt on a quarterly basis.

- The Ethics committee charge will also be paid via Novartis as per the EC SOP, and this cost is not included in the budget schedule.
- Unscheduled visits covers subject visits that are not expressly set forth in the Study Schematic of the Protocol but are otherwise required for the study. Medically necessary procedure, test performed during unscheduled visits would be paid as per actual bills. Payment for unscheduled visits will be payable to the institution within 60 days of receipt of original, itemized invoice by Novartis.
- All payments are based on actual patient visits.
- All values are in INR. All budget schedule payments are subject to TDS (subject to Government of India, Tax regulations) and GST as applicable. GST will be paid on providing valid tax invoice with relevant details mentioning GST registration number on it.
- Add provision of equipment terms E.g. leasing, Novartis own equipment lent or other ad hoc solution
- Sponsor shall provide INR 20,000 as Study start up fees.

ATTESTED
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Mangalore- 575 018, Karnataka

DocuSigned by: DKGS — Signer Name: Dr. K.S.G...
DocuSigned by: DPR — Signer Name: Dr. Prashanth RM
DocuSigned by: SM — Signer Name: saumya mathew

- Prior to site closeout, sponsor shall provide INR 1,25,000 for archival of study documents for 15 years. Archival fees is applicable only when Site has at least 1 randomized subject.
- Sponsor shall provide CRC fees of INR 10,000 per month from Site initiation visit to Site Closeout visit. This fee will not be applicable if Site is not able to randomize at least 2 Subjects before 31 December 2021
- Patient travel reimbursement of Rs.1500 per visit will be paid on submitting the related travel vouchers
- Appropriate Compensation for Serious Adverse Events will be paid to the Subjects or their nominees in compliance to the applicable laws and guidelines

The Institution shall be solely responsible for the payment of any and all taxes or other charges that are or may be levied. Unless expressly approved by Novartis prior to incurring the cost or expense, the Institution shall be responsible for all costs and expenses incurred by it in conducting the Trial. This includes, among other things, the payment of all investigational staff, including the Principal Investigator [and fees for the pharmacy and laboratory tests].

Study Budget:

Visit	Screening Visit	M -3 to -1	M -2 to -1	M -1 D-30	M -1 D-1 Treatment Optimization failure	Baseline	M 1	M 2	M3	M 4	M 5	M6	M 9	M12
Investigator Grant	15000	5000	5000	5000	5000	12000	7000	7000	9000	7000	7000	8000	7000	10000
Institutional Overhead (30%)	4500	1500	1500	1500	1500	3600	2100	2100	2700	2100	2100	2400	2100	3000
Total Per Patient Visit	19500	6500	6500	6500	6500	15600	9100	9100	11700	9100	9100	10400	9100	13000

Visit	M15	M18	M21	M24	M27 TC	M30	M33 TC	M36	M39 TC	M42	M45 TC	M48	Study Completion Visit	Follow- Up TC
Investigator Grant	7000	10000	7000	10000	4000	8000	4000	10000	4000	8000	4000	10000	12000	4000
Institutional Overhead (30%)	2100	3000	2100	3000	1200	2400	1200	3000	1200	2400	1200	3000	3600	1200
Total Per Patient Visit	9100	13000	9100	13000	5200	10400	5200	13000	5200	10400	5200	13000	15600	5200
Total Financial Break up for a completed patient								Rs 2,74,300/- per patient (For 28 patient visits)						

ATTESTED
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Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

DocuSigned by: DKGS
Signer Name: Dr K S Ga...

DocuSigned by: DPR
Signer Name: Dr. Prashanth PM

DocuSigned by: SM
Signer Name: saumya mathew

ANNEX 2: PRINCIPAL INVESTIGATOR – PERSONAL DATA DISCLOSURE FORM

1. You understand that Novartis may wish to process your personal data for administrative and commercial purposes for example in a database to be used for the organization of future clinical trials. You further understand and agree that your personal data may if necessary for these purposes, be transferred to third parties, including other companies related to Novartis in the form of a group and their advisors and third party service providers, as well as to regulatory authorities and tax authorities, as required by applicable law or relevant stock exchange rules.

You are not required to give your consent to the re-use of your personal data and your refusal may not impact the conduct of the current Trial, just further communications.

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

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

In that regard, Novartis is asking for your permission to submit your name, clinical trial site contact information, name of the clinical trial, sponsor, copy of the clinical trial agreement, and costs and fees relating to your site's retention, to a third party administrator of this database. This information will be maintained in that database for five years.

You are not required to give consent to this disclosure in order to proceed with this clinical trial. However, by doing so, you are helping to collect information on fair costs in clinical trials.

General terms of consent

I accept and agree that my personal data may be transferred to and processed in countries outside India, including the United States of America, where the level of data protection may be lower than in my country of origin. I have noted that Novartis will protect my data in this instance by entering into specific data transfer agreements, as established by the applicable privacy regulations contracts.

I am aware of my rights to access, ask for a free copy and/or request modification or deletion of my data as applicable by contacting Novartis's Data Protection Officer at [generic email address]. I also acknowledge my rights to lodge a complaint in front of the relevant Data Protection Authorities as needed.

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

Place and Date: 26-Aug-2021 | 11:47:54 GMT

DocuSigned by:
Dr. Prashanth RM
Signer Name: Dr. Prashanth RM
Signing Reason: I have reviewed this document
Signing Time: 26-Aug-2021 | 11:46:38 GMT
3A24EA222CEB4D4F9E998E28E3489E54

Name: Dr.Prashanth R.M

Principal Investigator

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

ANNEX 3

Applicable Anti-Corruption Legislation

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

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

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

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

(i) securing any improper advantage; or

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

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

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

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

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

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

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

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

(ii) transactions are recorded as necessary

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

(II) to maintain accountability for assets;

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

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

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

DocuSigned by: DKGS
Signer Name: Dr. K.S.Ga...

DocuSigned by: DPR
Signer Name: Dr. Prashanth PM

DocuSigned by: SM
Signer Name: saumya mathew

ANNEX 4:NOVARTIS PROFESSIONAL PRACTICES POLICY

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

[_____]

This privacy notice is addressed to:

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

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

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

Collection of Personal Data

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

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

Purposes and legal basis for processing your Personal Data

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

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DocuSigned by: DPR Signer Name: Dr. Prashanth PM
DocuSigned by: SM Signer Name: saumya mathew

	U.S.A. ("FDA") are identified and disclosed to the FDA1;	
6.	to ensure traceability and follow-up of drug safety notification.	compliance with legal and regulatory obligations.

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

Sharing of Personal Data

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

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

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

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

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

Duration of storage

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

What are your rights and how can you exercise them?

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

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

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

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
Mangalore- 575 018, Karnataka

DocuSigned by: DLGS
Signer Name: Dr. K S Ga...

DocuSigned by: DPR
Signer Name: Dr. Prashanth PM

DocuSigned by: SM
Signer Name: saumya mathew

Novartis Global Policy

Professional Practices Policy (P3)

Novartis Global Policy

March 1st, 2018

Version GIC 102.V1.EN

NOVARTIS

Contents

1 Introduction

Purpose

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

Scope and applicability

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

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

This Policy is effective as of March 1, 2018 and must be implemented by all Novartis affiliates. It replaces the existing versions of the divisional Professional Practices Policies.

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

2 Principles

Put patients first

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

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

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

Fund responsibly

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

The same rules apply for external in kind support.

Act with clear intent

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

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

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

Engage appropriately

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

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

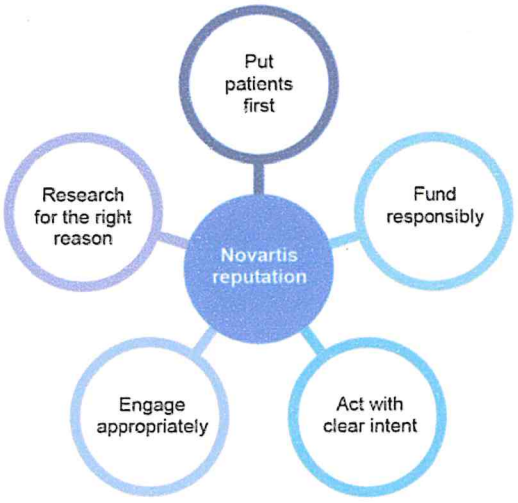
Allowable items of value, when provided to customers, must be modest, reasonable, infrequent, free from actual and perceived conflicts of interest, and disclosed where required.

Research for the right reason

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

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

Research and development activities must never be promotional in nature.



3 Policy

3.1 Clinical Research

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

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

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

3.2 Pricing and Market Access

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

3.3 Pre-Approval Communication and Scientific Exchange

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

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

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

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

3.4 Promotional Interactions

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

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

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

3.5 Promotional Content

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

3.6 Items of Medical Utility and Cultural Acknowledgements

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

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

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

3.7 Samples, Demonstration and Evaluation Devices

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

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

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

3.8 Events

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

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

Common types of events organized or funded by Novartis are:

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

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

3.9 Venue, Travel, and Hospitality

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

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

3.10 Fees for Service

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

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

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

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

3.11 Interactions with Patients and Patient Organizations

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

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

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

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

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

3.12 External Funding

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

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

4 Definitions

Adverse Event

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

Customer

Defined broadly as:

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

Caregiver

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

Disease Awareness Programs

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

Over the Counter (OTC) Product

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

Cultural Acknowledgements

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

Donation

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

Event

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

Gifts

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

Grant

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

Healthcare Organizations (HCOs)

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

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

Healthcare Professional (HCP)

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

Items of Medical Utility

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

Medical Services

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

Patient

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

Patient Organization

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

Patient Support Program

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

Pharmaceutical Samples

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

Promotional Aid

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

Public Official

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

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

Research and development activities

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

Scientific Exchange

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

Sponsorship

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

5 References

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

6 Implementation

Training

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

Third parties

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

Breach of this policy

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

Reporting potential misconduct/non-retaliation

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

Exceptions

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

Responsibilities

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

5,80,440 per patient (10 patients) - 58,04,400; Archival - 1,50,000; Approximate grant total = 59,54,400

CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (the "Agreement") is entered into as of this day of 14 oct 2021 (the "Effective Date"), by **AXIS Clinicals Ltd having registered office situated at 1-121/1, Miyapur, Hyderabad 500049**, [hereinafter referred as **"AXIS"**] acting as an independent contractor for **CURATEQ BIOLOGICS PRIVATE LIMITED. ("CuraTeQ")** located at **PLOT NO.2, MAITRIVIHAR, AMEERPET, HYDERABAD, Telangana, India, 500038**.[Hereinafter referred as **"Sponsor"**], represented in India by M/s Aurobindo Biologics(A Division of Aurobindo Pharma. Ltd.) Sanga Reddy Districts, Hyderabad, India [Hereinafter referred as **"Sponsor"**].

And

Dr. Jalaluddin Akbar [hereinafter referred to as **"*Principal Investigator*"**] employee/ affiliate of **Yenepoya Medical College Hospital [hereinafter referred to as "Institution or Site"] located at, University Road, Deralakatte, Mangalore-575018, Karnataka [Hereinafter referred as investigator]**

And

Yenepoya (Deemed to be University) Whose Principal place of business is, **University Road, Deralakatte, Mangalore, [Hereinafter referred as Institution")**

And

Samahitha Research Solutions Whose Principal place of business is, **Second floor, Old No.1204, New No.04, PID No. 64-120-04, 26th Main Road, 9th Block, Jayanagar, Bengaluru, Karnataka-560069 [Hereinafter referred as SMO]**

(Both Principal Investigator and SMO, Site of conducting the Clinical Research Study, hereinafter referred to as the **"Site"** which expression, unless repugnant to the subject or context therein, shall mean and include its authorized representative(s), administrators, executors, assigns & successors-in-interest).

WHEREAS, the Site has personnel and facilities for carrying out the study entitled "A Multicenter, Randomized, Double blind, Parallel, Phase III Global Study to Assess the Efficacy and Safety of BP01 (Bevacizumab) when compared to Avastin®-EU in Combination with Carboplatin and Paclitaxel during Induction phase and Bevacizumab alone during the Maintenance phase in patients with newly diagnosed or recurrent Stage IIIB/IV Non-Squamous (ns) Non-Small Cell Lung Cancer (NSCLC).

WHEREAS **Sponsor** is desirous of engaging the said Site for carrying out the Study titled "**AXIS CLINICALS LTD – Non-Squamous (ns) Non-Small Cell Lung Cancer (NSCLC)**" on behalf of and as authorized representative and agent of **CURATEQ BIOLOGICS PRIVATE LIMITED**

ATTESTED
Dr.Gangadhara Shivayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

NOW, THEREFORE, in consideration of the premises and the covenants and agreements of the parties as hereinafter set forth, the parties have agreed and do hereby agree with each other to the following:

DEFINITIONS

"Study" means the clinical study of the test for the SPONSOR conducted through and under control of AXIS and conducted at Site as specifically identified in this Agreement.

"SPONSOR'S Confidential Information" means all information (including, without limitation, study protocols, 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 Sites in connection with this Agreement or the Study; (2) Study data, results, or reports created by Institution, Investigation, or Study Staff in connection with the Study (except for a Study patient's medical records); and (3) cumulative Study data, results, and reports generated from all sites conducting the Study.

"Investigator/s" means the individual(s) responsible for the conduct of the Study at Site and for direct supervision of Study Staff.

"Study Staff" mean the individuals providing services on behalf of Site with respect to the Study at Site, including without limitation sub-investigator, study coordinator, and other Site employees, agents, or subcontractor.

"Invention" means any discovery, development, invention (whether patentable or not), improvement, work of authorship, formula, process, composition of matter, formulation, method of use or delivery, specification, computer program or model and related documentation, know-how or trade secret, that is made by Institution, Investigator, or Study Staff: (1) in connection with the Study; or (2) which incorporate **SPONSOR** Confidential Information.

"Study Timelines" means the Enrollment date, End Date, the Visits Completed Date and the eCRF Target Date set out in Section 1 of this Agreement.

"Study Supplies" means Study drug(s) and related devices, equipment (if required), or other trial supplies provided by AXIS/-Sponsor for the conduct of the Study.

"Protocol" means the written document that describes the Study and sets forth specific activities to be performed as part of Study conduct.

"eCRF or Electronic Case Report Form" means a printed, optical, or electronic document designed to record all of the protocol required information to be documented and reported on each patient.

"**Test/Investigation study**" means (A Multicenter, Randomized, Double blind, Parallel, Phase III Global Study to Assess the Efficacy and Safety of BP01 (Bevacizumab) when compared to Avastin®-EU in Combination with Carboplatin and Paclitaxel during Induction phase and Bevacizumab alone during the Maintenance phase in patients with newly diagnosed or recurrent Stage IIIB/IV Non-Squamous (ns) Non-Small Cell Lung Cancer (NSCLC).) -

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575018, Karnataka

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"Data" shall mean all information, reports, records, and document provided and/or generated under this agreement excluding patient hospital medical records (case sheets). Data shall be the sole and exclusive property of **Sponsor.**

1. STATEMENT OF WORK

The Site has study staff, other personnel and facilities for carrying out the Study in strict compliance with any and all applicable Central, State, and Local laws, Regulations and Guidelines, Good Clinical Practices, all requirements of the host institution or facility, and any other relevant professional standards, and specifically to conduct the Study in accordance with the 'Undertaking by the Investigator' and Protocol, which Principal Investigator has read, gone through in detail, discussed with AXIS signed, and delivered to AXIS prior to the commencement of the Study at the Site.

The Principal Investigator shall use his or her best efforts to recruit only qualified participants as per Inclusion and Exclusion criteria and shall not knowingly enroll any participants, which in his or her best professional judgment do not adequately meet the criteria for qualified participants.
The following plan will apply to the Study:

(1) Site acknowledges that Site's minimum enrollment goal is **10 patients** with **Non-Squamous Non-Small Cell Lung Cancer**. The timeline is **12 months** from the date of Site Initiation. Site will use its best efforts to reach the enrollment goal. If Site fails to adhere to such enrollment goal and failed to start enrollment within 30 days of Site Initiation, AXIS may reconsider Site's suitability to continue participation in the Study or may change its enrolment goal or do the pre-closure of the site.
(2) Institution or Investigator (Site) may enroll more study patients than Institution's allotted Enrollment number, after mutual agreement between both the parties and having a written communication from AXIS regarding the increase of more study patient/s.
(3) Investigator is responsible for obtaining from all subjects informed consents prior to screening for, or participation in the Study. All informed consents must be in the form approved by AXIS and Sponsor, comply with the requirements of all Applicable Laws, and have been reviewed and approved by applicable regulatory authorities and Institutional Review Boards ("IRBs") or Independent Ethics Committees ("IECs").
(4) Source Documents, electronic Case Report Forms ("e-CRFs") and other information associated with a patient's visit must be satisfactorily completed after the patient's visit or, if applicable, receipt of the patient's test results.
(5) Investigator and Site will be extending full cooperation for Remote Monitoring and will provide full assistance as per the provided manual.
(6) Investigator will provide the name of any SMO who has been contracted for the site activities.
(7) Investigator will provide the contract between the site and SMO to AXIS for reference after masking the confidential details.
(8) Investigator should provide the name of one dedicated and one back up CRC or Study Personnel/s for the study during site initiation.
(9) Investigator/Institution (Site) is totally responsible for the activities as mentioned in the CTA. It will be the investigator responsibility to monitor the work of any SMO/CRC/ Study Personnel/s appointed for the conduct of the study.
(10) All data Queries from SPONSOR/AXIS must be clarified completed and responded to AXIS/SPONSOR within a time frame acceptable with AXIS/sponsor.
(11) Any intentional changes of inclusion/exclusion criteria by the Principal Investigator or study team will not be the liability of AXIS.
(12) Investigator or Institute (Site) agrees to cooperate with the representatives of CRO and Sponsor who visits the Study Site. Site also agrees to ensure that Site Personnel does not harass, or otherwise creates a hostile working environment for such representative.
(13) Investigator may not be removed or replaced without prior written confirmation of AXIS and Sponsor. If Investigator is unable or unwilling to continue the Study or terminates employment relationship with Institution, Institution shall immediately notify AXIS and

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Sponsor in writing, and shall use all reasonable efforts to find a suitable replacement investigator acceptable to Sponsor and this Agreement will be amended accordingly. If Institution is unable to replace Investigator to Sponsor 's reasonable satisfaction promptly, AXIS/Sponsor shall have the right to terminate this Agreement/site.

(14) Site personnel/s who has ever been debarred, disqualified or banned from conducting clinical trials or is under investigation by any regulatory authority for debarment, disqualification, or any other similar regulatory action in any country will not be the part of the study. Site shall notify AXIS immediately if any such investigation, disqualification, debarment, or ban comes to the attention of Site during the Study.

AXIS/ SPONSOR will provide Principal Investigator with a sufficient quantity of study supplies to conduct the study at investigational site as per the study requirement in timely manner. Site shall use study supplies only to conduct the Study in accordance with the Protocol; shall not chemically, physically or otherwise modify Supplies; and shall handle, store, and ship or dispose of Supplies in compliance with all applicable Local, State and Federal laws, rules and regulations including, but not limited to, those governing hazardous substances. Institution and Investigator will not charge any payment to Study patient or third-party to pay for any Supplies, or for Study procedures for which payment by AXIS has or will be made under this Agreement. All study supplies such as Study drug(s) and related devices, equipment, or other trial supplies remain the sole property of SPONSOR/AXIS, unless otherwise designated. The Institution and Principal Investigator will be responsible for the return of excess, unused study supplies to the SPONSOR/ AXIS.

2. PAYMENT

In consideration for conducting the Study, AXIS shall pay Site as described in Exhibit A & B. The parties agree that these payment terms are consistent with the principles of fair market value payments for the performance of Study-related activities. All of AXIS's payment obligations are conditioned upon Site's compliance with standards identified in this Agreement. AXIS will not make payments, or, if payment has been made by AXIS, Site will repay to AXIS any payments, for study visits, procedures, or other work associated with a Study patient if AXIS determines that the patient's data is not evaluable because of a violation of the Protocol by Investigator or Study Staff.

Payment will be released within 30 days from the date of receipt of two copies of original invoices duly signed by the authorized and printed on letter head of the Institution with seal/stamp as per format provided by Axis Clinicals Ltd. Any Invoice format is used by the site/s also will be accepted if it is as per the present GST/ Government norms and acceptable to AXIS Finance department.

"If any pandemic situation arises again and government declares the partial/complete lockdown or curfew in Hyderabad, in that case payment will be delayed depending on the condition. If any lockdown/curfew condition arises at the site level, scan copies of invoices are allowed to be shared by the site team, but original copies need to be retained at the site level and should be either couriered or handed over once situation is back to normal. During the lockdown condition, sites which are unable to complete study related activities will not be paid irrespective of the point mentioned in the Annexures of the present CTA. The patient/s will be paid on Pro-rata basis. During the lockdown, if Principal Investigator and Medical Manager of AXIS, both jointly agree on opting for any specialized / emergency required activities like any diagnostic tests which is nearest to the patient's residence or handover of the study drug at patient's residence or any activities required for the safety of the patient/s, it will be paid as reimbursement after the submission of the proper invoice/s as per the guidelines."

ATTESTED
Dhanagadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

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Investigator and Institution "Site" agrees that their judgment with respect to the advice and care of each subject will not be affected by the payment they receive from this Agreement, that such

payment 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 Sponsor or AXIS provides any compassionate medication for use in the Study, Site agrees that they will not bill any subject, insurer or governmental agency, or any other third party, for such free products or items or for any visits, services or expenses incurred during the Study for which it has received payment from AXIS or Sponsor, or which are not part of the ordinary care they would normally provide for the subject.

AXIS shall pay on per patient basis and per visit completion for each Satisfactorily Completed Patient (as defined below) in accordance with Exhibit A and Exhibit B

"Satisfactorily Completed patient" shall be one in which a patient is a Qualified Participant (as per inclusion/exclusion criteria), has completed the specified Study period, and has been evaluated in accordance with the protocol. If a Patient is discontinued for reasons stipulated in the protocol, the Site shall be paid a prorated rate for extent of participation as per actual completed visits according to the applicable value mentioned in the Exhibit A for Induction part of the study and Exhibit- B for the maintenance part of the study.

Per Patient Costs: Payments will be made on a per visit/day basis for visits/days completed, in accordance with Exhibit A for Induction part of the study and Exhibit- B for the maintenance part of the study.
Screening visit cost will be paid prorated for consented patients for whom all/part screening procedures are performed.

A completed and evaluable patient defined as:

- All procedures must be performed and bound to be completed according to protocol.
- A patient has been included according to inclusion and exclusion criteria.
- All data documented accurately and completely.
- All data queries are resolved.
- All source, eCRF and other study related documents completed as per Good Documentation Practices / AXIS standard requirements. No document will be considered acceptable if AXIS requirements are not complied with for completed and evaluable patient.

The per patient costs 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 visit assessment and eCRF completion.
- Time and efforts of Principal Investigator/s and other Site personnel
- All manpower cost who are involved in the study conduct.
- Housing or hospital stay for patients including meals.
- Patient reimbursement/ Compensation
- All overhead costs of Institutions.
- Usage of Instruments/ equipment's which during the study should be having for proper instrument ID, maintenance and calibration certificate/ Annual Maintenance Contract
- Miscellaneous (telephone, fax, courier, storage cupboards and maintenance of Site infrastructure)

Screen Failures/ Dropouts: Screen failure rate should be minimized as mutually agreement between Sites and AXIS for Screen failures payments will be reimbursed for only completed investigations and Study Procedures as mentioned in Exhibit A & Exhibit B and for Dropouts payment will be made on a prorated basis for the number of completed visits.

ATTESTED
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Additional Testing, Treatment or Procedures: Reimbursement will not be made for any additional testing, treatment, or procedures not required by the Protocol, unless such additional testing, treatment or procedures are pre-approved by AXIS/ Sponsor in writing.

Patient Travel Reimbursement/Compensation: Subject Travel reimbursement will be done as per the details mentioned in Exhibit A. AXIS will release the funds to Site for each subject, i.e. for induction phase **INR 12000/- (Twelve Thousand Rupees Only)** and for maintenance phase **INR 19500/- (Nineteen Thousand Five Hundred Rupees Only).** However, it will be the obligation of Site to pay the subject reimbursement on pro rata basis as defined in Exhibit/s. A receipt will be provided by the Institution for amount paid to subject in a specified format supplied by AXIS/Sponsor on the letterhead of the Institution or as per the institutional practice.

Travel reimbursement will be paid for unscheduled visits if the unscheduled visit is related to any repeated sample collection as per protocol requirement or any safety follow up as per the principal investigator opinion.

Note: If Site is not providing original receipt of the Subject reimbursement / Compensation, as per government norms TDS will deducted from the invoice.

Management of Serious Adverse Event/s: In the event of any Serious Adverse Event (SAE) that will occur in the course of the study, same will be analyzed by Site and AXIS and the expenditure incurred by the Site for Medical Management will be reimbursed as per actuals after approval from the concerned Medical Manager of AXIS

EC Fees: EC fees will be reimbursed as per EC SOP.

Payee name	Yenepoya Research Centre
Account Number	84690100002628
Bank Name	Bank of Baroda
Branch Name	Yenepoya University Branch
Swift/IFSC Code	BARB0VJDEYU (5th letter zero)
PAN Number	AAATY1645F
GST No	29AAATY1645F1ZC

EC should provide a copy of PAN Card and Cancelled cheque for the mentioned account number.

Site Payments shall be directed as follows:

Payee Name (Account name)	Yenepoya Research Centre
Account Number	84690100002628
Bank Name	Bank of Baroda
Branch Name	Yenepoya University Branch
Swift/IFSC Code	BARB0VJDEYU (5th letter zero)
PAN Number*	AAATY1645F
GST No	29AAATY1645F1ZC

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* Payee/s should provide a copy of PAN Card and Cancelled cheque.

GST will be paid @ 18 % and the TDS will be deducted on actual wherever applicable.

Any ancillary supportive treatment for safety of patient as agreed upon by AXIS/Sponsor.
In case of Govt. of India will implement any other Tax regimen, the same will be implemented in due course of time with amendment/ Addendum of CTA.

Site/s will raise the invoice every three months interval in the prescribed/accepted format from the start of the patient enrollment, prorate activity/s completed as per the protocol and as per the criteria mentioned in Exhibit/s

In the event there is a refund due to AXIS at the time of premature termination by either party, the Site agrees to remit the same to AXIS within fifteen (15) days of the date of effective termination.

Last 3 patients' payment will be on hold till the site close out visit and will be released after successful completion of the documentation, all instruments provided to site for the study have been returned and other regulatory activities completed.

Tax deduction: All fees and amounts except patient reimbursement and otherwise specifically listed are inclusive of applicable tax (TDS- Tax Deduction at Source). Prevailing TDS rate will be deducted from each payment disbursed to the Site for the study as per the applicable existing tax laws in the country. Certificate for the tax deducted at source will be provided at the end of the financial year.

3. ETHICS COMMITTEE APPROVAL

The Principal investigator shall be responsible for obtaining approval of the protocol, related study documents and study conduct at the Site before initiation of the study.

Site also represents and warrants that EC registration and re-registration with Central Drug Standard Control Organization (CDSCO) and they have obtained and will maintain the required authorization from the Ethics Committee and any other required forms fully complying with the applicable regulations.

4. PROPRIETARY INFORMATION AND CONFIDENTIALITY

Sponsor shall have sole ownership of intellectual property developed in the Study by Investigators supported through Study funds. The Site shall disclose to AXIS/SPONSOR all inventions and other creative ideas and developments conceived or reduced to practice as a direct result of this Study. Such disclosure shall be made fully and promptly in writing to AXIS. All documents, data, know-how, formulas ("Data"), and unused drug provided to the Site for purposes of the Study are and will remain Sponsor's property and will be returned to Sponsor or their designate upon request.

SPONSOR/AXIS Confidential Information and all tangible expressions, in any media, of SPONSOR/AXIS Confidential Information are the sole property of SPONSOR/AXIS.

Institution agrees not to use SPONSOR/AXIS Confidential Information for any purposes other than to conduct the Study. Institution agrees not to disclose SPONSOR/AXIS Confidential Information to third parties except as necessary to conduct the Study and under an agreement by the third party to be bound by the obligations of this Section. Institution shall safeguard SPONSOR/AXIS Confidential Information with the same standard of care that is used with Institution's Confidential Information, but in no event less than reasonable care.

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The obligation of non-disclosure and non-use shall not apply to the following.

(1) Information, which at the time of disclosure hereunder, is generally available to the public;
(2) Information, which after disclosure hereunder, becomes generally available to the public, except through breach of this Agreement;
(3) Information that the Institution can demonstrate was in its possession at the time of disclosure by Sponsor and that was not acquired, directly or indirectly, from Sponsor;
(4) Information that becomes available to the Institution from a third party that is not legally prohibited from disclosing such information, provided such information was not acquired directly or indirectly from Sponsor; or
(5) Information that is required by law to be disclosed to representatives of a Governmental Agency and to which they are entitled when engaged in the proper performance of their duties.

The Investigator agrees to keep all aspects of the trial confidential. This includes the nature of the trial, the protocol and its attached forms as well as data generated by the trial.

The obligations of this Section shall survive till the termination of this Agreement.

5. HANDLING INVESTIGATIONAL PRODUCTS

The Investigator agrees to exercise adequate care in the application and handling of Investigational products.

Site shall use the drug, device, product or compound being tested (the "investigational Product"), and any comparator products provided in connection with the Study solely for the purpose of properly completing the Study according to the Protocol, the Agreement, and Applicable Laws. Site shall take reasonable measures to protect the investigational Product and any comparator products from loss or damage, including storing them in a locked, always secured area according to the Protocol, IMP manual/s and Applicable Laws. Site acknowledges that the investigational Product and any drugs and comparator products always remain exclusive properties of Sponsor. Upon completion or termination of the Study or at such times as Sponsor or AXIS may direct, Site shall return all unused investigational Product, compassionate medications, and any other equipment, and materials provided by SPONSOR or AXIS, in accordance with the instructions provided by SPONSOR or AXIS.

6. SERIOUS ADVERSE EVENT REPORTING

The Principal Investigator shall fully comply with adverse event assessment and reporting criteria as per the provisions of the Protocol. In the event of any omission of such provisions or in the event of the conflict of such provisions with the Regulations, then the Regulations shall apply in relation thereto.

The Principal Investigator shall also notify the IEC/Central licensing authority/Sponsor immediately of any Serious Adverse Events during the Study in accordance with the current existing regulations.

In the event of SAE injury, patients will be provided free Medical management if required by **CURATEQ BIOLOGICS PRIVATE LIMITED** and will provide complete medical care and financial compensation for injury and death as per current applicable regulatory requirements.

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7. USE OF OTHER PARTIES' NAMES

The Site shall not use SPONSOR's or AXIS's name or the name of any party hereto in connection with any advertising or promotion of any product or service without the prior written permission from Sponsor/ AXIS.

8. INDEPENDENT CONTRACTORS

Site shall perform services under this Agreement only as an independent contractor, and nothing contained herein shall be construed to be inconsistent with that relationship or status. This Agreement shall not constitute, create, or in any way be interpreted as, a joint venture, partnership, or business organization of any kind.

9. INSURANCE

Institution shall maintain medical professional liability insurance with limits in accordance with local standards for each medical professional involved in the Study or require that each medical professional maintain such insurance. Upon AXIS's request, Institution shall have its insurance carrier (or shall cause the medical professional to have his or her insurance carrier) furnish the certificate to AXIS that all insurance required under this Agreement is in force.

10. MONITORING; AUDIT; REGULATORY INSPECTIONS

The Site shall permit authorized personnel of the SPONSOR/ SPONSOR designee, AXIS and any Regulatory Authority including Ethics Committee to inspect the facilities the Site proposes to use for the Study; before, during and after the Study. There will be AXIS and sponsor audits during the study apart from the monitoring visit as per the mutually agreed dates.

The Site shall notify AXIS or Sponsor immediately by telephone or facsimile if the Drugs Controller General-India, or any other governmental or regulatory authority requests permission to or does inspect the Site's facilities or research records relating to this Study whenever and will provide in writing to AXIS copies of all materials, correspondence, statements, forms and records which the Site receives, obtains, or generates pursuant to any such inspection.

The Site will permit to Sponsor/Axis/EMEA/DCGI other regulatory authorities

a) Examine, inspect and audit the work performed here under and the facilities, systems and equipment at or with which the work is conducted.
b) Inspect and copy all data, documents and records related to such work and the study

The obligations of this Section shall survive termination of this Agreement.

Sponsor/Third-party Monitoring visits:

1. Sponsor will do the monitoring visit/s as per mutual agreement between the sites and AXIS and Sponsor.
   Monitoring visits: Monitoring visits will be carried out as per monitoring plan submitted to sites. In case of any eventuality Sponsor will do extra monitoring visit/s as per the situation requires.

2. **Axis QA Audit Visits:**

- Axis QA will do first visit – 1 SIV one day visits along with AXIS CRA.
- There will be 4 or 5visits will be there per year based on the number of patients enrolled in the respective site/s

ATTESTED
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Mangalore- 575 018, Karnataka

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11. TERM; WAIVER; SEVERABILITY

Unless earlier terminated in accordance with the provisions of this Agreement, the term of this agreement shall commence on the Effective Date and shall terminate 48 months after the Effective Date.

This Agreement will become effective upon the date it is fully executed by all parties and shall continue in effect for the full duration of the Study according to the Protocol unless sooner terminated in accordance with the provisions of this Agreement.

This Agreement may be terminated by either party upon giving at least a thirty (30) days' notice to that effect to the other party. A reasonable adjustment will be made between the parties to ensure the Site is reimbursed for project costs incurred to the date of termination of this Agreement. Any funds paid by AXIS to the Institution in excess of project costs will be returned to the AXIS.

AXIS or SPONSOR may terminate this Agreement, in whole or in part, with or without cause, immediately upon written notice to Institution. Notice by either AXIS or SPONSOR that the Study is terminated shall also constitute effective notice of termination of this Agreement.

12. EFFECT OF TERMINATION

(1) Upon notice of termination of this Agreement by either Institution or SPONSOR or AXIS, Institution shall cease enrolling patients into the Study, and shall discontinue conduct of the Study as soon as is medically practicable.

(2) Upon notice of termination of this Agreement by either Institution or SPONSOR or AXIS, Institution shall use reasonable efforts to revoke any financial obligations incurred and shall avoid incurring any additional costs in connection with the Study. Institution shall be compensated only for Study-related work performed or reimbursed only for expenses actually and reasonably incurred through the effective date of termination which AXIS has agreed to pay as part of the Study under this Agreement. If, upon the effective date of termination, AXIS has advanced funds which are unearned by Institution, Institution shall repay such funds within sixty (60) days of the effective date of termination. In the event Institution fails to repay such funds in a timely manner, AXIS may deduct/adjust an equivalent amount from any payment then or later due from AXIS to Institution under this or any other arrangement between the parties.

(3) Upon termination of this Agreement, all unused Materials and all SPONSOR Confidential Information (except for such records that Institution is required by law or regulation to retain) in Institution's possession shall be promptly delivered to SPONSOR at SPONSOR's expense, or, at SPONSOR's option, destroyed with the destruction must be certified in writing.

13. AMENDMENT

This agreement and protocol may only be extended, renewed or otherwise amended by the mutual written consent of the parties hereto. The parties agree that this agreement constitutes the sole, full and complete agreement by and between the parties and supersedes all other written and oral agreements and representation between the parties with respective to the Study. No amendments, changes, additions, deletions, or modifications to or of this agreement shall be valid unless reduced to writing and signed by the parties.

All changes and amendments to this agreement shall be agreed in writing between the parties.

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14. RECORDKEEPING/ DOCUMENT ARCHIVAL/ AND INVESTIGATIONAL PRODUCT RETENTION/BIOLOGICAL SAMPLES

Investigational Product/s will be retained either at Site or Third-party archival facility after having a mutually agreed decision with Sponsor, AXIS and Sites. The Investigational product will be re-

packed and sealed as per the requirements and retained at the site / Third party facility. In case if the IPs are retaining at third party facility, Site and Third party will have one agreement for the transfer of IP as per the required conditions. The payments towards the maintenance of retained samples at third party facility will be paid by AXIS on the receipt of Invoice from Third party. The Archival Charges for retaining the samples at the sites if any will be mentioned in the CTA and will be paid in due course of time. In case of retrieval requirement for the regulatory authority requirements, site will inform first to AXIS by mail requesting for the retrieval of IP, after obtaining the response from AXIS site will inform the Third-party facility about the retrieval as per the procedure. Any charges related to retrieval of the IPs/ documents AXIS will reimburse the same to the Third-party facility against proper Invoice. Under no other circumstance's sites will not be having any authority related to retrieval of retained IP/documents at any time.

Institution or investigator shall retain all records and documents pertaining to the trial and ensure the storage of data related to study in accordance with the requirements of current Good Clinical Practices, in suitable and secured storage facilities and under appropriate conditions, for a period of time required under the applicable laws and regulations in INDIA or until at least 5 years after completion of all regular activity, whichever period is longer, unless to the extent that AXIS/ SPONSOR require the return or destruction of this data, in which case this request shall be complied with to the extent allowed by applicable laws and regulations. Before the destruction or deletion of such data, sponsor/Axis written approval shall be obtained. Institution and Investigator will not use biological sample collected under the protocol in any manner or for any purpose other than that described in the protocol agreement.

15. ARCHIVAL FEE:

The Archival fee is onetime, non-refundable payment of **1,50,000/-**INR.

a) Payment shall be used for archiving and storage of Study files by Site for a period of Fifteen (15) years.
b) In accordance with Sponsor's Protocol requirements, Institution shall maintain all Study records in a safe and secure location to allow easy and timely retrieval, when needed.
c) Payment shall be used for archiving and storage of Study files by Institution for a period of fifteen years,
d) Payment shall be made upon completion and receipt by AXIS of all original contractual and regulatory documentation, and receipt by CRO of original invoice.

16. LIST OF STUDY INSTRUMENTS

The Investigator / Site agrees to exercise adequate care in handling of study instruments (Listed below if any) provided by AXIS/Sponsor. The Investigator / Site agrees to utilize study instruments solely in accordance with the protocol and to return to Axis/ Sponsor at the time of study Completion.

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Mangalore- 575 018, Karnataka

- **Data Loggers-01**
- **Thermohygrometer-03**

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The last payment will be released against the receipt of the above-mentioned Instruments along with the other terms and conditions mentioned in the CTA. In case any instruments have been broken

due to mishandling / negligence will be repaired or will be purchased new and the same amount will be deducted from the last payments until and unless a mutual agreement between Axis and institution.

17. DISCLAIMER

The Site acknowledges that the Sponsor has engaged AXIS to manage the Study. AXIS has performed no independent research or analysis regarding the safety or efficacy of the Investigational Product, materials or treatment procedures that are to be administered pursuant to the Study and therefore AXIS makes no warranties, expressed or implied concerning the Investigational Product, materials, treatment procedures; results to be obtained in administering the Investigational Product, or the Investigational Product's fitness for any particular purpose.

18. PUBLICATION

The parties acknowledge that the Sponsor shall retain ownership of all original Data that result from this Study. Data generated during the clinical study is the sole property of the sponsor. Therefore, Principal investigator agrees not to publish or present the results, or any information derived from the study.

19. GOVERNING LAW AND DISPUTE RESOLUTION

This Agreement shall be governed by and interpreted in accordance with the laws of India, without conflict of laws or principles. Any dispute between the Parties as to construction, meaning or effect of the Agreement or any clause contained therein or the rights, duties, liabilities and obligations of either Party there under, shall be resolved mutually within thirty days, failing which, shall be referred to arbitration before a sole arbitrator appointed by the Parties. The arbitration proceedings shall be conducted in accordance with the Arbitration and Conciliation Act, 1996 and rules made thereof in Hyderabad. The arbitration proceedings shall be conducted in the English language. The arbitrators' decision shall be final and legally binding and judgment may be entered thereon before the courts of competent jurisdiction. The arbitrator shall also decide on the costs of the arbitration proceedings.

Subhra.L

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DN: cn=Subhra.L, o=AXIS Clinicals Ltd, c=IN
Date: 2021.09.29 15:21:13 +05'30'

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

IN TESTIMONY WHEREOF, the parties hereto have caused this instrument to be executed, in duplicate, by their officers, thereunto duly authorized to sign on behalf of the party.

1. **Principal Investigator** :

   Signature & date And Stamp : 11/10/2021

   Dr. Jalaluddin Akbar K.C.
   Reg. No. 36449
   Professor & HOD, Dept. of Oncology
   Yenepoya Medical College Hospital

   Represented by (Name) : **Dr. Jalaluddin Akbar**

   Title :

2. **Instituion** : **Yenepoya(Deemed to be University)**

   Signature & date And Stamp : 13/10/2021

   Registrar
   YENEPOYA
   (Deemed to be University)

   Represented by (Name) : **Dr.K.S.Gangadhara Somayaji**

   Title : **Registrar**

   Witness

   Signature & date and Stamp : 13/10/2021

   Represented by (Name) : Vanamala Kulal

   Title : Clinical Research Site Coordinator

   Clinical Research Centre
   Yenepoya Medical College Hospital
   Constituent College of Yenepoya Deemed to be University
   Ground Floor, EMD Building
   University Road, Deralakatte
   Mangalore-575018

3. **SMO Name** : **Samahitha Research Solutions**

   Signature & date and Stamp : 14/10/2021

   Mr. Srivatsa G.S
   Managing Director
   SAMAHITHA RESEARCH SOLUTIONS
   PID No. 64-121-04, Second Floor,
   26th Main Road, Jayanagar 9th Block,
   Bengaluru, Karnataka-560 069.

   Represented by (Name) :

   Title

   Witness

   Signature & date and Stamp : 14/10/2021

   Represented by (Name) : Disha Shetty

   Title : Project Manager

   Samahitha® Research Solutions ISO 9001:2015 Certified

   ATTESTED

   Dr.Gangadhara Somayaji K.S.
   Registrar
   Yenepoya(Deemed to be University)
   University Road, Deralakatte
   Mangalore- 575 018, Karnataka

   14/10/2021
   Dr. Prakash R.M. Saldanha
   Medical Superintendent
   Yenepoya Medical College Hospital

4. AXIS Clinicals Ltd

Signature & date And stamp : Subhra Lahiri 29/09/21

AXIS CLINICALS LIMITED HYD.

Represented by (Name) : Dr. Subhra Lahiri

Title : Vice President & HOD (Clinical Research)

Witness

Signature & date And stamp : 29/09/21

AXIS CLINICALS LIMITED HYD.

Represented by (Name) : Mr. K. Nageswara Rao

Title : Clinical Research Associate

ATTESTED

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Registrar
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Mangalore- 575 018, Karnataka

EXHIBIT A- Non-Squamous Non-Small Cell Lung Cancer - Induction Phase

It is agreed that the Site will receive INR 2,49,540/- (**Two lakh forty nine thousand five hundred forty rupees only**) per completed patient in Induction phase according to the schedule indicated below. Completed Subjects will be paid **INR 12000/- (Twelve Thousand Rupees Only)** as a reimbursement for loss of daily wages due to participation in study.

Study Induction Phase Per Completed Subject Grant

Induction Phase Study Budget			
Tests and procedures	Per visit INR	Induction Period	
		Visits	Budget
Investigator charges	7000	8	56000
Co-Investigator charges	4000	8	32000
Chemotherapy Charges and Hospitalization/ day	2000	6	12000
ECG charges	100	8	800
2D-ECHO/MUGA charges	700	2	1400
Tumour Assessments (Chest, upper abdomen, Pelvis) with contrast (Without CT Brain)	11700	4	46800
Bone scan*	4000	1	4000
Brain CT	3400	1	3400
Haematology	250	6	1500
Biochemistry	600	6	3600
Urine Analysis	260	8	2080
PT/INR, PTT Charges	280	2	560
Study CRC Charges	3500	8	28000
Blinded CRC/Pharmacist Charges	1000	6	6000
Study Phlebotomist charges	1000	4	4000
Study Nurse Charges	1500	6	9000
Institutional overhead@30% (1,2)	30%		26400
Total			2,37,540

Note: Institutional Overhead charges here is applicable only on Investigator charges and Co-Investigator Charges.

*For Bone metastasis subjects. Bone Scan amount will be reimbursed on actual basis.

Patient Travel Reimbursement

Patient Travel reimbursement	Per visit INR	Induction Phase	
		Visits*	Budget
Travel reimbursement	1500	8	12000

*completed visits only calculated as prorata basis

Note:

- Any extra lab assessment / procedures that have been carried out for patient safety/SAE and other procedures charges after getting the approval from the Medical Manager/PI/Sponsor should be invoiced separately, will be paid against invoices.
- Screen failure payment will be done as per prorata calculation basis for completed assessments during screening.

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EXHIBIT B- Non-Squamous Non-Small Cell Lung Cancer- Maintenance Phase

It is agreed that the Site will receive **INR 3,30,900/- (Three lakh Thirty thousand Nine hundred rupees only)** per completed maintenance phase according to the schedule indicated below. Completed Subjects will be paid **INR 19,500/- (Nineteen thousand five hundred rupees only)** as a reimbursement for loss of daily wages due to participation in study.

Study Maintenance Phase Per Completed Subject Grant

Maintenance Phase Study Budget			
Tests and procedures	Per visit INR	Maintenance Period	
		Visits	Budget
Investigator Charges	5000	13	65000
Co-Investigator Charges	4000	13	52000
Day Care charges and chemotherapy charges	2000	12	24000
ECG charges	100	12	1200
2D Echo charges	700	1	700
Tumor Assessments (Chest, upper abdomen, Pelvis) with contrast (Without CT Brain)	11700	4	46800
Local Lab Investigations including all the initial test	1110	12	13320
PT/INR, PTT Charges	280	1	280
Study CRC Charges	3000	13	39000
Blinded CRC/Pharmacist Charges	1000	12	12000
Study Nurse Charges	1500	12	18000
Study Phlebotomist charges	1000	4	4000
Institutional overhead@30% (1,2)	30%		35100
Total			3,11,400

Institutional Overhead charges here is applicable only on Investigator charges and Co-Investigator Charges.

*For Bone metastasis subjects. Bone Scan amount will be reimbursed on actual basis.

Patient Travel Reimbursement

Patient Travel reimbursement	Per visit INR	Maintenance Phase	
		Visits*	Budget
Travel reimbursement	1500	13	19500

*Completed visits only calculated as prorata basis

Note:

- Any extra lab assessment / procedures that have been carried out for patient safety, SAE and other procedures charges after getting the approval from the Medical Manager of AXIS should be invoiced separately, will be paid against invoices.
- Screen failure payment will be done as per prorata calculation basis for completed assessments during screening.

Subhra.L
Digitally signed by Subhra.L
DN: cn=Subhra.L, mAXIS Clinicals Ltd, c=IN
Date: 2021.09.29 15:22:26 +05'30'

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Rs 28,500 per patient (60 patients) - Approximate grant total = 17,10,000

8

सत्यमेव जयते

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e-Stamp

Certificate No.	:	IN-KA29518415406677T
Certificate Issued Date	:	13-Oct-2021 04:22 PM
Account Reference	:	NONACC (FI)/ kaksfcl08/ HEBBAL1/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKAKSFCL08131624896449 35T
Purchased by	:	STRAND LIFE SCIENCES PVT LTD
Description of Document	:	Article 12 Bond
Description	:	MEMORANDUM OF AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	STRAND LIFE SCIENCES PVT LTD
Second Party	:	YENEPOYA MEDICAL COLLEGE HOSPITAL
Stamp Duty Paid By	:	STRAND LIFE SCIENCES PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

Acharya Souharda Credit Co-Operative Ltd.

Authorised Signatory

Please write or type below this line

Clinical Study Agreement

This Collaboration Agreement (the "Agreement") is entered into at Bangalore on 13 October 2021 (the "Effective Date")

by and between

A. STRAND LIFE SCIENCES PRIVATE LIMITED (Strand), a company incorporated under the Companies Act, 1956, duly represented by Mr. Anand Janakiraman, having its registered office at University of Agricultural Sciences, Convention Centre, Veterinary College Campus, Bellary Road, Bengaluru, Karnataka, 560024, India, (hereinafter referred to as the "CRO" which expression shall include, unless contrary to the meaning and context thereof, its successors-in-interest, permitted assigns and authorized representatives) for the First Part.

ATTESTED

Bheemaraddi Shivayogi K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575018, Karnataka

AND

Registrar

STRAND LIFE SCIENCES PVT. LTD. BANGALORE

Statutory Alert:
1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App 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.

B. Dr. Pavaman Sindgikar, Yenepoya Medical College Hospital, a constituent college of Yenepoya (Deemed to be University), University Road, Deralakatte, Mangalore-575018, Karnataka, India, (hereinafter referred to as the "**Principal Investigator**")

AND

C. Yenepoya (Deemed to be University) having its registered office at University Road, Deralakatte, Mangalore-575018, Karnataka, India, (hereinafter referred to as the "**INSTITUTION**" which expression shall include, unless contrary to the meaning and context thereof, its successors-in-interest, permitted assigns and authorized representatives)

Strand Life Sciences, Institution and Principal Investigator, shall hereinafter be referred to as such or wherever the context so permits it shall individually be referred to as "**Party**" and collectively as "**Parties**".

1. STATEMENT OF WORK

The Institution agrees to conduct the prospective, experimental, exploratory academic study entitled (study title: Measuring tumor-specific genetic alterations in cerebrospinal fluid (CSF) as a biomarker of tumor burden in malignant brain tumor patients ("Study"), as described in the protocol of this Study. The Study protocol ("Protocol") and any approved amendments thereto, as kept of record by the appropriate Ethics Committee constituted as per **ICH-GCP and ICMR guidelines, is** incorporated herein by reference. In the event of a conflict between the terms of this Agreement and the Protocol, the terms of this Agreement shall control except as regards Study participant care, in which case the Protocol terms shall control. The Institution represents and warrants that it has, or by the commencement of the Study will have, the experience, capability, resources, and competency for conducting the said study as per required law including, but not limited to, sufficient personnel and equipment, to efficiently and expeditiously perform the Study in a professional and competent manner

Institutional Ethics Committee: PI will begin the Clinical Study only after its Institutional Ethics committee ("IEC") has approved the study.

Enrollment: PI will use best efforts to enroll the requisite number of patients in the Clinical Study. In addition to strictly adhering to the Protocol's patient eligibility criteria, PI at all times will exercise independent medical judgment as to the suitability of each prospective patient for enrollment in the Clinical Study.

Patient Consent: Prior to enrollment in the Clinical Study, PI will obtain from each patient or each patient's authorized representative a signed Informed Consent Form, which has been approved by the Ethics Committee.

Clinical Study Records: PI and the Institution will keep complete and accurate records of the status and progress of the Clinical Study as required by the Protocol. PI and the Institution will retain organized original patient, laboratory and drug inventory records relating to the

ATTESTED
Dr.Gangadhara Sannayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018

STRAND LIFE SCIENCES PVT. LTD. BANGALORE

Clinical Study as prescribed by the Institution and regulatory agencies.

Immediate Notice: PI will immediately notify Strand of any (a) deviations from the Protocol necessary to protect the safety, rights or welfare of patients enrolled in the Clinical Study, (b) serious adverse patient reactions in the course of the Clinical Study or (c) communication with a regulatory agency concerning (i) the Clinical Study, including any requests to inspect, examine, copy or remove records of the Clinical Study, (ii) another clinical Study which might have an impact on the Clinical Study during the period of current study

Final Report: PI & CRO will complete a final report to be submitted to the Institution's ethics committee on the Clinical Study within one (1) month of completion of the Clinical Study.

Ownership: PI and Institution acknowledge that Strand is and shall at all times remain the sole owner of the data captured in the CRF and the final report prepared by the Institution, and all information contained therein.

Developments: Any discoveries, inventions, new uses or improvements, designs, developments, methods, ideas or know-how, whether or not patentable, provided, conceived or made by any personnel of the Institution, as a result of the Clinical Study or relating in any way to the Clinical Study, Product, or its use, or the Protocol, or data resulting from any of the foregoing (collectively, "Developments"), shall be solely owned by Strand. The Institution and its personnel, including, but not limited to the Principal Investigator, hereby assign and agree to assign all of their present and future patent and other proprietary and intellectual property rights in such Developments to Strand.

Non Disclosure of Confidential Information: During the Clinical Study and thereafter, PI or Institution shall not directly or indirectly publish, disseminate or otherwise disclose, deliver or make available to any third party any Confidential Information, other than in furtherance of the purposes of this Agreement, and only then with Strand's prior written consent. Institution/PI may disclose Confidential Information to a governmental authority or by order of a court of competent jurisdiction, provided that such disclosure is subject to all applicable governmental or judicial protection available for like material and reasonable advance notice is given to Strand.

Use of Confidential Information: PI and Institution will use Confidential Information solely for the purpose of conducting the Clinical Study.

Patient Information: Notwithstanding anything to the contrary in this Agreement or the Protocol, the parties agree to hold in confidence the identity of the patients and all other patient-related medical information, data and records, except to the extent necessary to be disclosed to regulatory agencies as part of the review process.

Indemnification by Strand: Strand agrees to defend Institution as well as its PI, employees, officers, directors, consultants, and agents (collectively "Institution Indemnitees") from all demands, losses, costs, and/or expenses (including reasonable attorneys' fees) (collectively "Losses") arising from any claim brought by or on behalf of a third party from activities by Strand outside of the limits of this protocol. Notwithstanding the foregoing, Strand shall not be liable to Institution Indemnitees in the event: (a) an Institution Indemnitee fails to obtain prior IEC approval for the Clinical Study and/or a signed and effective Informed Consent from

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018, Karnataka

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018

STRAND LIFE SCIENCES PVT. LTD. BANGALORE

a patient and such patient makes a claim; (b) an Institution Indemnitee fails to follow the Protocol in any material respect or to materially comply with federal, state, and/or local laws or regulations in connection with the Clinical Study; or (c) the claim or Losses are the result of negligence or willful misconduct on the part of an Institution Indemnitee, which negligence or misconduct results in the injury or illness which formulates the basis of the claim

Indemnification by Institution: Institution agrees to indemnify, defend, and hold harmless Strand from all Losses arising from any claim brought by or on behalf of a third party alleging illness or personal injury and/or loss as a result of: (a) PI's failure to obtain prior IEC approval for the Clinical Study and/or a signed Informed Consent from a patient and such patient makes a claim; (b) Principal Investigator failure to follow the Protocol in any material respect or to materially comply with local laws or regulations as applicable in India in connection with the Clinical Study; or (c) Principal Investigator, is negligent or willfully commits misconduct in connection with the Clinical Study, which negligence or misconduct results in the personal injury or illness which formulates the basis of the claim

Term and Termination: This Agreement will commence on the Effective Date and will continue until completion of the obligations established in this Agreement and the Protocol unless otherwise terminated as herein. Both parties may terminate this agreement with 30 days written notice.

Independent Contractor: The relationship between the parties is that of independent contractors and not of partners, joint ventures, employers, employees or any other kind of relationship. Institution will be solely responsible for its expenses and those of its employees.

Notice: All notices from one party to the others will be in writing and will be given by addressing the same to the other at the address in this Agreement as given below.

If to **Institution:**

YENEPOYA (Deemed to be University)

University Road, Deralakatte, Mangalore-575018, Karnataka, India

If to **CRO:**

Strand Life Sciences Private Limited.
University of Agricultural Sciences, Convention -Centre, Veterinary College Campus, Bellary Road, Bengaluru, Karnataka 560024 India,

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

If to **Investigator:**

Dr. Pavaman Sindgikar,
Department of NeuroSurgery,
YENEPOYA (Deemed to be University)
University Road, Deralakatte,
Mangalore-575018

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018

STRAND LIFE SCIENCES PVT. LTD. BANGALORE

Entire Agreement: This Agreement constitutes the entire agreement of the parties with regard to its subject matter.

No Modification: This Agreement may be changed only by a writing signed by the parties.

Severability: In the event that any one or more of the provisions contained in this Agreement will, for any reason, be held to be invalid, illegal or unenforceable in any respect, that invalidity, illegality or unenforceability will not affect any other provisions of this Agreement, and all other provisions will remain in full force and effect.

Applicable Law & Jurisdiction: This agreement, and any issues or disputes arising out of or in connection with it (whether such disputes are contractual or non-contractual in nature, such as claims in tort, for breach of statute or regulation, or otherwise) shall be governed by and construed in accordance with the laws of India, and the language shall be English. All disputes subject to exclusive jurisdiction of Courts at Bangalore, India. We will fully comply with all privilege laws of India and international conventions governing clinical study.

Publication: Any publications related to the Project undertaken together by the Parties, in journals, conferences, white papers, etc., will be co-authored by Strand and Institution, while providing due credit to each Party for its contribution and expertise.

TERM AND TERMINATION

a) Unless earlier terminated in accordance with the provisions of this Agreement, the term of this agreement shall commence on the Effective Date and shall terminate 2.5 years after the Effective Date. This Agreement may be terminated by CRO or Institution upon at least thirty (30) days prior written notice to the other party.

b) In addition, the Agreement may be terminated by either party if any of the following conditions occur:

- if the authorization to perform the Study is withdrawn by the Licensing Authority;
- if the Investigator conducting the Study is unwilling or unable to continue performing the Study and a successor acceptable to both CRO and Institution/investigator is not available. Regardless of whether this Agreement is terminated or naturally expires, CRO shall be responsible for payment for all services or procedures actually performed in compliance with the study protocol and all non-cancellable Institution expenses incurred or obligated prior to termination or expiration and shall remit such total within thirty (30) days of Institution's written request for final payment. In the event of any overpayment by CRO, the Institution shall refund such overpayment to CRO within thirty (30) days of CRO's written request for the payment.

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

Waiver: No waiver of any of the terms of this Agreement shall be valid unless in writing and signed by the parties. Failure by a party to enforce any rights under this Agreement shall not be construed as a waiver of such rights nor shall a waiver by a party in one or more instances

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be construed as constituting a continuing waiver in other instances.

Compensation: In consideration of conducting the Study hereunder, CRO shall pay the Institution in accordance with the budget, and according to the following payment schedule.

BUDGET

INSTITUTION	Yenepoya Research Centre
ADDRESS	Yenepoya university Campus,Deralakatte-Yenepoya University, Mangalore 575018
PHONE NUMBER	08242206000
All payments to the Investigator/institution will be made by Strand Life Sciences Private Limited on the basis of actual patient visit and data entry completed within 30 days of invoice submission	
CHECK PAYMENT INFORMATION:	
<<Cheques /NEFT shall be made payable to :>	/NEFT/ Cheque
<<Bank Name :>>	Bank of Baroda
IFSC Code	BARB0VJDEYU(5th letter zero)
<<PAN Number :>>	AAATY1645F
GST Number	29AAATY1645F1ZC
Account Number	84690100002628

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

STRAND LIFE SCIENCES PVT. LTD. BANGALORE

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018

Per Subject Breakdown

Cost components for all break ups are per patient and in INR:

Patient compensation: 10,000 (as a discount towards MRI for the patient)
Patient travel allowance per visit : 1,000 (total of 3 visits for this study)
PI/Co-PI Fees + coordinator Fees: 13,000
Institution overhead fees :1,500
Archival fees: 1,000
GST as applicable
Total per patient cost to Strand: 28,500 + GST
Ethics Committee Fees (One time cost to Strand): 75,000

Note:

1. SAE/AE /Hospitalization/Supportive Care charges as per actuals will be borne by the CRO
2. Institution will submit monthly invoices (as per actual recruitments done) to CRO
3. GST will be paid as per applicable rates

STRAND LIFE SCIENCES PVT. LTD. BANGALORE

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

IN WITNESS WHEREOF, duly-authorized representatives of the parties have signed this Agreement as a document under seal as of the Effective Date.

Strand Life Sciences

Name: Anand Janakiraman

Title: President Research Informatics

Signature: _____

Date: 19/10/2021

STRAND LIFE SCIENCES PVT. LTD. BANGALORE

ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:

By: Dr. Pavaman Sindgikar
Yenepoya Medical College Hospital
A constituent college of Yenepoya (Deemed to be University)

Title: Principal Investigator

Signature: _____

Date: 22/10/21

Dr. Pavaman Sindgikar
Reg.No.72198
Associate Professor & Head
Dept. of Neuro Surgery
Yenepoya Medical College

ACKNOWLEDGED AND AGREED BY YENEPOYA (DEEMED TO BE UNIVERSITY),

Name : Dr. K.S. Gangadhara Somayaji

Title : Registrar

Signature: _____

Date: 25/10/2021

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018

ACKNOWLEDGED AND AGREED BY YENEPOYA MEDICAL COLLEGE HOSPITAL, A CONSTITUENT COLLEGE OF YENEPOYA (DEEMED TO BE UNIVERSITY):

Name: Dr. Prakash Robert M Saldanha

Title: Medical Superintendent

Signature: _____

Date: 25/10/2021

Dr. Prakash R.M. Saldanha
Medical Superintendent
Yenepoya Medical College Hospital

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

9

सत्यमेव जयते

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Government of Karnataka

Rs. 100

e-Stamp

Certificate No.	:	IN-KA39174573042740T
Certificate Issued Date	:	04-Feb-2021 04:16 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ YELAHANKA11/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKACRSFL08593330445196O3T
Purchased by	:	ICBIO CLINICAL RESEARCH PVT LTD
Description of Document	:	Article 12 Bond
Description	:	DOCUMENTATION
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	ICBIO CLINICAL RESEARCH PVT LTD
Second Party	:	YENEPOYA MEDICAL COLLEGE HOSPITAL
Stamp Duty Paid By	:	ICBIO CLINICAL RESEARCH PVT LTD
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

सत्यमेव जयते

YMSSH (Branch) Authorised Signatory BANGALORE-560064

Please write or type below this line

CLINICAL TRIAL AGREEMENT

This Memorandum of Understanding (hereinafter referred to as the "CTA") is entered into on **04 Feb 2021** by and between **ICBio Clinical Research Pvt. Ltd.** having its Registered Office at Bangalore #16, ICBio Tower, Yelahanka Main Road, Chikkabetahalli, Vidyaranyapura, Bangalore - 560 097, INDIA which expression shall unless be repugnant to the context includes its successors and assigns of FIRST PART AND

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

Statutory Alert:
1. The authenticity of this Stamp certificate should be verified at 'www.shcilestamp.com' or using e-Stamp Mobile App of Stock Holding. Any discrepancy in the details on this Certificate and as available on the website / Mobile App 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.

ATTESTED
Dr Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
[illegible], Karnataka

Dr. Prabha Adikari

Professor & HOD of Geriatric medicine

Yenepoya Medical College Hospital,

Constituent college of Yenepoya (Deemed to be University)

University Road, Deralakatte,

Mangalore-575018

(Hereinafter referred to as "Investigator") which expression shall unless be repugnant to the context includes his successors and assigns of SECOND PART.

On behalf of Yenepoya university:

Registrar

Yenepoya University

University Road, Deralakatte,

Mangalore-575018

(Here in after referred to as Institution) which expression shall unless be repugnant to the context includes his successors and assigns of THIRD PART.

ICBio Clinical Research Pvt. Ltd. and **Investigator** are hereinafter individually referred to as "**party**" and collectively as "**parties**".

WHEREAS **ICBio Clinical Research Pvt. Ltd.** is one of the leading clinical research service provider based in Bangalore, which excels in preferred research partner for several Pharmaceutical, Biotechnology and Medical device companies across the globe and assist in their product development.

AND WHEREAS ICBio Clinical Research Pvt. Ltd. Is willing to conduct a clinical trial entitled

STUDY TITLE: "A Prospective, Interventional, Open label, Randomized, Parallel Group, Multi-centric, Comparative clinical Study to Evaluate the Efficacy and Safety of test drug, Potassium Chloride (K-Lyte) 600 mg Immediate Release Tablet in comparison to reference drug, Potassium Chloride (Klor-Con) 600 mg Extended Release Tablet in the Treatment of the patients with Hypokalemia."

Protocol No: ICBio/CR/TALL/0528/94 **Version 01 Dated: 28 May 2019**

ATTESTED
Dr. Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

ICBio Clinical Research Pvt. Ltd. * Bangalore *

Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

And has approached the Investigator to perform the study in regards to the said IP in accordance with the Declaration of Helsinki, the ICH Guidelines on Good Clinical Practice and Local Regulations and has accordingly finalized the Clinical Trial Protocol.

AND WHEREAS Investigator **Dr. Prabha Adikari** shall conduct Clinical Trials for ICBio Clinical Research, **study purpose is to Evaluate the Efficacy and Safety of test drug, Potassium Chloride (K-Lyte) 600 mg Immediate Release Tablet in comparison to reference drug, Potassium Chloride (Klor-Con) 600 mg Extended Release Tablet in the Treatment of the patients with Hypokalemia."**

Protocol No: ICBio/CR/TALL/0528/94 **Version 01 Dated: 28 May 2019**

Is attached here to as Exhibit A (herein after called "**Protocol**").

AND WHERE AS **Investigator** shall coordinate with Dr. Harish. S, Director–Clinical Research, ICBio Clinical Research Pvt. Ltd.., Bangalore with such other official of the company as may be communicated in writing from time to time, for the Clinical Trial Project as agreed upon the terms and conditions of this agreement.

AND WHERE AS the clinical trial to be conducted according to the Protocol is here in after referred to as "**Study.**"

AND WHEREAS under this CTA

(i) **ICBio Clinical Research Pvt. Ltd.** shall be the legal CRO of the Study in India and has right to enter into clinical trials **CTA** with **Investigators** involved in the conduct of the **Study** in India.

(ii) **Investigator** shall be responsible for the co-ordination and management of the **Study** activities.

AND WHEREAS **ICBio Clinical Research Pvt. Ltd.** desires that, **Investigator,** should conduct the **Study** activities pursuant to the Protocol and as described herein.

AND WHEREAS the **Investigator** has received and reviewed the Protocol and desires to participate as an **Investigator** in the **Study** under the terms and conditions set forth herein.

AND WHEREAS the parties are desirous of reducing all the terms & conditions agreed upon in writing as mentioned herein below:-

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

ICBio Clinical Research Pvt. Ltd. * Bangalore *

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

NOW, THEREFORE THE PARTIES AGREE AS FOLLOWS:

ICBio Clinical Research Pvt. Ltd. hereby declares that all the necessary permissions and licenses required under the provisions of relevant Acts and Rules namely New Drugs and Clinical Trial Rules 2019 have been obtained by it for the conduct of above said clinical **Study**. **Investigator** agrees to conduct the **Study** in strict compliance with criteria set forth in the Protocol. The **Investigator** confirms that he has read and understood the clinical trial Protocol entitled: **Study Title: "A Prospective, Interventional, Open label, Randomized, Parallel Group, Multi-centric, Comparative clinical Study to Evaluate the Efficacy and Safety of test drug, Potassium Chloride (K-Lyte) 600 mg Immediate Release Tablet in comparison to reference drug, Potassium Chloride (Klor-Con) 600 mg Extended Release Tablet in the Treatment of the patients with Hypokalemia."**

Protocol No: ICBio/CR/TALL/0528/94 **Version 01 Dated: 28 May 2019**

Exhibit-A & Exhibit-B have also been read and understood by the parties. The Investigator agrees to the Protocol marked as Exhibit-A.

1. The **Investigator** expressly agrees that the Protocol may be changed by **ICBio Clinical Research Pvt. Ltd.** from time to time after execution of this **CTA** as necessary and deemed fit and agrees to continue to conduct the **Study** pursuant to such new versions of the Protocol. Any such change in the Protocol shall not be considered as an amendment to this **CTA** and therefore shall not require the consent of **Investigator** and **Investigator** expressly agrees to conduct the **Study** with the changed/revised Protocol as changed. However **ICBio Clinical Research Pvt. Ltd.** shall provide notice of any changes to the Protocol to the Investigator. In case the **Investigator** requires clarifications with respect to changes made to the Protocol subsequent to the signing of this **CTA**, the **Investigator** shall immediately contact **ICBio Clinical Research Pvt. Ltd.** in order to obtain clarification about any such changes.

2. **Investigator** along with any **Co-Investigator** shall personally review all case report forms to assure completeness and accuracy. A case report form is deemed complete when

   (i) The case report form has been completed by the **Investigator** in accordance with **Study** requirements,

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

ICBio Clinical Research Pvt. Ltd. ICBio Bangalore

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore - 575 018

(ii) It relates to a properly qualified subject who participated in and completed the **Study** in accordance with all **Study** requirements and directions from **ICBio Clinical Research Pvt. Ltd.** and

(iii) It can be used in all analyses of the **Study** results.

All data shall be submitted in a timely manner by **Investigator**.

3. It is anticipated that **20 subjects** shall be recruited at the above site and the **Investigator** agrees to enroll **20** completed evaluable patients.

4. **Institutional Review Board/Ethics Committee** (herein after referred to as "**IRB/EC**") or its local equivalent shall review and approve informed consent form to be signed by Parents/LAR of the **Study** subjects prior to initiation of **Study** by **Investigator** as per the **Protocol** (original or modified version). Upon approval of the informed consent form by the **IRB/EC**, a letter or certificate indicating such approval shall be sent to **ICBio Clinical Research.** The approved informed consent form shall be provided to **Investigator** who shall obtain consent from each of the patients enrolled in the **Study** in accordance with applicable laws and regulations.

5. **Investigator** shall at all times exercise independent medical judgment as to the compatibility of each patient with the **Study** as per Protocol requirements. **Investigator** shall notify **ICBio Clinical Research Pvt. Ltd.** promptly of any deviations from the Protocol, and within 24 hours of any serious adverse events (as defined in the Protocol) considered related to the **Study** Drugs and of overdoses and any other event to **ICBio Clinical Research Pvt. Ltd.** and as set forth in further detail in the Protocol. The **IRB/EC** shall be informed of any deviations in the Protocol in periodic **Study** reports, as per the **IRB/EC** working procedures. If subjects will suffer injury or any adverse event or death as a result of drug administration, or from any of the procedures carried out during this study, medical care will be given without charge by a nurse or physician, either at ICBio Clinical Research Private Limited or at the nearest convenient hospital taken care by ICBIO. You will be aware that financial compensation for injury or death will be paid as per new drug clinical trials rules 2019 by the ICBio Clinical Research Private Limited on behalf of sponsor.

6. **Investigator** shall provide **ICBio Clinical Research Pvt. Ltd.** with the names of all members of the committees involved in the **Study** (e.g. without limitation **IRB/EC** members) in India and of their qualification and shall also provide the copies of the correspondences exchanged with **IRB/EC** and/or with its members on monthly basis.

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

ICBio Clinical Research Pvt. Ltd. ICBio Bangalore

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

7. **Investigator** agrees to fully co-operate with **ICBio Clinical Research Pvt. Ltd.** in monitoring the procedures and in transferring all necessary information to **Study** subjects for the time period prescribed by the Guidelines, guidance and policies and good clinical practices of India in accordance with applicable laws, rules & regulations and safety & regulatory measures.

8. **ICBio Clinical Research Pvt. Ltd.** shall have the right to review and copy all patient information, including, original reports of laboratory testing, and all other notes, charts, reports or memoranda pertaining to **Study** subjects. **ICBio Clinical Research Pvt. Ltd.** undertakes to ascertain confidentiality of any such reviewed and/ or copied information.

9. **Investigator** agrees to make every diligent effort, as instructed by **ICBio Clinical Research,** to contact and obtain follow-up information of **Study** subjects that are non- compliant with the Protocol or **Study** visit appointments, then **Investigator** shall be compensated for such diligent efforts in follow-up as deemed reasonable by **ICBio Clinical Research.** It being understood that in case of prolonged periods of non-compliance or failure of **Study** subjects to attend site visits, considerable adjustments of payments to **Investigator** for such **Study** subjects may be made.

10. **ICBio Clinical Research Pvt. Ltd.** or its authorized representatives, and regulatory authorities to the extent permitted by law, may, during regular business hours and with prior reasonable notification.

(i) Examine and inspect the Institution's facilities whenever **Investigator** is conducting **Study**

(ii) Inspect and copy all data and work products relating to the **Study**, and

(iii) Confer with **Investigator** for the purpose of determining compliance with the terms of this CTA.

11. **Investigator** shall retain and preserve only one copy of all data generated in the course of the **Study** for

(i) 5 years after the **ICBio Clinical Research Pvt. Ltd.** has discontinued its research with respect to such drug; or discretion to sponsor.

(ii) Such longer period as required by applicable regulatory requirements, in particular, without limitation, GUIDELINES, GUIDANCE AND POLICIES AND GOOD CLINICAL PRACTICES OF INDIA.

At the end of five year or such longer period mentioned above as the case may be, **Investigator** must obtain written approval from **ICBio Clinical Research Pvt. Ltd.** before destruction of such data.

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

ICBio Clinical Research Pvt. Ltd. Bangalore

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

12. **Payment:**

(a) **ICBio Clinical Research Pvt. Ltd.** shall compensate **Investigator** in accordance with the fees outlined in the schedule attached hereto as **Exhibit B** (hereinafter referred to as "**Financial Details**"). The fees outlined in the Financial Details shall remain firm for the duration of the **Study**.

(b) Upon early termination of this, **ICBio Clinical Research's** sole obligation shall be to pay to **Investigator** a prorated amount as agreed, for actual work performed for the **Study** pursuant to the Protocol and in compliance with the terms of this **CTA**. **Investigator** shall refund to **ICBio Clinical Research Pvt. Ltd.** within fifteen (15) days after termination, any amounts already paid by **ICBio Clinical Research Pvt. Ltd.** to **Investigator** that are in excess of what was due under this section. Termination of this **CTA** shall not affect any rights or remedies of either party at law or equity.

13. **Archiving of data:**

The Investigator will treat the conduct and the results of the study as confidential. The filled out case report forms and all other study material will be archived at the **ICBio Clinical Research Pvt. Ltd.** #16 & 18 ICBio Tower, Yelahanka Main Road, Chikkabettahalli, Vidyaranyapura, Bangalore - 560 097, India. After completion of the study, the photocopies of trial paper (Case report form) will be retained by the Investigator and originals will be collected by the ICBio Clinical Research Pvt. Ltd. for purposes of data analysis.

14. However **Investigator** may disclose Confidential Information to their co- investigator who have a need to know such information, hospital authorities, **IRB** members and others who are required to be involved in the **Study** and all such individuals/authorities shall also be bound by obligations of confidentiality with respect to such confidential information at least as stringent as those provided herein. The obligations of confidentiality hereunder shall continue for a period of ten years from the date the Confidential Information is disclosed or developed. The obligation of confidentiality hereunder shall not apply to information that:

(a) At the time of disclosure to **Investigator** is in the public domain;

(b) After disclosure to **Investigator** becomes part of the public domain by publication or otherwise, except by breach of this **CTA** by **Investigator** or their successors or assigns;

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

(c) By written records was in **Investigator**'s possession at the time of disclosure by **ICBio Clinical Research Pvt. Ltd.** to **Investigator** and was not acquired directly or indirectly from **ICBio Clinical Research Pvt. Ltd.**

(d) **Investigator** receives from a third party legally in a position to provide **Investigator** with information, provided, however, that such was not obtained by said third party directly or indirectly from **ICBio Clinical Research Pvt. Ltd.** under an obligation of confidentiality.

(e) Is accepted by prior written approval of **ICBio Clinical Research Pvt. Ltd.**

15. All clinical data, including case report forms and other information and discoveries resulting from the **Study** shall be the sole property of **ICBio Clinical Research Pvt. Ltd.** and may be used by the **ICBio Clinical Research Pvt. Ltd.** in any manner.

IN WITNESS WHERE OF, the parties have caused this **CTA** to be executed by their duly authorized representatives as of the date first written above.

Adhikari Prabha M.R.
Reg. No. 19270
Professor & HOD, Geriatric Medicine
Yenepoya Medical College

For **ICBio Clinical Research Pvt. Ltd**
Signature: _____

Dr. Harish .S
ICBio Clinical Research Pvt. Ltd
16, ICBio Tower, Yelahanka Main Road
Chikkabettahalli, Vidyaranyapura,
Bangalore – 560094
Karnataka, India

For **Investigator**
Signature: _____

Dr. Prabha Adikari
Prof & HOD of Geriatric medicine
Yenepoya Medical College Hospital
Constituent College of Yenepoya
(Deemed to be University)
University Road Deralakatte
Mangalore-575018

For Institution
Signature: _____

Registrar
Yenepoya University
University Road, Deralakatte,
Mangalore-575018

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

WITNESS:

1. Signature: 01 Feb 2021

Name: Pavithra.M

Address:

WITNESS:

2. Signature: _____

Name:

Address:

Exhibit B (Declaration on Financial Agreement)

Dr. Prabha Adikari

Prof & HOD of Geriatric medicine

Yenepoya Medical College Hospital,

Constituent college of Yenepoya (Deemed to be University)

University Road, Deralakatte,

Mangalore-575018

ICBio Clinical Research Pvt. Ltd. will be furnishing funds in support of clinical trial entitled

STUDY TITLE: "A Prospective, Interventional, Open label, Randomized, Parallel Group, Multi-centric, Comparative clinical Study to Evaluate the Efficacy and Safety of test drug, Potassium Chloride (K-Lyte) 600 mg Immediate Release Tablet in comparison to reference drug, Potassium Chloride (Klor-Con) 600 mg Extended Release Tablet in the Treatment of the patients with Hypokalemia."

Protocol No: ICBio/CR/TALL/0528/94 **Version 01 Dated: 28 May 2019**

These funds are meant for the expenses incurred in execution of this clinical trial, so that neither the subject nor an insurance program nor public assistance agency / hospital/ Lab are billed for the same. Part of the fund is also meant for the professional and clerical allowances for the activities as per the Protocol including preparation of the subject records, medication accountability records and other trial related documentation. Details of the comprehensive grant which will be given to the study team will be as follows

ICBio Clinical Research Pvt. Ltd. ICBio Bangalore

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

Trial Budget (Investigator) for 20 Subjects

DETAILS	INR
Investigator's Fee, Trial Staff Fee and subject conveyance with Lab investigations.	6,000/-Per patient

Note: - Screen failures allowable up to 2-5 subjects only, No Investigator fee applicable for the screen failures. Payment will be made as per the following schedule:

PAYMENT MILESTONES (final amount anticipating 20 total completion of Subjects):

Institutional Overhead Charges	Rs.30,000/-
At Site Initiation	10%
At 100% enrollment	30%
At Monitoring Visit	30%
At Site Close Out	30%

* Institutional Overhead Charges will be paid after study completion.

THE LAB TESTS:-

Sl.No	Laboratory Test	No. Of Times
1.	Serology HIV, HbsAg	1 (SCR)
2.	Hematological Test (Hb, Platelet count)	2 (SCR+EOT)
3.	Renal Function Test (Urea, Creatinine)	2 (SCR+EOT)
4.	Liver Function Test (SGOT, SGPT)	2 (SCR+EOT)
5.	Stool occult blood	1 (EOT)
6.	- Serum potassium, Serum phosphate	(SCR to EOT)
	- Serum chloride, serum glucose, Serum magnesium	1 (SCR)
	- ECG monitoring - Urine PH	1 (EOT)

*After transferring all Data from the Site at monitoring visits without any Discrepancies

You agree to observe all policies and procedures including financial aspects, of the institution with which you are associated. You will notify the sponsor in case of any conflict between the terms of this agreement.

ICBio Clinical Research Pvt. Ltd. ICBio Bangalore

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

The payments mentioned above will be made in accordance with the mutually agreed schedule and on the pro-rated basis of the number of patients completing the Protocol.

In the event that the study is terminated at your center, the payments to be made will be the actual reasonable expense already incurred or committed to at the time of termination, less payments already made.

We will deduct tax at source for the payments according to the prevailing laws of the land, where applicable, further we would be requiring PAN number or income tax exemption certificate of the receiver of the aforesaid funds as per applicable regulations of Govt. of India for disbursement of funds. TDS certificate will be issued if it is deducted from the actual amount.

We agree to pay the service tax according to the prevailing service tax rate on receipt of Invoice for the services rendered (as per the schedule mentioned above) with service tax and ST No. mentioned on the Invoice.

Please also note that the payment shall be released in the name/favoring as mentioned in your invoice which will be in agreement to the CTA signed.

If the foregoing is acceptable to you, please sign and date the copy of this letter as confirmation of your acceptance and return the same to me

Best regards,

On behalf of ICBio Clinical Research Pvt. Ltd.

Signature:

Name: Dr. Harish. S

Date:

Seal:

ICBio Clinical Research Pvt. Ltd. * Bangalore * ICBio

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Accepted and agreed to

Signature: Prabha M.A.

Name: Dr.Prabha Adikari

Date: 11/2/2021

Seal: Dr. Adhikari Prabha M.R.
Reg. No. 19270
Professor & HOD, Geriatric Medicine
Yenepoya Medical College

Accepted and agreed to

Signature: Prabha M.A.

Date: 11/2/2021

Seal:

Dr. Adhikari Prabha M.R.
Reg. No. 19270
Professor & HOD, Geriatric Medicine
Yenepoya Medical College

Accepted and agreed to

Signature:

Name: Dr K S GANGADHARA SOMAYAJI

Date: 13/02/2021

Seal:

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

ICBio Clinical Research Pvt. Ltd. Mangalore

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

महाराष्ट्र MAHARASHTRA ◐ 2020 ◐ XV 592042

प्रधान मुद्रांक कार्यालय, मुंबई
प.मु.वि.क्र. ८०००००३
29 DEC 2020
सक्षम अधिकारी

श्री. सी. टी. आंबेकर

CLINICAL TRIAL AGREEMENT

This contract (hereinafter **"the Contract"**) is made as of the **12-01-2021** (hereinafter **"the Effective Date"**), by and among:

Dr. Manjunath Shenoy, Yenepoya Medical College Hospital Constituent College of Yenepoya (Deemed to be University), Basement -1, Department of Dermatology ,University road, Deralakatte, Mangalore, Karnataka, 575018

Hereinafter "the **INVESTIGATOR**",

AND

Yenepoya University, University Road, Deralakatte, Mangalore, Karnataka, 575018

Hereinafter "the **INSTITUTION**" study site

AND

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

Hereinafter "the **SPONSOR**"

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Initials INVESTIGATOR Initials INSTITUTION Initials SPONSOR

Dr. Manjunath Shenoy M.
Reg. No.35098
Prof. & HOD, Dermatology
Yenepoya Medical College

Registrar
YENEPOYA
(Deemed to be University)

ALKEM LABORATORIES LIMITED MUMBAI, INDIA

3.2 The INVESTIGATOR and the INSTITUTION

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

WITNESSETH:

WHEREAS, the SPONSOR is to perform a clinical trial (hereinafter the "**Study**") to evaluate its product **[SPI2]** (hereafter the "Investigational Product") in accordance with a protocol of SPONSOR entitled 'A Randomized, Double Blind, Multicentric, Parallel-group, Phase III Clinical Trial to evaluate the Efficacy & Safety of 5% Spironolactone Topical Cream versus Placebo in Patients with Acne Vulgaris' **[ALK20-SPI2]**and its amendments (hereinafter collectively the "Protocol"),

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

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

ARTICLE 1. PROTOCOL

The Study shall be performed in strict compliance with the Protocol a copy of which has been provided and signed by the INVESTIGATOR, INSTITUTION and SPONSOR, as such Protocol is submitted to the Yenepoya Ethics Committee, Mangalore for favorable opinion/ approval and as the Protocol may be amended from time to time thereafter.

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

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

ARTICLE 2. STUDY SITE

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

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

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

ARTICLE 3. COMPLIANCE

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

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar (Nominee of the Chancellor, Deemed to be University)
Yenepoya Road, Mangalore
Bangalore-575 018, Karnataka

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

ALKEM LABORATORIES LIMITED MUMBAI, INDIA

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR

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

ARTICLE 4. TERM

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

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

ARTICLE 5. ITEMS SUPPLIED BY THE SPONSOR

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

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

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

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

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

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

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

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

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

ARTICLE 6. SUBJECTS' RECRUITMENT

6.1 The INVESTIGATOR has estimated that he/she may require to recruit a maximum of 30 (Thirty) Subjects (the "**Subjects**"), within Six months of commencement of the Study. This target of recruitment can be increased only upon written agreement of the SPONSOR. In addition, SPONSOR may establish a threshold number of Subjects and rate of accrual of Subjects (e.g, x Subjects per day/week/month) to allow for appropriate monitoring of the Study and will communicate this information to the INVESTIGATOR. The INVESTIGATOR undertakes to comply with these limitations and conditions for further recruitment at the Study Site as required by the SPONSOR.

ATTESTED
Dr. Sanjeeva Poojary
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

ALKEM LABORATORIES LIMITED MUMBAI, INDIA

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR

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

6.3 The SPONSOR reserves the right to request the INVESTIGATOR to limit the recruitment of further Subjects or cease the recruitment, notably in case the recruitment target for the Study has been reached. In such case, the SPONSOR shall inform the INVESTIGATOR to stop the recruitment of any subject who has not yet signed informed consent. The INVESTIGATOR shall upon receipt of the written notice stop immediately further recruitment of Subjects. Payments shall only be made according to the number of Subjects recruited up to the date of receipt of the notice by indicating no further recruitment. The SPONSOR will not take any responsibility and make any payment for the Subjects recruited after this date.

ARTICLE 7. CONSENT OF THE SUBJECTS

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

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

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

ARTICLE 8. MONITORING OF THE STUDY

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

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

ARTICLE 9. DUTY OF INFORMATION

The INVESTIGATOR and/or the INSTITUTION shall immediately inform the SPONSOR, Licensing Authority (Drug Controller General of India, New Delhi) &Yenepoya Ethics Committee, Mangalore of any serious adverse event ("**SAE**") or other events as defined in the Protocol.

ARTICLE 10. FINANCIAL TERMS AND CONDITIONS

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

ARTICLE 11. CONFIDENTIALITY AND RESTRICTED USE

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

ATTESTED

Dr Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
Mangalore Road, Deralakatte
Mangalore-575 018, Karnataka

ALKEM LABORATORIES LIMITED MUMBAI, INDIA

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR

INVESTIGATOR and the INSTITUTION shall use the Confidential Information solely for the purposes of the Study.

11.2 Furthermore, the Parties agree to adhere to the principles of personal data confidentiality in relation to the Subjects, the INVESTIGATOR, the INSTITUTION and the Collaborators involved in the Study. Each Collaborator shall be subject to these obligations of confidentiality and restricted use. The INVESTIGATOR shall inform the Collaborators of the confidential nature of the Study and will only provide them with the Confidential Information that is strictly necessary for the accomplishment of their acts.

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

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

ARTICLE 12. RECORD RETENTION

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

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

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

ARTICLE 13. DATA PROTECTION

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

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

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

ARTICLE 14. PUBLICATIONS AND COMMUNICATIONS

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

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

ATTESTED
Dr.Sangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

ALKEM LABORATORIES LIMITED MUMBAI, INDIA

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR

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

ARTICLE 15. PROPERTY RIGHTS

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

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

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

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

ARTICLE 16. LIABILITY – INDEMNIFICATION – INSURANCE

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

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

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

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

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

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

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

ARTICLE 17. AUDITS AND INSPECTIONS

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

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

ATTESTED
Prof. Gopinatha Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

ALKEM LABORATORIES LIMITED MUMBAI, INDIA

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR

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

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

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

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

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

ARTICLE 18. TERMINATION OF THE CONTRACT

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

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

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

ARTICLE 19. DEBARMENT AND SENTENCING FOR MALPRACTICE

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

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

ARTICLE 20. CONFLICT OF INTERESTS AND FINANCIAL DISCLOSURE

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

ARTICLE 21. MISCELLANEOUS

ATTESTED

Dr. Jagadeesha Somayaji R.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

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

ALKEM LABORATORIES LIMITED MUMBAI, INDIA

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR

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

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

21.4 If either Party is prevented from fulfilling its obligations in accordance with the terms of this Contract due to force majeure (as defined by competent law and/or competent court), this Party shall be released from performance to the extent that it is so prevented from doing so for the duration of the intervening circumstances. The Party wishing to claim relief on the grounds of the said circumstances shall notify the other Party in writing without delay on the intervention or cessation thereof. The Party so prevented from fulfilling its obligation shall devote its best endeavors to remove or avoid the impediment as soon as possible. If the Party is prevented from fulfilling its obligations under this Contract due to force majeure for a period exceeding two (2) running months, each Party shall have the right to terminate this Contract by registered mail with acknowledgment of receipt. The termination will become effective forthwith.

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

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

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

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

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

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

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

ALKEM LABORATORIES LIMITED MUMBAI INDIA

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR

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

ALKEM LABORATORIES LIMITED

ALKEM LABORATORIES LIMITED MUMBAI, INDIA

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

INVESTIGATOR

Dr. Manjul[illegible]noy M.
Reg. No.35098
Prof. & HOD, Dermatology
Yenepoya Medical College

Name: Dr. Manjunath Shenoy
Designation:Principal Investigator 19 Jan 21

INSTITUTION

19/01/2021

Name: Dr. K.S.Gangadhara Somayaji
Designation:

Registrar
YENEPOYA
(Deemed to be University)

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR

EXHIBIT 1

1. The SPONSOR will pay Investigator fees per visit as per table below for subjects included in accordance with the Protocol and who has completed these visits as per protocol requirement.

SPIRONOLACTONE STUDY Site Budget				
Visit. No	**Particulars**	**CRC Fees**	**PI grant Non PK**	**Total**
1	Screening	500	2,000	2,500
2	Baseline - W0	1,000	3,000	4,000
3	W2	500	2,000	2,500
4	W4	500	2,000	2,500
5	W8	500	2,000	2,500
6	W12	500	2,000	2,500
7	W13	500	3,000	3,500
Per Patient Grant (A)		**4,000**	**16,000**	**20,000**
Additional Grant (B)				3,000
1	Screenfailure (20%)			Actual
2	Lab Cost			6,000
3	Instituitional Overheads (30%)			
Total (A+B)				**26,000**

The above fees is inclusive of Investigator, coordinator, Nurse, Phlebotomist, Social worker fees, any other administrative cost such as OPD fees/admission fees, Institutional overhead charges, etc.

2. Ethics Committee fees will be on actual basis.

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

4. The patinet will be provided with Rs. 500/- as a travel reimbursement for each visit.

5. Start up cost Rs. 15000/- to be paid initialy, Archival charges for 5 years will be 25,000/-, will be paid at closeout visit.

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

7. Sites to Procure Camera Model Sony DSC W830 Cyber-Shot 20.1 MP Point and Shoot Camera with 8X Optical Zoom and also tripod stand to have stability in images. This model can be purchased from amazon or any other convenient platform to site. Combined Cost approved for Camera and tripod is upto Rs. 10000/-, this will be reimbursed on submission of invoice with supporting's.

8. A sum of Rs 3,000/- (Three thousand only) per subject will be paid as investigator fees for upto 20% of screem failure subjects at site, this sum includes investigator fees, patient travel and meals. Lab investigations of screening visit for all screen failure subjects will be paid as per actuals.

9. The payment for recruited Subjects will be made to the INSTITUTION upon presentation of the invoices within 45 days as per below payee account details.

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

ALKEM LABORATORIES LTD. MUMBAI, INDIA

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR

NAME OF PAYEE	
Payment through Cheque:	
Name of Payee:	Yenepoya Research Centre
Address of Payee:	Deralakatte-Yenepoya University, Mangalore 575018
PAN / TAN Number:	AAATY1645F
GST No.	29AAATY1645F1ZC
Payment through wire transfer:	
Beneficiary's Account Name:	84690100002628
Beneficiary's Account Number:	84690100002628
Bank Name:	Bank of Baroda
Bank Address:	Deralakatte-Yenepoya University, Mangalore 575018
IFSC:	BARB0VJDEYU(5th letter zero)

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

11. All payments made shall be subject to tax deducted at source.

12. The final payment will occur only after:

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

ALKEM LABORATORIES LIMITED MUMBAI, INDIA

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore-575018, Karnataka

Initials SPONSOR Initials INSTITUTION Initials INVESTIGATOR

सत्यमेव जयते

INDIA NON JUDICIAL

Government of Karnataka

e-Stamp

Certificate No.	:	IN-KA84185984844788S
Certificate Issued Date	:	16-Jul-2020 01:13 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ MAHALAKSHMI/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKACRSFL08709460042021815
Purchased by	:	REMIDIO AND BIO DESIGN
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	REMIDIO AND BIO DESIGN
Second Party	:	YENEPOYA DEEMED TO BE UNIVERSITY
Stamp Duty Paid By	:	REMIDIO AND BIO DESIGN
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

for AISHWARYA MAHILA MULTI PURPOSE CO-OPERATIVE SOCIETY LTD.

Authorised Signatory

Please write or type below this line

Clinical Trial Agreement

"The purpose of this Clinical Trial Agreement is to enable the Parties to enter into an agreement for a single-centre, open label study to establish the efficacy of mechanical ventilation device (RespirAID R20) designed for the purpose of providing breathing support for those patients who face difficulty in breathing.

ATTESTED

Dr. Ganesh Somayaji R.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

PREAMBLE

This CLINICAL TRIAL AGREEMENT (This "AGREEMENT"), effective as of 16th July 2020 The "Effective Date"), is entered into by and among Remidio Innovative Solutions Pvt Ltd. No. 1-

For Biodesign Innovation Labs Pvt. Ltd.

Director

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

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.

51-2/12, II Floor, Vacuum Techniques Compound, 1st Cross Road, Peenya Industrial Area, Phase-I, Bengaluru, Karnataka 560058 & Biodesign Innovation Labs Pvt Ltd, 2nd Main, No. 57/65, C.L.Layout, Hosur Main Road, DRC Post, Bangalore, Bengaluru (Bangalore) Urban, Karnataka, 560029 (herein after referred as the 'Sponsor'),

AND

Yenepoya (Deemed to be University), University Road, Deralakatte Mangalore, Karnataka 575018 (herein after referred as the 'Institution')

AND

Dr. Meghna Mukund, Assistant Professor, Department of Anaesthesia and **Dr. Irfan, Associate Professor,** Department of Respiratory Medicine, Yenepoya Medical College Hospital, Yenepoya (Deemed to be University), University Road, Deralakatte Mangalore 575018, Karnataka 575018 (herein after referred as the 'Principal Investigators').

WHEREAS the purpose of this Agreement is to enable the Parties to enter into an agreement under standardised legal terms;

WHEREAS the Sponsor is an entity involved in the research, development, manufacture and sale of RespirAID R20 – Automated Ambu Bag Repiratory Assist Device.

WHEREAS the Sponsor is developing new products for its business expansion.

WHEREAS the Institution is engaged in the business of general education in areas of interest to the sponsor.

WHEREAS Sponsor has requested Institution's employee, Principal Investigators, to conduct the Study on behalf of Institution involving the Study Product according to this Agreement, the Protocol including subsequent Protocol amendments and;

WHEREAS Principal Investigators is equipped and authorized to undertake the Study and Principal Investigators have agreed to perform the Study on the terms and conditions hereinafter set forth;

NOW THEREFORE, in consideration of foregoing promises and the mutual covenants contained herein, the parties hereto agree as follows,

APPLICABLE LAW AND REGULATIONS

The Parties shall comply with all applicable national and international laws, regulations and guidelines, especially those governing the conduct of clinical trials, dealings in medicinal products, responsibilities of clinical Investigators, informed consents, protection and privacy of personal data and storage of data and records, including, without limitation, the ICH Guidelines and the European Guidelines on Good Clinical Practice (hereinafter referred to as "ICH-GCP"), Good Laboratory Practice, the revised versions of the Declaration of Helsinki Directive 95/46/EC and Directive 2001/20/EC of the European Parliament and of the Council, and professional industry association regulations.

ETHICS COMMITTEE (EC) - AUTHORIZATIONS

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

For Biodesign Innovation Labs Pvt. Ltd.

Director

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

Institution/Principal Investigators shall assist Sponsor in obtaining all necessary approvals from the Ethics Committee, hereunder but not limited to the Protocol and its amendments and informed consent form, and relevant regulatory authorities.

In the event that EC requires amendments in the Protocol or informed consent form, such amendments shall be agreed upon by both the Institution/Principal Investigators and Sponsor and be documented in writing.

CONDUCT OF STUDY

The Parties shall conduct the Study in accordance with the Protocol (Annexure I) and its amendments, the terms of this Agreement, and the terms and conditions of the approval of relevant authorities.

Institution/Principal Investigators shall adhere to separate manuals and specific procedures provided by Sponsor applicable for conducting the Study.

Institution/Principal Investigators shall ensure that all the Institution's employees and collaborators, who are involved in the Study fully, understand and adhere to the Protocol and the obligations of both the Institution and the Principal Investigators.

PRINCIPAL INVESTIGATORS

The Institution oversees the conduct of certain clinical trials managed by the institution faculty members (each person as "Principal Investigators"). The Principal Investigators shall perform the trail at the Institution. The principal Investigators will be responsible for conducting this trail. Dr. Meghna Mukund and Dr. Irfan of the Institution shall serve as the Principal Investigators.

DATA AND SAFETY REPORTING

Institution/Principal Investigators shall submit written reports, in accordance with all laws, regulations and guidelines including the Ethics Committee standards, to Sponsor and the EC regarding the Study being conducted at the Institution on request.

RECORD MANAGEMENT

Institution may store Study documents on site or at a mutually agreed third party site at Sponsor's expense. Such documents will only be accessed with the written consent of the Institution/Principal Investigators. In case of retrieval of the Study documents, stored on behalf of the Institution/Principal Investigators, prior written authorization is required. If the Institution/Principal Investigators wants to move the Study documents to another location, the Sponsor must be notified in writing.

Institution/Principal Investigators shall maintain accurate data collection and up-to-date records of all Study subjects; Institution/Principal Investigators shall record and evaluate all Adverse Events experienced by the Study subjects in accordance with the Protocol.

STUDY PRODUCT

Sponsor shall provide free of charge, or as appropriate, reimburse Institution for materials that Sponsor is required to provide per the Protocol including Study Product, necessary for the conduct of the Study.

ATTESTED
Dr.Gangadhara Samavedam
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

REMEDIO INNOVATIVE SOLUTIONS PVT. LTD.

For Biodesign Innovation Labs Pvt.Ltd.
Director

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

Institution/Principal Investigators shall ensure that the Study Product are handled correctly and stored securely for the duration of the Study and any period thereafter as required by applicable law or this Agreement, whichever is later, in accordance with the Protocol.Only those persons who are part of the study team or under the supervision of the Principal Investigators shall have access to the Study Product.

Institution/Principal Investigators shall not use the Study Product for any purpose other than the conduct of the Study.

Upon termination or completion of the Study, all unused Study Product shall be retained as mutually agreed upon or shall be returned to Sponsor at Sponsors expense.

INFORMED CONSENT

Institution/Principal Investigators undertakes to use the participant information sheet as approved by the Ethics Committee and to obtain written informed consent from each Study subject prior to inclusion or initiation of any Study specific procedures for screening according to the Protocol.

STUDY SUBJECT ENROLMENT

Institution/Principal Investigators shall make reasonable efforts to ensure that the recruitment target of eligible subjects in accordance with the Protocol is met timely and that data from all eligible Study subjects are available on or before the expiration of the Study.

TERM

This agreement begins on the effective date and ends upon receipt by the sponsor all the data generated by the Investigators and after completion of the close out activities at site including the archival. Either party can terminate the Agreement by giving 30 days written notice to the other party.

CHANGES TO THE PROTOCOL

Any party who becomes aware of the need for a deviation from the Protocol will immediately inform the other Party to this Agreement of the facts causing the deviation as soon as the facts are known to the party. The Sponsor may also, from time to time, make changes to any Sponsor-Initiated Protocol. Any such changes may not be implemented before approval by the other party and the Ethics Committee.

CONFIDENTIALITY

The Institution will not disclose confidential information unless it is necessary for this study. Any information considered by the Sponsor to be confidential will be clearly marked by the Sponsor, in writing, as 'Confidential'. Any information that is transmitted orally or visually, in order to be protected hereunder, shall be identified as such by the disclosing party at the time of disclosure, and identified in writing to the receiving party, as Confidential Information. Except as required by law or with permission from the Sponsor, the Institution will not disclose confidential information for a period of 2 years from the end of this agreement. This obligation does not apply to information that was known to the Institution prior to its receipt from the Sponsor, is independently developed by the Institution, is required to be disclosed by law or regulation, or becomes known at any time to third parties through no fault of the Institution. The Institution will use reasonable efforts to protect the confidentiality of such information while in its possession.

ATTESTED
Dr.Gangadhara Sompady
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

REMIDIO INNOVATIVE SOLUTIONS PVT. LTD.

For Biodesign Innovation Labs Pvt.Ltd.

Director

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

Permitted Disclosures: Confidential Information may be disclosed to the extent that it:

(a) is disclosed to Study Staff, but only to the extent required in connection with the performance of the Study, and only if such Study Staff are subject to obligations of confidentiality and non-use at least as restrictive as those mentioned under this agreement;
(b) is disclosed to Study Subjects or prospective Study Subjects as reasonably necessary or appropriate in the course of discussions regarding the Informed Consent, or the performance of the Study;
(c) is disclosed to personnel at other study sites as required for the performance of the Study;
(d) is disclosed to a physician or a Study Subject as reasonably necessary or appropriate in connection with the medical treatment of the Study Subject;
(e) is disclosed to employees of the Institution for patient care, but only if such employees are subject to obligations of confidentiality and non-use at least as restrictive as those mentioned under this agreement; or

PUBLICATION

The Institution will not publish Trial results nor disclose confidential information received from the Sponsor without prior written consent of the Sponsor.

INVENTION RIGHTS

Title to any new inventions, developments, or discoveries resulting directly from the Trial shall solely belong to the sponsor or can be shared by the parties as mutually agreed upon based on the contribution of each party.

INSTITUTION NAME

The Sponsor will not use the Institution's names to suggest that the Institution endorses a product or service. The Sponsor will not use the Institutions' names without prior written approval, except to identify the Institution as the Trial site when required to do so by law. The Sponsor shall publicly acknowledge in any forum/form the Institution's contribution to the conduct of the study.

INDEMNIFICATION

The Sponsor will indemnify, defend, and hold harmless the Institution, its trustees, officers, agents, and employees from any demands, claims, or costs of judgment that may be made or instituted against any of them by reason or injury (including death) to any person, or damage to property, arising out of or connected with performance of the Trial, provided, however, the Sponsor will have no liability for loss or damage resulting from failure to adhere to the terms of the Protocol or the Sponsor's written instructions concerning use of the Trial product or service, failure to comply with applicable government requirements, or negligence or wilful malfeasance by the Institution, its trustees, officers, agents, and employees, but only to the extent that such demands, claims or judgments are due to the negligence or wilful malfeasance of the Institution, its trustees, officers, agents, and employees.

SUBJECT INJURY

ATTESTED
Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

REMIDIO INNOVATIVE SOLUTIONS PVT. LTD.

For Biodesign Innovation Labs Pvt.Ltd.

Director

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

The Sponsor shall reimburse actual and reasonable medical expenses incurred in treating any injury or illness to a Study Subject that is directly related to the administration of the device or the proper performance of any other procedure, each in accordance with the Protocol and the Sponsor's written instructions to the Institution. The Sponsor is not required to provide compensation for (a) other injury- or illness- related costs (such as lost wages), (b) medical expenses that are paid for by a third party (provided that neither the Institution nor the Study Subject shall be obligated to seek reimbursement from a third party insurer), (c) medical expenses that are incurred as the result of a violation of the Protocol or other misconduct or negligence, in each case by any agent or employee of the Institution (including the Study Staff), or (d) medical expenses for injury or illness unrelated to the test/device and unrelated to the proper performance of any other procedure required by the Protocol or Sponsor's written instructions to the Institution.

In case of any injury to the Study Staff or to the participant due to malfunction of the device or due to improper instructions or training by the Sponsor for the use of the device; the Sponsor shall reimburse actual and reasonable medical expenses incurred in treating any injury or illness. The malfunctioning device shall be replaced by the Sponsor without any cost to the Institution.

LIABILITY AND INSURANCE

Sponsor carries general liability and product liability insurance or is self-insured in an amount sufficient to support its obligations under this Agreement. Sponsor shall provide Institution with certificates of insurance evidencing the required insurance coverage.

OWNERSHIP OF DATA AND RECORDS

All rights, title, and interest in (i) the completed case report forms, any electronic databases required to be created under the Protocol, and any Study reports prepared by the Institution for the Sponsor (including, with respect to the data contained in such case report forms, electronic databases, and reports, only the compilation of data or any substantially similar compilation) (collectively, "Study Deliverables"), (ii) the Protocol, (iii) the operations manuals provided by the Sponsor for use at the Study site, and (iv) any other scientific, technical, business, or other data or information relating to the Drug or this Agreement that is disclosed to the Institution by the Sponsor ((ii) through (iv) collectively, the "Sponsor Data"), including copyrights in the Study Deliverables and the Sponsor Data, shall be the sole and exclusive property of the Sponsor. All rights, title, and interest in (x) "Source Documents" (as defined by International Conference on Harmonization (ICH) Guidance E6 "Good Clinical Practice") generated by the Institution in the course of the Study, and (y) all documents other than the Study Deliverables that the Protocol requires the Institution to deliver to the Sponsor, shall be the sole and exclusive property of the Institution; provided, however, that Sponsor shall have the right to use the information and data contained in the documents described in clause (y) for any purpose whatsoever, subject to Applicable Law and the terms of the Informed Consents.

USE OF NAME

Neither Party may use the name, logo, or trademark of the other Party or its employees or affiliates in any press release, publicity, or advertising without the prior written approval of the other Party, except as required by Applicable Law or expressly permitted by this Agreement.

ATTESTED
Dr.Gangadhara Somayaji
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018, Karnataka

REMIDIO INNOVATIVE SOLUTIONS PVT. LTD.

For Biodesign Innovation Labs Pvt.Ltd.

Director

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

PAYMENTS

The Sponsor shall make payments to Institution according to the payment schedule attached hereto as Annexure II (the "Payment Schedule") and shall reimburse the Institution for post-termination expenses.

TERMINATION OF AGREEMENT

This Agreement may be terminated:

- By either Party upon thirty (30) days prior written notice.
- Upon the occurrence of an event qualifying as a termination event.

If this Agreement is terminated before completion of the Study, the Institution shall cease enrolling Study Subjects immediately (or, in the case of termination by the Sponsor, as soon as the Institution has been notified of such termination), and shall cease conducting the procedures set out in the Protocol to the extent that doing so is medically permissible and appropriate. The Sponsor and the Institution shall negotiate in good faith on the subsequent treatment or transfer of the Study Subjects. In case of termination of the Study before completion, the Sponsor shall reimburse the Institution for (i) obligations incurred in accordance with the Study budget that cannot be cancelled or mitigated by the Institution using reasonable efforts, (ii) reasonable costs incurred in connection with the safe withdrawal of Study Subjects from the Study, and (iii) mutually agreed post-termination expenses.

AMENDEMENT

This agreement represents the entire understanding of the parties with respect to the subject matter. Any modification of this agreement must be made in writing and signed by the parties.

ENTIRE AGREEMENT; COUNTERPARTS

This agreement together with all attachments and exhibits constitutes the entire agreement and understanding between the parties and supersedes any prior or contemporaneous negotiations, agreements, understandings, or arrangements, of any nature or kind, with respect to the subject matter herein. In the event of any inconsistency between this agreement and any Protocol, the terms of this Agreement shall govern. This Agreement may be executed in any number of counterparts, each of which shall be an original and all of which together shall be one document binding on all parties.

SEVERABILITY

The invalidity or unenforceability of any term or provision of this Agreement shall not affect the validity or enforceability of any other term or provision of this Agreement.

WAIVER

No waiver of any term, provision or condition of this Agreement whether by conduct or otherwise in any one or more instances shall be deemed to be or construed as a further or continuing waiver of the same term, provision or condition, or of any other term, provision or condition this Agreement.

ATTESTED

Dr. Gopalakrishna Somayaji K.S.
Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore-575 018, Karnataka

For Biodesign Innovation Labs Pvt.Ltd.

Director

REMIDIO INNOVATIVE SOLUTIONS PVT. LTD.

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

ACCEPTANCE

IN WITNESS WHEREOF, the parties hereto have caused their duly authorized representatives to execute this Clinical Trial Agreement as of the date first written above.

SPONSOR 1

Signed By:

Name: Wilfred D'Souza

Title: Head Operations

Address: Remidio Innovative Solutions Pvt Ltd
Bengaluru – 560058

SPONSOR 2

For Biodesign Innovation Labs Pvt.Ltd.

Director

Signed By:

Name: GAUTHAM PASUPULETI.

Title: CEO&MD

Address: Biodesign Innovation Labs Pvt ltd
Bangalore – 560029

INSTITUTE

Signed By:

Name: Dr. KS GANGADHARA SOMAYAJI

Title: REGISTRAR

Address: Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte
Mangalore 575 018

PRINCIPAL INVESTIGATORS

I hereby acknowledge that I have read and agree with the terms of this Agreement, and that I will act and perform my duties in the study in accordance with the content of this Agreement.

Signed By:

Name: MEGHNA MUKUND

Title: INVESTIGATOR I - ASSOCIATE PROFESSOR
DEPT OF ANAESTHESIA

Address: YENEPOYA MEDICAL COLLEGE
HOSPITAL
DERALAKATTE

Signed By:

Name: IRFAN

Title: ASSOCIATE PROFESSOR
DEPT OF RESPIRATORY MEDICINE

Address: YENEPOYA MEDICAL COLLEGE
HOSPITAL
DERALAKATTE

ATTESTED

Dr.Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

Annexure II

Payment Schedule

The Institution has agreed to provide the services outlined in the table below to the Sponsor as per the Clinical Trial Agreement (CTA) and the charges are outlined accordingly.

Sl. No	Description	Total Cost
1	ICU Charges	17,500
2	Investigators fees	60,000
3	Site Coordinator fees	15,000
4	Overhead @15%	13,875
Total		**106,375**

Payment Terms:

GST, Ethics Committee Fees and other Investigations are chargeable extra as per actuals.

Any other services provided by either the Institution or its affiliated organisations including Yenepoya Foundation for Technology Incubation ("Incubator") will be costed extra and a consolidated invoice will be raised by the Incubator which is payable as per the terms and conditions outlined in the respective invoice.

The sponsor agrees to pay 60 % of the total costs before the initiation of the study and the rest 40 % is payable at the time of completion of the study.

ATTESTED
Prof. Gangadhara Somayaji K.S.
Registrar
Yenepoya(Deemed to be University)
University Road, Deralakatte
Mangalore- 575 018, Karnataka

For Biodesign Innovation Labs Pvt.Ltd.

Director

Registrar
Yenepoya (Deemed to be University)
University Road, Deralakatte