This Agreement is entered on **27 JAN 2023** between,

Dr. Chandan S. N. (BDS, MDS) (**hereinafter referred as the INVESTIGATOR/ PRINCIPAL INVESTIGATOR**) having his address as "**JSS Dental College & Hospital** Mysore, Shri Shivarathreeshwara Nagar Mysore, Karnataka- 570015.", presently acting as the Reader oral and Maxillofacial surgery.

AND

Dr. Dhakshaini M R of "JSS Dental College and Hospital, Shri Shivarathreeshwara Nagar Mysore 570015" (**Hereinafter referred to as INSTITUTE/INSTITUTION**);

AND

Ethicare Clinical Trial Services (ECTS), acting as CRO having its registered office at 410 to 412, G- Block, Titanium City Centre, 100 Feet Road, Nr. Sachin Tower, Satellite, Ahmedabad – 380015, Gujarat, India (**hereinafter referred to as ETHICARE**) are desirous of conducting "**A Randomised, Double-blind, Multicentre, Placebo-controlled, Parallel Study to Evaluate the Efficacy and Safety of Tranexamic Acid Mouthwash of Morningside Healthcare Limited, UK, to Reduce Bleeding in Subjects Undergoing Tooth Extraction Who Are on Drugs Affecting Hemostasis**" and **Protocol No.: ECTS/19/004** (**hereinafter referred as Study**), and whereas the Investigator has agreed to conduct the above said study in the Institute, with the prior approval of **Ethics Committee –" JSS Dental College and Hospital Institutional Ethics Committee"** India, having its **CDSCO Registration** ECR/1170/Inst/KA/2019/RR-22.

Now this agreement witnessed as under:

Principal Investigator

Head of Institution

Principal
JSS Dental College & Hospital,
Mysuru-570 015

Ethicare

Dept of Oral and Maxillofacial Surgery
JSS Dental College & Hospital
Shivarathreeshwara Nagar, Mysuru-570 015

Background:

WHEREAS **Morningside Healthcare Ltd,** Morningside House, Unit C, Harcourt Way, Meridian Business Park, Leicester, LE19 1WP(**hereinafter referred as Sponsor**)has requested the ETHICARE to act on its behalf and enter into a contractual relationship with the Investigator and Institute to conduct the Study.

Investigator has agreed to perform the study on the terms and conditions set forth and Institute- **"JSS Dental College and Hospital, Shri Shivarathreeshwara Nagar Mysore 570015" (herein referred as Institution)** is equipped to undertake the study.

1. Services:

In this undertaking the Investigator agrees to perform the work required by this Agreement (more specifically as defined under Exhibit – A). Investigator representing that she is duly authorized by the Ethics Committee to do so, agrees to enroll of a maximum of 20 to 40subjects as it is a placebo-controlled (provided there may be an increase in enrolment upon ETHICARE's request) meeting all eligibility criteria described in the protocol. Investigator acknowledges that enrollment for the study is competitive and that the enrollment period may be terminated at any time. The estimated enrollment duration is 04 - 05months. The estimated study duration per subject is 15 days including screening and follow-up.

2. Informed Consent:

Investigator shall ensure that all appropriate informed consent forms have been obtained in compliance with an applicable regulatory requirements and that such informed consent forms have been signed by all study subjects as necessary for their participation in the study, in accordance with the protocol. Investigator confirms that Ethics Committee approval of the informed consent form has been obtained or shall be obtained prior to any use thereof.

3. Safety Reporting:

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Principal Investigator | Head of Institution | Ethicare

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Principal JSS Dental College & Hospital, Mysuru-570 015

a. A "Serious Adverse Event" ("SAE") includes all adverse experiences which are defined as serious in accordance with (local) regulations, ICH guidelines and any other applicable guidelines and/or procedures.

b. The Investigator is responsible for the identification and documentation of any and all adverse events in participating subjects.

c. The Investigator is responsible for reporting all SAEs immediately to DCGI, Ethics Committee, Head of Institute and Sponsor and/or ETHICARE as directed in the protocol. The Investigator will act reasonably to provide DCGI, Ethics Committee, Head of Institute and Sponsor and/or ETHICARE with at least the minimum essential information about SAE, as identified in Sponsor and/or ETHICARE SOPs and training materials, which Sponsor and/or ETHICARE will provide to the Investigator. The Investigator agrees that as soon as minimum essential information about an SAE becomes available to Investigator, Investigator will immediately report that information to DCGI, Ethics Committee, Head of Institute and Sponsor and/or ETHICARE. The Investigator will not postpone reporting said information to DCGI, Ethics Committee, Head of Institute and Sponsor and/or ETHICARE irrespective of whether more detailed information may become available at a later time, or because the available information is not yet confirmed.

d. The Investigator is responsible for making available any and all other safety information, as directed by Sponsor and/or ETHICARE in accordance with regulatory standards and the Protocol.

4. Payments:

a. In consideration for performance of the Study, the Investigator or Institute as mentioned below (in clause 4c) will be provided compensation in accordance with the approved payment rates and payment milestones as detailed in the budget proposal. At any stage ETHICARE reserves the right to adjust the payment based on the number of subjects enrolled and/or completed in the study.

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b. The consideration mentioned under budget proposal is the total consideration and includes the consideration for purchase of any equipment or hiring of any manpower, required if any, in connection with the study. The budget may be modified only upon the prior written consent of ETHICARE. Non-emergency additional tests or services (tests or services not required by the protocol or performed in excess of protocol requirements) shall not be compensated hereunder unless the written consent of ETHICARE has been obtained prior to the administration of such tests or services.

c. PI amount, CRC fees, Patient Compensation and Institutional Overhead due under this Agreement shall be paid to the

Payee Name: JSS AHER Research & Development Fund Account

Payee Account Number: 64060381103

Payee Bank: State Bank of India, Shivarathreswara Nagar Branch, Mysore 570015

Preferred Mode of Payment: Online

PAN Number: AABTJ1350M

GST Number: 29AABTJ1350M1ZH

IFSC Code: SBIN0040547

d. The Ethics committee fee will be paid by ETHICARE, and is not included in per subject grant.

Payee Name: Research Account, JSS Dental College & Hospital, Mysore

Payee Account Number: 54003222827

Payee Bank: State Bank of India, Shivarathreswara Nagar Branch, Mysore 570015

Preferred Mode of Payment: Online

PAN Number: AABTJ1350M

GST Number: 29AABTJ1350M1ZH

IFSC Code: SBIN0040547

e. Laboratory charges will be paid by ETHICARE as per budget details.

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f. The investigator shall raise the appropriate invoice every month or once in every three month depending on the recruitment in the study, which shall be paid within 30 days of the receipt of the same. The payment shall be made with deduction as per applicable tax laws. ETHICARE reserve the rights not to pay or changes the payment terms in case agreed time line is not met with.

g. If ETHICARE have made excess payment than actual work done by Investigator then Investigator will refund that excess amount within 15 days of receiving intimation from ETHICARE or on recognizing the fact.

h. ETHICARE reserves the right to hold 10% payment of the total contract awarded to Investigator/Institute, which will be paid after the successful Close-Out Visit (COV)

5. Completion of Subject related procedures:

For the purpose of making final payment to the investigator, subject related procedures will be considered completed when all of the following criteria are met:

a. Receipt by ETHICARE of complete and legible (handwritten in black ballpoint pen) case report forms/duly complete Electronic Case Report Form and all other forms provided to the investigator by ETHICARE for each subject entered in the study.

b. Compliance with all aspects of the protocol.

c. Completion of the full course of medication and/or participation through the course of the study with appropriate recording on case report forms of all the tests and assessments contained in the protocol.

d. Investigator agrees to enter the data in Case Report Form (electronic) within **03 days** of the visit and agrees to resolve all queries generated via Data Clarification Form (paper or electronic) within **03 days** of receiving hard copy of paper Case Report Form or queries raised in e-Case Report Form

6. Termination:

Principal Investigator

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The Study may be terminated by written notice from Sponsor and/or ETHICARE to Investigator for any of following reasons:

a. Notification to Sponsor and/or ETHICARE from local Regulatory Authorities to terminate said Study.
b. Determination by Sponsor and/or ETHICARE that Investigator/Institute, is not performing the Study as required in the Protocol and/ or is not meeting the agreed upon enrollment.
c. Failure of Investigator/Institute to provide access by Sponsor and/or ETHICARE representatives to any and all original medical records necessary to verify entries on Study case report forms.
d. Failure of Investigator/Institute, associated staff or any other person engaged in the study (excluding subjects) to be available, upon reasonable notice by sponsor and/or ETHICARE, to meet with ETHICARE monitors during the course of the study as necessary to discuss information relevant to the study.
e. Failure of Investigator/Institute, to comply with all regulatory requirements, defined under local regulations of India.
f. Unauthorized replacement of Investigator/Institute.
g. Determination by Sponsor that business or scientific considerations require termination.
h. Case report forms provided to Investigator/Institute by ETHICARE for use in the study, are not completed and/or not forwarded to ETHICARE or its designated representative, within the timelines prescribed by ETHICARE.

In the event that sponsor wishes to exercise its right to terminate this study based on any of the enumerated grounds above; written notice of its decision to exercise such right shall be given by email/registered mail delivered thirty (30) days before said termination.

Immediately upon receipt of any notice of termination, the Investigator agrees to stop entering patients into the study and shall cease treatment with the drug, to the extent medically permissible, on subjects already entered into the Study. In the event of termination, the

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payments under this Agreement shall be prorated based on actual work performed in accordance with the Protocol. Any funds not due under this calculation but already paid shall be returned to ETHICARE within 15 days.

7. Relationship with ETHICARE and Sponsor:

In undertaking to perform professional services for ETHICARE it is understood that the Investigator/Institute shall be considered independent contractors and shall not be construed for any purpose as the partner, agent, employee or representative of ETHICARE or Sponsor.

Accordingly, payments for services rendered under this Agreement shall be made in full at the agreed rate free from any deduction or withholding, this being in conformity with non-employee status.

8. Final Payment:

Upon completion or termination of the study, Investigator/Institute agrees to provide written acknowledgement to ETHICARE that all work requested under this Agreement has been completed and all money due have been received. In any event, acceptance of the payments as "final" constitutes such acknowledgement. All the payments for CRC will be provided by Investigator.

9. Publications:

The Sponsor might agree that the Investigator and the Institution's staff might be permitted to present at symposia, national or regional, professional meetings, and to publish in journals, theses or dissertations, the methods and results of the Clinical Trial, subject to the prior written permission of sponsor. Investigator must request for the permission in writing. All such data will be submitted to the sponsor for review and comment prior to publication or presentation.

10. Confidentiality:

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Head of Institution
Principal
JSS Dental College & Hospital,
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a. All of the information disclosed by Sponsor and/or ETHICARE or developed hereunder by the Investigator and/or Institute or associated staff shall be subject to the following provisions:

(a) neither the Investigator and/or Institute nor associated staff shall disclose the information to any third party (other than Sponsor or its representatives) without the prior written permission of Sponsor and/or ETHICARE and

(b) neither the Investigator and/or Institute nor associated staff shall use the information for any purpose other than the conduct of the study. However, nothing herein shall be construed as preventing the Investigator and/or Institute from publishing the data generated from the study, as provided in paragraph 9 above.

b. In handling a study subject's medical records, the Investigator and/or Institute and associated staff shall hold in strict confidence the identity of the patient, and shall comply fully with any and all applicable laws regarding the confidentiality of such records.

11. Use of Name:

No party hereto shall use the name of another party hereto either expressly or by implication in any news or publicity release, policy recommendation or commercial fashion without the express written approval of that party. Nothing herein shall be construed as prohibiting Sponsor from reporting on this study to a governmental agency and to other investigators studying the Drug, or of exercising its publication rights under paragraph 9 above.

12. Ownership of Property and Data:

Sponsor shall have sole ownership and rights to any inventions or discoveries relating to the Drug, whether patentable or not, made in the performance of work under this Agreement.

13. Record Retention and Site Audits:

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a. The Investigator and/or Institute will be responsible for retaining all records pertaining to the trial for a period of 15 years or as per regulatory applicability of the study or as directed by Sponsor and/or ETHICARE and in accordance with local regulatory and legal requirement.

b. ETHICARE, Sponsor and/or its designee's may monitor and audit the Investigator's performance of any work relating to services provided in connection with this Study and detailed under this agreement. Such audits may, as ETHICARE and/or Sponsor so elect, comprise:

(a) inspection of the Investigator's facilities and records relating to the rendering of services to or for trial;

(b) review of the Investigator's compliance with applicable federal, state and other licensures and certifications; and

(c) the Investigator's adherence to relevant laws, regulations and codes of practice including in particular, but without limitation, Good Clinical Practice, ICH and/or Food and Drug Administration regulations and all applicable regional/local standards and recommendations.

The Investigator will inform ETHICARE and/or Sponsor within 24 hours of any regulatory audit pertaining to this study (Although this study is not intent for regulatory submission). The Investigator shall cooperate fully with ETHICARE and/or Sponsor in any such investigation and in the implementation of appropriate action plans for such observations.

14. Archival:

Investigator and/or Institute, agrees to archive the records after the Study Close Out Visit (SCV) for a period of 15 years or as per applicable regulatory trials or as directed by Sponsor and/or ETHICARE.

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Dept of Oral and Maxillofacial Surgery
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The archival might be required for 15 years in total. The charges for 05 years archival will be INR 25,000/- which includes the consideration for purchase of any equipment or hiring of any manpower, required if any, in connection with the study.

After the completion of the 05 year term, if continuation of archival is required, then the contract will be renewed on mutual agreement and prevailing archival charges at that time shall be applicable.

15. Indemnification:

a. Sponsor shall indemnify and hold harmless, the Investigator and/or Institute, and associated staff and ETHICARE, its directors, employees and permitted assigns from any and all liability, loss or damage they may suffer as the result of claims, demands, costs or, judgments against them arising out of the activities to be carried out pursuant to this Agreement provided, however, that any such liability, loss, or damage resulting from

(1) failure to adhere to the terms of the protocol, or this Agreement or Sponsor written instructions relative to use of the Drug; and

(2) negligence or willful malfeasance by the Investigator and/or Institute, or associated staff is excluded from this agreement to indemnify and hold harmless.

b. The Investigator and/or Institute, agree to notify Sponsor and/or ETHICARE as soon as they become aware of a, claim or action as to which Sponsor has indemnification obligations under paragraph 14 (a) and to cooperate with and to authorize Sponsor and/or ETHICARE to carry out the sale management and defense of such claim or action. Sponsor agrees, at its own expense, to provide attorneys to defend against any such claim or action, whether or not such claim or action is rightfully brought or filed. Neither the, Investigator and/or Institute, nor associated staff shall compromise or settle any claim or action without the prior written approval of Sponsor.

c. Sponsor shall pay the cost of all reasonable and necessary medical, diagnoses and treatment of any injury or illness sustained by a Study subject arising out of or reasonably

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attributable to the Study Drug, but only to the extent that said subject's insurance or other third-party insurance is insufficient to cover said costs. Payments for patients lost wages will not be made available by Sponsor.

16. Debarment:

a. Investigator and/or Institute, represents that he has never been, and his employees, who will be rendering services to Sponsor and/or ETHICARE have-never been debarred or - convicted of a crime for which a person can be debarred under the provisions of the Drugs And Cosmetics Act, 1945, and rules made there under or any other enactment that may be in force in India.

b. Investigator and/or Institute, agrees that it will promptly notify ETHICARE in the event of any such debarment, conviction, threat or indictment occurring during the term of this Agreement, or the three (3) year period following the termination or expiration of this Agreement.

c. During the term of this Agreement Investigator and/or Institute, agrees not to employee or otherwise engage any individual who will be rendering services to Sponsor who has been (i) debarred or (ii) convicted of a crime for which a person can be debarred.

d. Upon ETHICARE's request from time to time, Investigator and/or Institute, will certify to ETHICARE's in writing, Investigator and/or Institute, compliance with the foregoing provisions of this paragraph.

17. Financial Disclosure:

Pursuant to Indian regulatory requirements, Investigator and/or Institute, who is directly involved in this Study shall promptly return to ETHICARE, a financial disclosure form that has been completed and signed by Investigator. Such form shall disclose any applicable interests/investments held by Investigator, or her spouse or dependent children, prior to the commencement of the Study, ETHICARE may withhold payments if it does not receive a

Principal Investigator
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Head of Institution
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completed form from Investigator. Investigator shall ensure that all such forms are promptly updated, as needed to maintain their accuracy and completeness during the Study and for one year after its completion. The Investigator acknowledge that the completed forms may be subject to review by governmental and/or regulatory 'agencies, as well as Sponsor and/or ETHICARE, and that the Investigator hereby expressly consent to any and all such reviews.

18. Assignment:

This Agreement may be assigned by ETHICARE to the Investigator and/or Institute.

19. Miscellaneous:

a. This Agreement (a) shall be governed by the laws of the Republic of India in all respects of validity, construction and performance thereof; (b) sets forth (together with the protocol) the entire Agreement and understanding among the "parties as to the subject matter hereof and has priority ,over all documents, verbal consents or understanding made between the parties with respect to the subject matter hereof; (c) shall not be amended or modified except in a written instrument signed by the parties hereof; and (d) cannot be assigned to another investigator nor moved to another institution without the prior written consent of ETHICARE and Sponsor. In addition, any amendment to the protocol must be approved in writing by ETHICARE, Sponsor and the appropriate Ethics Committee.

b. Investigator hereby represents that she has all power and authority (corporate or other) to execute and deliver this Agreement and to perform its obligations hereunder and, further, that Investigator's execution and delivery of, and performance under, this Agreement have been duly and validly authorized by all necessary action of Investigator.

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Principal Investigator

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Head of Institution

Principal
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In the Witness thereof, this Agreement has been executed by the parties hereto through their duly authorized officers as of the date set forth above.

ACCEPTED AND AGREED:

INVESTIGATOR

30-JAN-2023

Dr. Chandan S. N.
Title: Principal Investigator
Date

Dept of Oral and Maxillofacial Surgery
JSS Dental College & Hospital
S.S. Nagar, Mysuru-570 015

INSTITUTE: JSS Dental College and Hospital

30.1.23.

Dr. Dhakshaini M R
Title: Head of Institute
Date

Principal
JSS Dental College & Hospital,
Mysuru-570 015

ETHICARE

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02 FEB 2023

Dr. Milan Satia
Title: Chief Executive Officer
Date

Exhibit – A: LIST OF SERVICES

1. To sought written informed consent form before any study procedures are performed.
2. Screening & Recruiting patients for the study as per protocol inclusion & exclusion criteria.
3. Taking complete medical history of the patients.
4. Physical examination -Signs and symptoms of all the patients.
5. Usage of Study Drug
6. Responsibility for adverse events reporting.
7. Writing the patient treatment summary and providing access to original source documents and study related facilities.
8. Maintenance of Site master file in compliance with ICH GCP and local regulations.
9. Accountability of Investigational Product and other study related supplies.
10. Completion of Case Report Forms (electronic)&Data Clarification Forms (paper or electronic) on a timely basis.
11. Comply with Monitoring &Audits by the Company representatives.
12. Comply with Inspection by the regulatory authorities.
13. Overall conduct of clinical trial as applicable institutional and regulatory policies.
14. Comply with all protocol related requirements.
15. Co-operation with Sponsor and/or ETHICARE representatives.

INVESTIGATOR	INSTITUTE	ETHICARE
Dr. Chandan S.N.	Dr. Dhakshaini M R	Dr. Milan Satia
Dept of Oral and Maxillofacial Surgery JSS Dental College & Hospital S.S. Nagar, Mysuru-570 015	Principal JSS Dental College & Hospital, Mysuru-570 015	ETHICARE AHMEDABAD INDIA

TIME OF PAYMENT

ECTS anticipates that 30 to 40 Subjects will be included in the study.

Timeline for payment will be every month or once in every three month depending on the recruitment in the study, which shall be paid within 30 days of the receipt of the same

Notes:
All payments except patient compensationare subjects to tax deduction at source (TDS) under all applicable laws including Income TaxAct, 1962.

The actual cost of the following will be paid by ETHICARE/SPONSOR on producing bills:

1. Ethics Committee
2. SAE management Cost related to study and procedure
3. Laboratory cost, if any

The undersigned personnel's/representatives/organizations/institutes agree that they have reviewed and will comply with the entire CTA and agree to all the exhibits and budget sheet. Any change to the CTA and/or Budget sheet will be at the discretion of ETHICARE only.

INVESTIGATOR	INSTITUTE	ETHICARE
Dr. Chandan S.N.	Dr. Dhakshaini M R	Dr. Milan Satia

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Note: Budget sheet has to be attached with the Clinical Trial Agreement

PROPOSED BUDGET OF TRANEXAMIC ACID MOUTH WASH STUDY

Sr. No.	Visits	INR per patient		
		Investigator charge per patient	CRC charges per patient	Procedure and Consumables
1.	Visit-1: Screening visit: Day -5 to 1	1000	1000	1000
2.	Randomization: Day 1	1000	500	500
3.	Visit-2: Follow up visit: Day 4	500	500	500
4.	Visit-3: End of study visit: Day 8	1500	500	500
	Total completed visit	4000	2500	2500
Grand Total		9000		
Institutional overhead will be provided 10% (Rs. 400/-) of PI Charges.				
Subject Travelling Allowance will be given as Rs. 300/- visit, amounting to a total of 1200/- per completed subject.				
GST as applicable.				

Payment Terms:

a. The payment shall be released pursuant to an invoice raised by the Investigator based on inputs received from Investigator on monthly basis for activities completed by a cheque in favour of Payee's Name. In case invoice not received for particular month on time, payment dues shall be carried forward for the next month.

b. For drop outs or discontinued couples' payment shall be made to the Investigator on prorate basis as per above mentioned table.

c. The charges shall be inclusive of all taxes and will be subject to Tax Deducted at Source (TDS). To receive the payment is the responsibility of the Investigator.

d. In the event any laboratory examination or tests are to be conducted on the Subjects during the visits as per the Protocol in accordance with Clause, the actual charges incurred by investigator/institution for such examination or tests shall be reimbursed to investigator/institution on submission of requisite supporting documents including adequate bills/invoices for such examination. In the event such charges are to be directly paid by the CRO to the hospital or laboratory, the Investigator shall verify adequate bills/ invoices or other documents pertaining such examination or test before submitting such bills/ invoices for payment to CRO.

e. All laboratory parameters (**CBC, PT, INR, PTT, and UPT**) will be paid on monthly basis up on raising invoice every month as explained in point no "d" by laboratory. Any unscheduled laboratory test in case of adverse event, if required, will be paid by Ethicare

but Investigator has to take care that all other charges should be in a reasonable range. This payment shall be done on producing actual invoice of a lab.

f. The investigation charges including laboratory investigations for AE or SAE if any shall be paid on an actual basis on submission of supportive documents for such investigation charges incurred to the CRO.

g. For obtaining necessary approvals from Ethics Committee in connection with the Study, payment shall be paid to the Ethics Committee directly, upon receipt of necessary invoice(s) from the Ethics Committee.

h. Per Subject compensation will be given which includes travel of 4 visits. In case of unscheduled extra visit, travel allowance will be provided on bases of generation of bill.

Date: 09-01-2023 For Principal Investigator

(DR. CHANDAN. S.N)

Place: MYSORE Authorized Signatory

Date: 10-01-2023 For Ethicare Clinical Trial Service

Place: Ahmedabad Authorized Signatory

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Annexure-I: Laboratory parameters and Diagnosis test for Tranexamic acid Study

Sr. No	Laboratory Parameters	No of Times
1.	Hemoglobin, Total Red Blood Cell (RBC) count, Total White Blood Cell (WBC) count with differential, Platelet count, Haematocrit (HCT)	2 visits
2.	Prothrombin time (PT), International normalization ratio (INR), activated Partial prothrombin time (aPTT),	2 visits
3.	Glycosylated Hemoglobin	1 visit
4.	Urine Pregnancy Test	1 visit