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14 JUN 2022

Scitus Pharma Services Pvt. Ltd.  
Chennai - 56

CT 369856

L. MATHANAGOPALAN  
S.V.L. No. 02/CH/3/2010 Dt: 7.3.2010  
No. 3, Alakkoran street,  
Kamaraja Nagar, Avadi, Chennai-7

## CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement (hereinafter the "Agreement") is executed on the day of 25 Jun 2022 (hereinafter referred to as the "Effective Date") by and between:

Scitus Pharma Services Private Limited, a company organized in accordance with the laws of the Republic of India (Companies act of 2013), having its registered office at Flat #102, Samy Apartment, Plot#27, Ponnu Green Farm, OMR, Padur, Chennai-603103 (hereinafter referred to as "CRO", which expression shall, unless repugnant to the meaning or context thereof, be deemed to include its agents, representatives, administrators, and assignees, as applicable) of the First Part;

AND

MGM Medical College & Hospital with PAN: AAATM4256E, having its registered office at N-6 Cidco, Aurangabad- 431003, Maharashtra, India. (hereinafter referred to as the "Institution," which expression shall, unless repugnant to the meaning or context thereof, be deemed to include its agents, representatives, administrators, and assignees, as applicable) of the Second Part;

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Version # 1.0

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AND

**Dr. Ashish Deshmukh**, the principal investigator at the Institution, having office at N-6 Cidco, Aurangabad- 431003, Maharashtra, India. (hereinafter referred to as the "Investigator," which expression shall, unless repugnant to the meaning or context thereof, be deemed to mean and include his/her heirs, representatives and assigns) of the Third Part;

AND

**Oxygen Clinical Research and Services**, the Site Management Organisation (SMO) having its office at Saiyankar apartment, near Laxmi apartment, Sawangi Meghe Wardha 442001, Maharashtra, INDIA (hereinafter referred to as the "SMO)," which expression shall, unless repugnant to the meaning or context thereof, be deemed to include its agents, representatives, administrators, and assignees, as applicable) of the Fourth Part.

(Each of CRO, the Institution, the Investigator and the SMO may hereinafter be referred individually as a "Party" and collectively as the "Parties.")

**WHEREAS** CRO, as a sponsor representative who is representing the sponsor Novitium Pharma (a subsidiary of ANI Pharmaceuticals INC.), 70 Lake Drive, East Windsor, NJ 08520, USA, desires to conduct a clinical trial titled- 'A Randomized, Double Blind, Placebo Controlled, Parallel Design, Multi-Center, Clinical Endpoint Bioequivalence Study of Ketoconazole Shampoo 2% (Test Product) Compared with Ketoconazole Shampoo 2% (Reference Product) In Adult Subjects with Tinea Versicolor' and enter the agreements on its behalf with the Investigator, the Institution and the SMO who have represented willingness to participate in the Clinical Trial.

**AND WHEREAS** CRO wishes the Study to be conducted in terms of the protocol, which includes the objectives, design, methodology, statistical considerations and organization of the Study attached hereto as Exhibit A including amendments made thereto from time to time (hereinafter referred to as the "Protocol");

**AND WHEREAS** CRO may also conduct sub-studies from time to time (hereinafter referred to as each "Sub-Study") in conjunction with the Study, and upon written notification of a Sub-Study, all applicable references in this Agreement to 'Study' shall include such Sub-Study and all references in this Agreement to 'Protocol' shall include the protocol related to such Sub-Study;

**AND WHEREAS** the continuance in force of this Agreement shall be related to the continuance of the provision of research funding and other support to CRO;



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**AND WHEREAS** in order to generally meet with international regulatory and other standards as also requirements as to the design and conduct of a clinical trial, and to better ensure the robustness and broader applicability of the results of the Study, it is necessary for CRO to carry out the Study in collaboration with centers that are located in numerous cities across India;

**AND WHEREAS** Investigator and Institution possess the resources and expertise to carry out the Study at the various sites of the Institution (hereinafter individually referred to, for the purposes of this Agreement, as the "Study Site"), and wish to assist CRO in conducting the Study;

**AND WHEREAS** the Institution/Investigator has appointed SMO to assist the Institution and the Investigator in the Study, to provide site support for the smooth conduct of the Study at the Institution, and to facilitate the collection and disbursement of funds on behalf of the Institution.

**AND WHEREAS** the Parties wish to enter into this Agreement to record their understanding in this regard and other related understandings between the Parties.

**NOW THEREFORE**, in consideration of the mutual promises and conditions stated herein, and other good and valuable consideration, the receipt of which is hereby acknowledged, the parties agree as follows:

## **1. Definitions and Interpretations**

1.1 In this Agreement:

**"Adverse Event"** shall mean adverse event(s) as provided in the Protocol or any Clinical Trial Document, which may occur to a Subject during the Clinical Trial.

**"Applicable Laws"** shall mean any applicable statute, law ordinance, regulation, rule, guideline, order, bylaw, administrative interpretation, writ, injunction, directive, judgment, or decree or other instrument which has the force of law in India.

**"Budget"** shall mean the budget agreed by the Parties in respect of conducting the Clinical Trial as more specifically described in Schedule B.

**"Case Report Form"** shall mean the case record form in electronic format for each Subject in the form and manner provided by the Sponsor.

**"Clinical Trial"** shall mean a clinical trial conducted as per the Protocol.

**"Clinical Trial Documents"** shall mean and include all documentation received from the Sponsor in respect of a Project, including but not limited to (i) Protocol; (ii) Information Brochure, (iii) Informed Consent Form; (iv) Case Report Form; (v)



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Questionnaires; (vi) Patient Diaries and (vii) any other document as the Sponsor may, from time to time, provide.

**“Disability”** shall mean an event where either Party may be delayed or hindered in or prevented from the performance of any act required hereunder by reasons of strike, lockouts, labor troubles, inability to procure materials or services, failure of power or restrictive government or judicial orders, or decrees, riots, insurrection, war, acts of god, inclement weather or other reason or cause beyond that Party’s reasonable control.

**“Dispute Notice”** shall mean a written notice issued by an aggrieved Party to the other Party in relation to any controversy, conflict or dispute of any nature arising out of or relating to or in connection with the provisions of this Agreement.

**“Drug”** or **“Clinical Trial Drug”** shall mean the chemical compound invented by the Sponsor, excluding a Vehicle, in respect of which the Clinical Trial is being conducted.

**“Drugs Act”** shall mean the Drugs and Cosmetics Act, 1945 and rules made there under or any other enactment that may be in force in India.

**‘Effective Date’** shall mean the date of execution of this Agreement on which date it shall come into effect’ (execution date is stated at the start of the Agreement).

**“Ethics Committee”** shall mean the ethics committee formed by the Site and in accordance with the Applicable Laws to review and approve all types of research proposals involving human participants on the Site with a view to safeguard the dignity, rights, safety and wellbeing of all such actual and potential research participants.

**“Fee”** shall mean the fees, expenses and pass-through costs incurred in performing the Services payable by the Sponsor, or if so authorized by CRO in respect of each Project and/or Clinical Trial as provided in Schedule B, herein.

**“ICH GCP Guidelines”** shall mean the International Conference on Harmonization-Good Clinical Practice issued by Helsinki Declaration in June 1964 with applicable updates and amendments thereof.

**“ICH”** shall mean International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

**“Indian GCP”** shall mean Good Clinical Practice guidelines, issued by the Indian Council of Medical Research.

**“Information Brochure”** shall mean the information brochure of the Sponsor.

**“Informed Consent Form”** or **“ICF”** shall mean a written consent form provided by the Sponsor which is duly approved by the appropriate authorities and the Ethics Committee in respect of a Clinical Trial, which is required to be signed and acknowledged by the Subject.



“**Investigational Devices**” shall mean the test and reference devices as mentioned in the protocol and supplied by the Sponsor, in respect of which the Clinical Trial is conducted.

“**Invoice**” shall mean an invoice issued in respect of the services performed by the PI and/or the Site, in accordance with this Agreement.

“**Subject**” shall mean the patient upon whom the Clinical Trial is being conducted by the PI and/or the Site.

“**Payment Milestone**” shall mean payment milestones for payment of the Fees as more specifically described in Schedule B.

“**Protocol**” shall mean **Protocol No. KETO-22-002** as provided by the Sponsor.

“**Payment**” shall mean the approved payment rates detailed in the budget proposal attached hereto as Schedule ‘C’ and in accordance with the milestones mentioned therein (the “Payment Schedule”). The Payment shall include the consideration for purchase of any equipment or hiring of any manpower, required if any, in connection with the Clinical Trial.

“**Screen Failure**” shall mean the screen failure as defined in the Protocol.

“**Serious Adverse Event**” or an “**SAE**” includes all adverse experience(s) which are defined as serious in accordance with the Protocol, ICH guidelines and/or any other Applicable Laws.

“**Services**” shall mean the services detailed in Schedule ‘A’.

“**Site Indemnitee**” shall mean the Site and its employees and its associated staff.

“**Sponsor**” shall mean Novitium Pharma (a subsidiary of ANI Pharmaceuticals INC.), NJ 08520, USA who has developed the generic drug product of ketoconazole shampoo 2% and is desirous of conducting the aforementioned clinical trial.

“**Sponsor Property**” shall mean all data and information generated or derived by CRO arising out of any Services performed by CRO.

“**Standard Operating Procedures**” or “**SOP**” shall mean the written code specifying the standard operating procedures in respect of the Clinical Trial of the relevant Party.

## 2. Statement of Work

- 2.1. The Investigator and Site agree to conduct the study in accordance with protocol number **KETO-22-002** (the “Protocol”) titled ‘A Randomized, Double Blind, Placebo Controlled, Parallel Design, Multi-Center, Clinical Endpoint Bioequivalence Study of Ketoconazole Shampoo 2% (Test Product) Compared with Ketoconazole Shampoo 2% (Reference Product) In Adult Subjects with Tinea Versicolor’ (Study). The Investigator and Site agree to conduct the Study and perform the work under this agreement in cooperation with CRO and all other agents of the Sponsor.
- 2.2. The Protocol shall be considered final after it has been signed by each of Sponsor and Investigator, and approved by the Institutional Review Board/Independent Ethics



- Committee ("IRB/IEC"). Any amendments to the Protocol shall be made only upon the prior written consent of the Sponsor and subsequent approval of the IRB/IEC.
- 2.3. Prior to commencing the enrolment of subjects in the Study, Investigator shall submit the following to CRO: executed signed Clinical Trial Research Agreement, executed signature page of the Protocol, current curriculum vitae of the Investigator, all sub-investigators and other personnel involved with the conduct of the Study, copies of current medical licenses of participating investigators, Investigator Undertaking form, IRB/IEC approval to conduct the Study, composition of the IRB/IEC, IRB/IEC approved subject informed consent, Financial Disclosure forms for the Investigator and all sub- investigators, other Study documents required by Sponsor prior to enrolment.

### 3. Consideration

- 3.1. In consideration of the performance by Site and Investigator of the terms and conditions of this Agreement, CRO agrees to pay the amount itemized in and as outlined in the Payment Schedule, attached hereto as Schedule A.

### 4. Conduct of the Study

- 4.1. Investigator and/or Site shall be responsible for the following:
- 4.1.1. Recruitment is **competitive**. There is **no upper limit for recruitment**. Recruitment at all participating studies will continue until the protocol specified number of subjects have been enrolled. However, Investigator agrees to randomize minimum 10 subjects per month for the Study till the desired recruitment (about 40 subjects) is achieved at the site or till CRO/Sponsor notifies Investigator to cease further recruitment.
- 4.1.2. Upon request, Investigator shall inform CRO of the recruitment status of the Study. CRO/Sponsor may, in its sole discretion, extend the enrolment period at any time by delivering a notice of extension. If an insufficient number of subjects have been enrolled at the Investigator's Institution three (3) months from the date of initiation, based on the number of subjects for recruitment as agreed to between the parties and as outlined in Section 4.1, CRO may notify Investigator to terminate further recruitment of subjects at the Site. CRO/Sponsor may elect to either terminate the Study or the Site or both at any time for safety reasons, or if no patients have been enrolled. In the event of termination, Site and Investigator shall follow the guidance of the CRO/Sponsor with respect to completing participation of subjects enrolled on the date of such notice.
- 4.1.3. The parties agree that in respect of a multi-centre Study, enrolment shall be on a competitive basis in relation to each Study centre. Once the goal of competitive enrolment for the entire multi- centre Study has been reached, CRO/Sponsor reserves the right to notify Investigator to cease further recruitment. In such event, Site and Investigator shall conduct the Study with the subjects enrolled on the date of the notice.
- 4.1.4. Investigator shall exercise independent medical judgment as to the compatibility of each subject with Protocol requirements. Prior to the screening and treatment phases



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of the Study, Investigator shall ensure a medical professional competent to answer questions concerning the Study, obtains from each subject an informed consent, approved by the IRB/IEC. The informed consent shall be signed by the subject or a legally authorized representative (LAR) and the signature of the subject or LAR witnessed.

- 4.1.5. Investigator or appropriately qualified designee shall review and sign all informed consents. Investigator shall review and sign all Study related forms and Case Report Forms (CRFs) to ensure their accuracy and completeness and provide these forms and any other Study data or samples to Sponsor in the format and manner agreed by the parties. Site and Investigator shall use their reasonable efforts to meet the time schedules set forth in the Protocol and this Agreement. Investigator agrees to resolve any discrepancies or errors in the informed consents and CRFs and cooperate with the monitor and any audit requirements pertaining to original case records, laboratory reports and other raw data sources underlying the data recorded on the CRFs, as may be required by CRO/Sponsor, Drugs Controller General of India ("DCGI"), or other regulatory authorities, as the case may be.
- 4.1.6. Immediately after it comes to the attention of Investigator, Investigator shall adhere to timelines of initial and follow-up SAE reporting, analyzed, narrative after due analysis, to DCGI and EC as per the New Drugs and Clinical Trials Rules 2019 & GCP guidelines. The Investigator shall be responsible for making available all other safety information, as directed by CRO and/or the Sponsor, in accordance with regulatory standards and the Clinical Trial Documents.
- 4.1.7. CRO/Sponsor shall inform Investigator of any new developments and information pertaining to the drug under Study. Investigator shall inform all subjects of such new developments and information immediately after receipt of such information from CRO/Sponsor.
- 4.1.8. CRO/Sponsor shall not be liable for the failure of Investigator to inform subjects of new developments and information, particularly with respect to developments and information concerning health and safety of the Study drug.
- 4.1.9. Investigator will ensure that all Study personnel are appropriately qualified and educated on the Study conduct as outlined in the Protocol.
- 4.1.10. Regulatory Agency Audit: The Investigator and the Site shall inform CRO within twenty-four (24) hours of being notified of a regulatory agency audit (if notice is given by any applicable regulatory agency) or within twenty-four (24) hours of the beginning of any applicable regulatory agency audit (if no notice is given by the applicable regulatory agency). The Investigator and the Site shall provide CRO with a copy of all Clinical Trial specific observations made during a regulatory audit at the Investigator and/or the Site's facilities, immediately upon receipt of such information. The Investigator shall cooperate fully with CRO in any such investigation, and in the implementation of appropriate action plans for such observations. In discharge of its respective obligations under this Agreement, each



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Party shall also carry out all the statutory obligations which it is otherwise required to carry out under the provisions of applicable law, in force.

4.2. CRO shall be responsible for the following:

- i. Clinical Trial Supplies: Providing all the Clinical and Non-Clinical Trial Supplies including the Investigational devices, case report forms and any other relevant document in advance or on time to the PI and/or the Site on behalf of Sponsor.
- ii. Other Duties: Training on Study Protocol with related procedures, Site Monitoring, Central Laboratory Management, Medical and Safety Monitoring, Clinical Data Management, Statistical Programming, Clinical Study Report preparation & IP logistics management.

## 5. Representations, Warranties and Covenants

5.1. CRO represents, warrants and covenants to the Institution and Investigator as follows:

(a) Formation/Power and Authority: CRO is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Compliance with Applicable Law: CRO represents and warrants that it is in full compliance always and shall continue to comply always with all Applicable Laws of India.

(c) Freedom to Use: CRO hereby represents and warrants that the Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including the Sponsor Property and any deliverables, that CRO conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

(d) Debar: CRO certifies that it has not been debarred under any Applicable Laws and that it will not employ any person or entity that has been so debarred in respect of any Clinical Trial. CRO agrees that it will promptly notify the other Parties in the event of any such debarment, conviction, threat or indictment occurring during the Term.

5.2. The Site represents, warrants and covenants to CRO and the Sponsor as follows:

(a) Formation/Power and Authority: The clinical study site is duly formed and validly existing under the laws of India and has all requisite power and authority, to own and operate its business and properties and to carry on its business as such business is now being conducted and to execute and deliver this Agreement and to perform its obligations hereunder.

(b) Compliance with Applicable Law: The Site represents and warrants that it is in full compliance always and shall continue to comply always with all Applicable Laws of India.





(c) Ethics Committee: The Site represents that it is duly authorized by the Ethics Committee of the Site to conduct the study as per protocol (or shall receive approval of the ethics committee before implementing the protocol), agrees to enrol Subjects up to such higher numbers as agreed upon with CRO in writing from time to time to meet the subject selection criteria described in the Protocol.

(d) Ability to conduct the Trial: The Site hereby represents and warrants that it has man-power, infrastructure, and facilities necessary for the conduct of the Trial as per the Protocol, New Drugs and Clinical Trials Rules, 2019 and GCP guidelines.

(e) Freedom to Use: The Site hereby represents and warrants that CRO/Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights and any other advice, data, information, inventions, works of authorship or know-how, including the Sponsor Property and any deliverables, that the Site conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

(e) Debar: The Site represents that it has never been, and its employees, and investigators, who will be rendering their services in respect of the Clinical Trial have never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.

The Site agrees that it shall promptly notify CRO in the event of any such debarment, conviction, threat or indictment occurring during the Term, or the three (3) year period following the termination or expiration of this Agreement.

The Site agrees not to employ or otherwise engage during the Term any individual who will be rendering services to the Investigator and/or the Site in respect of the Clinical Trial who has been (i) debarred or (ii) convicted of a crime for which a person can be debarred.

Upon CRO request from time to time, the Site shall certify in writing, the Site's compliance with the foregoing provisions of this paragraph.

5.3. The Investigator represents, warrants and covenants to CRO as follows:

Power and Authority: The Investigator hereby represents that he/she is duly registered in accordance with the Applicable Laws, and has all power and authority (legal, corporate or other) to execute and deliver this Agreement and to perform his/her obligations hereunder in accordance with the terms and conditions hereof.

Ethics Committee: The Investigator representing that he/she is duly authorized by the Ethics Committee of the Site to conduct the study as per protocol (or shall receive approval of the ethics committee before implementing the protocol), agrees to enrol Subjects up to such higher numbers till the study recruitment target is achieved as agreed upon with CRO in writing from time to time to meet the subject selection criteria described in the Protocol.

Freedom to Use: The Investigator hereby represents and warrants that CRO/Sponsor may freely use, practice, reproduce, distribute, make and sell all intellectual property rights



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and any other advice, data, information, inventions, works of authorship or know-how, including the Sponsor Property and any deliverables, that the PI conveys or provides hereunder without restriction and without infringing or misappropriating any third party's (e.g., a university's or corporation's) intellectual property or other rights.

Debar: The Investigator represents that it has never been debarred or convicted of a crime for which a person can be debarred under the provisions of the Drugs Act or any other Applicable Laws.

The Investigator agrees that it shall promptly notify CRO in the event of any such debarment, conviction, threat or indictment occurring during the Term, or three (3) year period following the termination or expiration of this Agreement.

Upon CRO request from time to time, PI shall certify in writing, the PI compliance with the foregoing provisions of this paragraph.

- 5.4. Institution and Investigator each represents to the best of its/his/her knowledge that none of Institution, Investigator or any of their/his/her personnel performing the Study is under investigation by DCGI or any other regulatory authority, shall notify CRO immediately upon any inquiry or the commencement of any proceeding concerning any such person(s).
- 5.5. Investigator and Institution shall properly perform and direct the Study in accordance with the Protocol, good clinical practices (GCP) and all applicable regulatory requirements. Institution or Investigator shall notify CRO and the IRB/IEC of any failure to comply with or deviations from the Protocol immediately after it comes to the attention of Institution or Investigator.

## 6. Records, Audits and Storage

- 6.1. Investigator and Site shall comply with all reporting requirements contained in the Protocol. Investigator shall ensure the accuracy, completeness, legibility and timeliness of the data reported to CRO /Sponsor in the CRFs and all required reports. Site or Investigator shall provide Sponsor or Designee, CRO with direct access to source data and documents for monitoring, audits, IRB/IEC reviews and regulatory inspections upon reasonable notice and during business hours, and provide copies of all reports provided to the IRB/IEC listing the title of the Protocol, any Protocol revision date and the date of approval.
- 6.2. Upon termination of the Study by any party for any reason whatsoever, or on completion of the Study, Institution and Investigator shall furnish a Final Report acceptable to Sponsor.
- 6.3. Investigator and Site shall maintain accurate and complete records in accordance with good clinical practices and all applicable laws and regulations.
- 6.4. CRO / Sponsor may monitor and audit the Site and the PI's performance of the Clinical Trial. Such audits may, as CRO /Sponsor so elect, comprise: (a) inspection of the Investigator's and/or the Site's facilities and records relating to the rendering of services to or for the Clinical Trial including adherence to Protocol; (b) review of



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the Investigator and/or the Site's compliance with licensures and certifications as per the Applicable Laws; and (c) the Investigator's adherence to Applicable Laws, including, but without limitation, Indian GCP and ICH GCP Guidelines.

- 6.5. The Site shall return all records and documents pertaining to this Clinical Trial to the CRO at the end of completion of patient recruitment and all clinical trial related activities are completed. The CRO shall retain these documents at its own facility or at third party facility as long as it is deemed appropriate.
- 6.6. The Site shall retain its source documents pertaining to the trial subjects for a period of at least fifteen (15) years, following the latest of the following dates: (a) the date on which a marketing application for the particular Clinical Trial Drug is approved by the appropriate government body and/or other applicable regulatory authorities and until there are no pending or contemplated marketing applications in an ICH region (any other applicable regulation) (b) the date of completion of the Clinical Trial, or (c) if the Clinical Trial is discontinued before completion, the date on which any applicable regulatory authorities are so notified. Following the Retention Period, as instructed by Sponsor/CRO, the Investigator or Institution will either forward such records to Sponsor/CRO at Sponsor's/CRO's expense, retain such records for a reasonable additional charge to be negotiated, or destroy the records, and send Sponsor/CRO proof of such destruction.
- 6.7. If the sponsor/CRO so requires, the Investigator and Site shall maintain storage of Investigational devices for the minimum time of years as required by the sponsor/CRO ("Retention Period"). The cost for storage of Investigational Device, if required by the sponsor, will be made as separate payments by CRO on mutually agreed terms.
- 6.8. In the event Sponsor/CRO requires storage of samples or data beyond the minimum storage outlined in this section, Institution and Investigator agree to continue to store the data and samples until the parties have agreed on payment terms and conditions. Time shall be of the essence in respect to coming to an agreement on further storage.

## 7. Clinical Data

All clinical data, including CRFs, underlying data and all scientific and technical information generated as a result of the Study shall be promptly and fully provided to Sponsor, subject to any regulatory requirements pertaining to patient privacy. Such data is the sole and exclusive property of Sponsor and may be freely utilized by Sponsor/CRO. Site and Investigator agree to provide Sponsor/ designee access to the data to examine and make copies of such data (excluding any personal identifying information of the Study subject) upon reasonable notice and during normal business hours.

## 8. Inventions

In addition to the rights referred to in Section 7, any inventions or discoveries arising out of the work performed under this Agreement will be disclosed promptly to Sponsor and will become the property of Sponsor. Institution and Investigator agree,



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and agree on behalf of the personnel involved or affiliated with the Study, to execute, acknowledge and deliver at Sponsor's expense all such papers and documents as may be necessary, and to perform such other actions as Sponsor may reasonably request, to secure, verify or reflect such ownership or to secure proprietary protection in the name of Sponsor for such inventions or discoveries. Sponsor shall have full power and authority to file and prosecute patent applications throughout the world on such inventions or discoveries.

## 9. Publicity

- 9.1. Subject to Section 10, Site, Investigator and Sponsor agree to obtain prior written permission from each other before using the name, symbols or marks of the other in any form of disclosure in connection with the Study, unless required by law or to carry out the purpose of this Agreement. No party shall, without the prior written consent of the other, use the name of the other parties or any of the personnel involved or affiliated with it, in any press release, advertising, promotional literature, or any other publicity matters.
- 9.2. The Investigator and Institution may, without the consent of the Sponsor, disclose the existence of this Agreement, identify the parties to this Agreement, disclose the title or a general description of the Study, the duration of the Study, and the nature and amount of funding and/or other support provided by the Sponsor for the Study in the Institution's customary publications or otherwise in satisfaction of the Institution's reporting requirements.

## 10. Publication

The PI and the Site shall not publish any article or paper nor make any presentations, nor assist any other person in publishing any articles or papers or in making any presentations, relating or referring to:

- (a) the Study or any results, data or insights therefrom;
- (b) the Services performed hereunder; or
- (c) any data, information or materials obtained or generated in the performance of its obligations hereunder, in whole or in part, without the prior written consent of CRO and Sponsor, which consent may be granted or withheld depending on the Study Sponsor's sole discretion.

## 11. Declaration

Institution and Investigator warrant that this Study will be performed in compliance with the Protocol, good clinical practice, requirements of the IRB/IEC, New clinical trials regulations 2019 and all applicable DCGI and local laws, regulations, governmental and institutional guidelines governing or pertaining to clinical trials and studies, and any is thereto or any successor document thereof.



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## 12. Insurance

Sponsor/CRO shall maintain all adequate human clinical trial insurance covering the subjects, Sponsor/CRO, the PI and the Site during the Term.

Sponsor/ CRO shall deliver copies of the certificate evidencing the insurance coverage in accordance with Clause 13.4.1 to the Site and the Investigator.

## 13. Indemnification


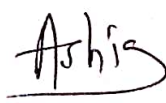
13.1. Indemnity: CRO, on behalf of the Sponsor, shall indemnify, defend and hold harmless the Site, the Investigator, SMO, the Site Indemnitees and any of the associated staff against any liability, loss, damage or expense (including reasonable attorneys' fees and expenses of litigation) ("Loss") incurred by or imposed on the Site Indemnitees or the Site, or the Investigator, in connection with any claims, suits, actions, demands or judgments made or instituted against Site, the Investigator to the extent (i) they are the direct result of the administration of the Study Drug to a Study Subject furnished by or on behalf of Sponsor or by a properly-performed Study procedure, and (ii) such activities were conducted in compliance with the Agreement, the Protocol and Investigator's Brochure.

13.2. Exclusions from Indemnification: CRO obligation to indemnify in accordance with Clause 13.1, expressly excludes any indemnity obligations to indemnify, defend and hold harmless any Study Subject liability, damage, loss or expense incurred by or imposed on the Investigator, the Site or the Site Indemnitees or any one of them about any claim, suit, action, demand or judgment arising:

- (i) from malpractice, negligence, recklessness, intentional or wilful misconduct or omission of, or the breach of the Agreement and/or the Protocol on the part of the PI, the Site or any Site Indemnitee;
- (ii) from any activities contrary to or outside the scope of the Protocol or to other information provided to the PI, the Site or any Site Indemnitee in connection with the Study or the Study Drug or the Clinical trial, including, but not limited to information provided in the Investigator's Brochure;
- (iii) from any unauthorized representations and/or warranties made by the PI, the Site or any Site Indemnitee concerning the Study Drug or the Clinical trial;
- (iv) in any case in which a Study Subject did not sign and agree to an Informed Consent Form;
- (v) due to any failure on the part of the Investigator, the Site or a Site Indemnitee to comply with any Applicable Laws, regulations or governmental requirements for which the PI and the Site shall indemnify, defend and hold harmless Sponsor and its employees, officers, directors, contractors, successors, assign, representatives or agents;
- (vi) due to an omission by any Site Indemnitee to inform Study Subjects, to



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- a. inform Investigator and/or Site of any new diseases or medical conditions that have arisen during the Study;
- b. immediately notify Investigator, and/or Site of a personal injury or other damage that may be the consequence of the Study;
- c. agree in writing to all reasonable measures (which may include a post-mortem examination) the objective of which is to investigate the cause and the extent of the damage suffered or to mitigate such damage.

13.3. The Site, the Investigator, the Site Indemnitees, (each Party referred to as “**Indemnified Party**”) seeking indemnification under Clause 13 above, directly or due to a third-party claim shall give written notice to CRO, against whom such indemnification rights are claimed. Pursuant to Clause 13 after receiving written notice of any such claim or legal proceeding against it or discovering the liability, obligation, or facts giving rise to such claim for indemnification, describing the claim, the amount thereof (if known and quantifiable), and the basis thereof in reasonable detail; provided, however, that the failure to so notify CRO /Sponsor shall not relieve CRO /Sponsor of its obligations hereunder except to the extent such failure shall have materially prejudiced CRO /Sponsor or its defences.

With respect to any claim by a third party with respect to which indemnification is being sought by the Indemnified Party under Clause 13 above, the Indemnified Party shall have the right, at its election and at the sole cost and expense, to proceed with the defense (including settlement or compromise) of such claim or legal proceeding on its own provided that:

(i) the Indemnified Party shall obtain the prior written consent of CRO/Sponsor (which shall not be unreasonably withheld or delayed) before entering into any settlement of a claim if:

(A) pursuant to or as a result of such settlement, injunctive or other equitable relief will be imposed against the CRO/Sponsor,

(B) such settlement does not expressly unconditionally release indemnified party from all liabilities and obligations with respect to such claim or legal proceeding and all other claims arising out of the same or similar facts and circumstances, with prejudice; or

(C) involves criminal or quasi-criminal allegations against CRO/Sponsor; provided, however, such consent shall not be required if such settlement provides solely for the payment of monetary damages and an unconditional release of liability of the Indemnified Party with respect to such claim;

(ii) no such settlement or compromise shall be conclusive evidence of the amount of Loss incurred by the Indemnified Party or payable by the CRO/Sponsor in connection with such claim or legal proceeding;



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*[Handwritten signature]*

(iii) CRO/Sponsor shall be entitled to participate in the defence of such action, lawsuit, proceeding, investigation or other claim giving rise to the Indemnified Party's claim for indemnification, at its own expense; and

(iv) if the Indemnified Party abandons or fails to reasonably assume the defence of any such claim or legal proceeding, CRO/Sponsor may assume control of the defence of such claim or legal proceeding at its own expense; provided that if CRO/Sponsor shall control the defense of any such claim or legal proceeding it shall select legal counsel reasonably acceptable to the Indemnified Party, CRO/Sponsor shall obtain the prior written consent of the Indemnified Party (which shall not be unreasonably withheld) before entering into any settlement of a claim or ceasing to defend such claim.

13.4. Clinical Trial Insurance: Nothing herein contained shall be deemed to be a waiver of the insurance obligations of the Investigator, the Clinical Trial and CRO as contained in the Clinical Trial Agreement.

13.5. Entire Obligation:

The foregoing terms constitute the entire indemnification obligation of CRO/Sponsor in relation to the Study.

13.6. CRO shall pay the cost of all reasonable and necessary medical diagnoses and treatment of any injury or illness sustained by a Subject arising out of or reasonably attributable to the Clinical Trial Drug, but only to the extent that said Subject's insurance or other third-party insurance is insufficient to cover said costs or as per the regulatory requirement. CRO shall not be liable for payments for a Subjects' lost wages.

#### 14. Independent Contractors

The parties to this Agreement agree that Site and Investigator are independent contractors in relation to Sponsor or CRO and shall not be construed for any purpose whatsoever as a partner, agent, employee, servant, joint-venturer or representative of Sponsor. The employees or agents of Site or Investigator shall not be considered to be the employees of Sponsor and neither Site nor Investigator shall enter into any contract or agreement with a third party, other than patients in accordance with this Agreement, which purports to obligate or bind Sponsor/CRO. Sponsor/CRO shall not be responsible for any fiscal (tax) implications of whatever sort or nature, which may arise as a result of payments made pursuant to this Agreement.

#### 15. Conflict of Interest

15.1. Investigator certifies that:

- a) There is no conflict of interest between Investigator and any other party that would inhibit or affect the performance of the work specified in this Agreement;



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- b) The performance of the work specified in this Agreement does not violate any other agreement Investigator may have with any other party; and
- c) No gifts or other benefits have been offered to any family members.

15.2. Investigator further certifies that Investigator will promptly advise Sponsor or CRO in writing in the event any conflict of interest that arises during the Term of this Agreement.

## 16. Survival

The provisions of sections 4, 6, 13, 19, 17, 24 & 25, shall survive termination of this Agreement.

## 17. Governing Law

This Agreement shall be governed by and construed in accordance with the Laws of the Republic of India within the jurisdiction of the courts of Chennai, India and will have exclusive jurisdiction over any disputes under this agreement without giving effect to its conflict of laws.

## 18. Counterparts

This Agreement may be signed in any number of counterparts which, when taken together will constitute one and the same Agreement. Counterparts may be executed in either original or faxed form and the parties adopt any signatures received by a receiving fax machine as original signatures of the parties, provided that any party providing its signature in such manner shall promptly forward to the other party an original of the signed copy of this Agreement, which was so faxed.

## 19. Entire Agreement

This Agreement, including all Schedules and any Addendums from time to time, represents the entire understanding of the parties with respect to the matter contained herein and supersedes all previous agreements and undertakings with respect thereto. In the event of any discrepancies in respect of a particular matter conflicts with a provision contained in this Agreement or the Protocol, the Agreement shall prevail. Any change, amendment or modification to the Protocol or this Agreement, including any Schedules hereto, requires and shall have the prior written approval of Sponsor.

## 20. Assignment

No part of this Agreement may be assigned, delegated, or subcontracted by any party to any other person or third party without the prior written approval of the other parties.





## 21. Disclaimer

The Investigator and the Site shall carry out the Study in accordance with the Protocol. However, neither the Investigator nor the Site promises success in achieving any particular result. The Investigator and the Site make no representations, conditions, or warranties, either express or implied, with respect to the results of the Study.

## 22. Force Majeure

Noncompliance by any party with the obligations of this Agreement due to force majeure, (laws or regulations of any government, war, civil commotion, destruction of production facilities and materials, fire, flood, earthquake or storm, labour disturbances, shortage of materials, failure of public utilities or common carriers) or any other causes beyond the reasonable control of the applicable party, shall not constitute breach of this Agreement and such party shall be excused from performance hereunder to the extent and for the duration of such prevention.

## 23. Study Subject Information

23.1. If the identity of any Study subject participating in the Study is disclosed to the CRO/Sponsor, its agents or employees, the CRO/Sponsor shall:

23.1.1. ensure that such information is deleted or destroyed;

23.1.2. not disclose such information to any third parties; and

23.1.3. Notify the Institution of such disclosure.

23.2. The Sponsor acknowledges that the Institution is a public body subject to the provisions of the Indian law and that the collection, use, disclosure and release of personal information under this Agreement is governed thereby.

## 24. Confidential Information

24.1. All information provided to Site and Investigator by Sponsor or CRO during the course of the Study including, but not limited to, the Study Protocol, preclinical data, formulae, manufacturing and toxicology information and any other information on the Study drug, CRFs, all oral and written information and information sent or stored electronically (the "Confidential Information"), will be kept confidential and confined to the personnel affiliated with or involved in the Study. Such Confidential Information shall be marked in writing as "Confidential" or if disclosed orally or in other than documentary form shall be reduced to writing within thirty (30) days thereafter. The obligation to maintain confidentiality shall survive the completion or early termination of this Agreement and shall remain in effect for a period of five (5) years following the completion or early termination of the Study.

24.2. All reports and information, including all clinical data, about the Study or its progress will also constitute Confidential Information of Sponsor/CRO and will not be



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provided by either Site or Investigator to any party other than Sponsor/CRO and, in confidence, the IRB/IEC, without the prior written approval from Sponsor/CRO except as otherwise permitted under this Agreement.

24.3. Confidential Information shall exclude any information:

- a) already possessed by the Investigator or Site prior to receipt from the CRO/Sponsor, other than through prior disclosure by the Sponsor, as evidenced by the Investigator's or Site's business records;
- b) that is in or becomes part of the public domain through no act or failure to act by the Site or Investigator and without breach of the Agreement;
- c) obtained by the Investigator or Site from a third party with a valid right to disclose it, provided that said third party is not under a confidentiality obligation to the Sponsor;
- d) independently developed by employees, agents or consultants of the Investigator or Institution who had no knowledge of or access to the Sponsor's information, as evidenced by the Institution's or Investigator's business records;

**25. Term and Termination**

- 25.1. This Agreement shall commence on the Effective Date and shall continue in effect until CRO satisfactorily receives all completed and corrected CRFs, reports and other documentation required by the Protocol and final payment is made (the "Term").
- 25.2. Unless otherwise provided herein, Sponsor reserves the right to terminate this Agreement without cause upon thirty (30) days' written notice. In this event, any amounts due to Site under this Agreement shall be limited to pro-rated fees based on actual work performed pursuant to the Protocol and reasonable general and administrative expenses and non-cancellable expenses related thereto, to the actual date of termination.
- 25.3. Site or Investigator may terminate this Agreement at any time on thirty (30) days' prior written notice to Sponsor or designee prior to the time subjects commence taking the Study medication. During such thirty (30) day period, Site and Investigator shall continue to perform those services reasonably requested by Sponsor and will be entitled to payment therefore. In the event Site or Investigator wishes to terminate the Study after subjects have commenced taking the Study medication, Investigator agrees to either find a replacement Investigator or terminate recruitment. Site and Investigator agree to cooperate fully with any replacement in respect of matters pertaining to the Study. Institution agrees not to substitute another investigator as Investigator of this Study without the prior written consent of Sponsor or Designee.
- 25.4. All parties shall have the right to terminate the Study at any time for safety reasons on notice to the other parties. In such instance, Institution and Investigator shall ensure that no Study subject receives the Study drug after receiving the notice of termination



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from the Sponsor. Investigator shall ensure that subjects return all Study medication and Study materials that they may have in their possession to Investigator. Investigator shall continue to monitor subjects as required by the Protocol and regulatory authorities and provide appropriate therapy and follow-up for subjects, for health and safety reasons.

*Signature page follows*

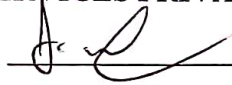


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IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be duly executed in four (4) counterparts, each of which shall be deemed to be an original, as of the day and year first above written.

**SCITUS PHARMA SERVICES PRIVATE LTD**

Signature: \_\_\_\_\_



Date: \_\_\_\_\_

25 Jun 2022

Print Name:

**Dr. S.D. Rajendran**

Print Title:

Director & Head-Operations

Seal:



**INVESTIGATOR**

Signature: \_\_\_\_\_



Date: \_\_\_\_\_

25 Jul 2022

Print Name:

**Dr. Ashih Deshmukh**

Print Title:

Professor and HOD Department of Dermatology

Seal:

**Dr. A. R. Deshmukh**  
M.D., D.N.B.  
Professor & HOD  
Dept. of DVL  
MGM Medical College & Hosp. A'bad.  
Reg. No. 86220

**THE HOSPITAL**

Signature: \_\_\_\_\_



Date: \_\_\_\_\_

29 Jul 2022

Print Name:

**Dr. Rajendra Bohra**

Print Title:

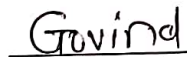
DEAN, MGM Medical College & Hospital

Seal:

**DEAN**  
**MGM'S MEDICAL COLLEGE**  
**AURANGABAD**

**The SMO**

Signature: \_\_\_\_\_



Date: \_\_\_\_\_

09/08/2022

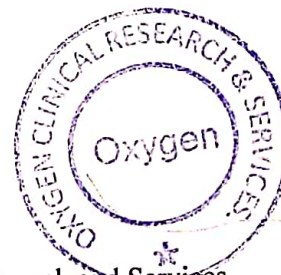
Print Name:

Mr. Govind Pawar

Print Title:


Director, Oxygen Clinical Research and Services

Seal:



Confidential  
Version # 1.0

HOD

Signature :  2'

Date : 28 Jul 2022

Print Name : Dr. Deepak Bhosle

Print Title : HOD pharmacology Department  
clinical trial center

**Professor & H.O.D.**  
Department of Pharmacology  
MGM's Medical College  
Aurangabad.

## SCHEDULE A

### PAYMENTS

1. As consideration for performance of the Study under the terms of this Agreement, CRO shall pay to Institution/ SMO the amounts as set forth in the Payment Schedule and Payment Rule Form that is attached hereto as Exhibit C (hereinafter referred to as the "PRF"). Payments shall be made in the manner and on the terms set forth in the PRF. All fees set out in the PRF shall be full and final and shall remain unchanged for the duration of the Study, unless otherwise agreed in writing by all Parties. All fees set out in the PRF shall be paid with all applicable taxes. Institution and Investigator each agree and undertake not to seek any payment from any third party or Participant for any services provided to a Participant in connection with such Participant's participation in the Study or the costs incurred in connection therewith.
2. Institution/ SMO shall be responsible for the payment of any or all taxes that may apply to any payment received pursuant to this Agreement, including, without limitation, for paying any GST or similar tax imposed by the taxation authorities in any jurisdiction.
3. Institution/Investigator shall review the payment details generated by CRO that shall accompany each payment and shall inform CRO in writing in accordance with the instructions provided in the payment details of any discrepancies that may exist in the payment(s) received and the payment(s) expected. After each payment, Institution and Investigator shall ensure that any such discrepancies that may exist, if any, are brought to the attention of CRO. The Parties shall work diligently and in good faith to resolve any such discrepancies.
4. The Parties agree that, other than as described herein, CRO will not be liable to contribute and/or make any other payment to Institution or Investigator for undertaking the Study.
5. The Institution/Investigator has appointed SMO to assist the Institution and the Investigator in the Study, to provide staff support for the smooth conduct of the Study at the Institution, and to facilitate the collection and disbursement of funds on behalf of the Institution/Investigator. Accordingly, invoices shall be raised by SMO in the name of PI and Institution, referring to this Agreement, and Institution/Investigator shall approve such invoices and forward to CRO for payment processing. All payments under this Agreement shall be made to SMO on behalf of the Institution/Investigator with TDS deducted under SMO's PAN, and such payment shall amount to due discharge of SMO's obligations under this Agreement. Notwithstanding the foregoing, the Institution and the Investigator shall remain responsible for the services that are to be rendered to CRO for the Study and have explained the terms of this Agreement to SMO, and the said terms of the Agreement shall be binding upon SMO.
6. Any logistical, equipment, stationary, man power, training/courses, registration costs, travel cost (project related only) may be provided by the society/CRO (first party); however, the same may be deducted from the research society or PI fees or the study grant to the institute



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## PAYMENT SCHEDULE

### Fees & Payment Schedule

*The detailed payment break-up for per visit, activity or test etc is mentioned in Annexure I.*

1. Institution/SMO shall provide the detailed draft invoice which will be shared in advance with CRO for review and approval.
2. Institutional overheads of 30% shall be applicable only for the billing towards Investigator fees. The same shall be mentioned separately in the invoice.
3. Any extra billing towards any additional visits, activities, tests etc shall be mentioned separately in the invoice.
4. Invoicing by the SMO shall be done for the completed visits. For the purpose of invoicing, a visit for a subject shall be deemed as completed when all activities and tests applicable for the visit are done and complete data regarding the visits is entered into EDC system through the eCRF and the same is verified by the CRO monitor.
5. Any activity or test done outside of the mandatory activities or tests during a visit by the subject shall be invoiced along with its documentary evidence and the same is verified by the CRO monitor.
6. The following costs incurred by site, where applicable, would be reimbursed to Institution/SMO upon receipt by CRO of original receipts/ bills:
  - i. SAE management costs: The SAE management costs are applicable to all SAEs only related to the Clinical Trial/ protocol/ Investigational Product. The costs would be reimbursed to the site once the original bills/receipts are made available to CRO i.e. bills pertaining to hospitalization, investigations & procedures, medications for the SAE.
  - ii. This Clinical Trial will not involve any monetary expenses. Subjects will be reimbursed for all their expenses about this Clinical Trial on actual basis (e.g. travel costs) by CRO. Subject travel re-imburement will be paid up to Rs. 1000/- per visit upon producing the vouchers for the same to CRO. Any additional or exceptional travel reimbursement shall need approval in advance or will be considered on a case-to-case basis with prior approval.
  - iii. Trial related tests: The tests required as per protocol shall be paid on actual basis, upon receipt of the original bills and supporting rate list.
7. Lab test required per protocol will be paid on actual upon receipt of the supporting rate list approved prior to the initiation of the trial.
8. The archival of study documents will be done by the site. CRO will be provide archival charges as per site SOP.
9. It is agreed that, a study grant of Rs. 18000/- (Rupees Eighteen Thousand Only) per completed patient (which includes investigator fee, other study staff fee and SMO fee of Rs. 800/- per visit per patient). The study grant will be paid to the SMO by CRO by



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online transfer to the bank account mentioned in this CTA. The SMO will be responsible for the payment of PI fee and other study staff fee.

10. Initial advance payment of Rs. 25,000/- (Rupees Twenty-five Thousand Only) will be paid within fifteen days for start-up activities after getting clearance of the IRB/IEC, a fully executed copy of this Agreement, receipt of copies of all regulatory documents necessary to start the Study, and the initiation of the Study at the Site. The advance payment will be adjusted against subsequent payment(s) until the entire Advance amount is adjusted.
11. Subsequent payments will be made based upon actual procedures and visits performed as evidenced by case report forms retrieved by CRO, in an amount equivalent to 90% of the total budgeted amount described below.
12. Institution/SMO will reimburse CRO under the following conditions: (1) if no Study participants are randomized into the Study within one (1) month following receipt of the Study drug, INVESTIGATOR/INSTITUTION will reimburse CRO all money received from CRO or (2) if the Study is closed out by CRO, INVESTIGATOR/INSTITUTION will reimburse all money received from CRO in excess of the pro-rata amount due for actual Study participant visits performed as of closing of the Study.
13. CRO, if so authorized, shall pay the invoiced amount within thirty (30) business days of the date of the invoice.
14. All payments will be made by bank transfer only as per the company policy and shall be subject to applicable tax deduction.
15. Taxes such as Goods and Service Tax or other government instituted tax or levy that may become payable in respect of the services offered in this Agreement shall be to CRO account. The payment shall be made after deducting all deductions as per Applicable Law, including tax deducted at source and GST will be included on each invoice.
16. Full and final payment will be made upon clarifying all data queries and after return of all study drug and study documents to CRO.
17. Final Payment: Upon completion or termination of the study, the PI and/or the Site shall provide a written notice to CRO that all work requested under this Agreement has been completed and all monies due have been received. Acceptance of the payments as "final" constitutes such acknowledgement.
18. The payment shall be paid to below payee details after TDS deduction and GST as applicable as per the law.



**Payee details:**

Instruction for Payment Payee Details	
Payee Name	Oxygen Clinical Research and Services
PAN No	DDRPP5137E
Bank Account Number	4505040100548153
Bank Name	Axis Bank
Bank Address	Plot No 2560 to 2562, Ground & 1st Floor, Indira Market Rd, Wardha, Maharashtra 442001
Bank Swift Code / IFSC Code	UTIB0000808
GST No	Not Applicable
Address of Account holder	Saiyankar Apartment Sawangi Meghe Wardha 442204, Maharashtra, INDIA.

Final Payment: Upon completion or termination of the study, the PI and/or the Site shall provide a written notice to CRO that all work requested under this Agreement has been completed and all monies due have been received. Acceptance of the payments as "final" constitutes such acknowledgement.

The SMO will raise separate invoices to CRO for professional fees and pass-through expenses, except for hospital overhead charges. Invoices will be raised as per the budget schedule given below and in compliance with the Goods and Service Tax Act. Invoices will be raised on monthly basis and payment shall be made against invoices sent every month.

The Parties understand and agree that the currency of the payment is and shall remain India Rupee (INR). All invoices shall be sent to the following address:

Kind Attn: Dr. S. D. Rajendran  
Director & Head-Operations,  
**Scitus Pharma Services Private Limited**  
Module 36, 2<sup>nd</sup> floor, SIDCO Multistoreyed building,  
SIDCO Industrial Estate, Thirumazhisai, Chennai-600124 (INDIA).

Invoice shall be sent in original as hard copy (PDF or fax copies are not acceptable) and contain, as a minimum, the following information:

- The Site's Name and Address as it is written in the beginning of this Agreement
- A description of the work activities associated with the invoice
- The total invoice amount in INR, Payee Name, PAN & GSTIN of the site, as well as the PAN & GSTIN of CRO
- Signed & date by authorized signatory.

Notes:

- Along with the invoice the Site shall provide declaration that CRF for the invoiced activities are updated as applicable.





2. Annexure 1

#	PARTICULARS	COMPENSATION
1	Administrative Institutional overhead (On PI fees of Rs. 6000/- per completed patient only) Note: Calculated based on PI fee of Rs. 1500/- per visit per patient	30%
2	EC submission fee (without TDS deduct)	At actuals
3	EC annual review fee	NA
4	EC amendment fees (without TDS)	As per EC SOP
5	All investigation charges as mentioned in the protocol will be on actual at various visits	Yes
6	Patient travel reimbursement per visit up to	Rs. 500
7	Expenses for AE/SAE management will be billed on actuals. SAE compensations for related SAEs including trial related injury/Deaths are CRO responsibility	Yes
8	Applicable Taxes Present GST rate (18%) are not included in the pass-through budget	Yes
10	Central Lab expenses	Will be under the scope of CRO
11	Any local lab expenses mandated by the study protocol	At actuals



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