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Dr. Prabhakar Kumar Singh
 Vice-Chancellor
 Uttar Pradesh University of Medical Sciences
 Salai, Etawah (U.P.)-206130

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Kha/5/24, Faizullaganj Near Sita Ram Mandir Lucknow-226020 Uttar Pradesh, India, represented by Name of the authorized representative acting as Site Management Organization, shall hereinafter be collectively referred to as the "SMO" or "Helsinki Clinical Solutions", which expression shall unless repugnant to the context or meaning thereof be deemed to include its successors and assigns of the second part)

Uttar Pradesh University of Medical Sciences & Helsinki Clinical Solutions Private Limited are individually referred as party & collectively referred as "Parties".

Helsinki Clinical Solutions Private Limited is desirous of working with Investigator & Study site for the purpose of conducting ICH-GCP compliant Phase I-IV Clinical Trials for new drugs & treatments.

1) **Tenure of MOU:** This Memorandum of Understanding (MOU) shall be effective for a period of five years from the date of signature by both parties, unless terminated earlier in accordance with the provisions of this MOU. Both parties agree to exchange clinical trial data based on a mutual relationship, which will be renewed every five years from the effective date of this agreement. Upon signing by both parties, "Helsinki Clinical Solutions Private Limited" will be designated as the second party, serving as the "Site Management Organization" at Uttar Pradesh University of Medical Sciences, Saifai, Uttar Pradesh, 206130, India.

2) Helsinki Clinical Solutions Private Limited shall fully indemnify, hold harmless and defend Uttar Pradesh University of Medical Sciences and its directors, doctors, medical staff, officers, employees, agents, members and affiliates from and against all claims, demands, actions, suits, damages, liabilities, losses, settlements, judgments, costs and expenses arising out of clinical trials on the basis of this MOU.

3) SCOPE OF SERVICE (HELSENKI CLINICAL SOLUTIONS CLINICAL PVT LTD)

Helsinki Clinical Solutions will be responsible for the site management activities required to conduct trial as per requirements of the Hospital/ Institute, Institutional Ethics Committee (IEC) and Central Regulatory Guidelines. Activities are listed below

- 3.1) This Agreement allows the Parties to specify distinct Clinical Trial activities to be performed by the "SMO" Helsinki Clinical Solutions PVT LTD for the Clinical Trial.
- 3.2) Providing assistance to Uttar Pradesh University of Medical Sciences for getting IEC registration & other documentation required for clinical trials.
- 3.3) Helsinki Clinical Solutions PVT LTD on behalf of Sponsor hereby declares that all the necessary permissions and licenses required under the provision of all relevant acts and rules such as Drug & Cosmetics Act and Drug & Cosmetic Rules 1945 and its subsequent amendments (including New Drugs and Clinical Trials Rule 1945) are

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obtained by them prior to starting of Clinical Trial.

- 3.4) The Helsinki Clinical Solutions PVT LTD will allocate highly qualified and trained personnel, materials (except as otherwise may be provided herein) and facilities as are necessary or useful to perform the Clinical Trial.
- 3.5) In performing the Clinical Trial, each Party shall fully comply with all applicable laws and regulations, and all terms and conditions of the Protocol and this Agreement.
- 3.6) The Helsinki Clinical Solutions PVT LTD is a clinical Research Site Management Services as per ICH and The Clinical Trial Guide Line for New Drug GSR 227 (E) Schedule-III Table 3, and ICH GCP E6 (R1) and E6 (R2) guidelines.
- 3.7) Helsinki Clinical Solutions PVT LTD will appoint a staff (here in afterreferred as CRC) who will be responsible to coordinate and over-see the progress and management of CRC activities and trial, regular visit to study site to ensure data- quality and resolve screening/recruitment/ general issues, if any, follow-up on post- monitoring action elements and study specific training needs and provide regular back-up to study site and Sponsor on trial progress.
- 3.8) The financial term will be decided on project basis.
- 3.9) Institutional Ethics Committee Fees
Helsinki Clinical Solutions agrees to pay the pre-decided Institutional Ethics Committee fees as stipulated by the Standard Operating Procedures (SOP) of UPUMS.
- 3.10) Helsinki Clinical Solutions shall bear all the administrative cost related to the various activities (i.e. Study Specific) undertaken by PM, CRC or any other staff placed by Helsinki Clinical Solutions, which includes telecommunication, travel cost to meet various clients across India and abroad, training cost at various centres across India and abroad.
- 3.11) Based on mutual agreement, Helsinki Clinical Solutions, Uttar Pradesh University of Medical Sciences and Sponsor will enter into separate & detailed clinical trial agreement before commencement of the study. All payment will berouted through Helsinki Clinical Solutions since Helsinki will be responsible to pay the institute in real time within 30 days of Invoice. Getting defined payment from sponsor and giving to study site shall be the responsibility of Helsinki Clinical Solutions

- 3.12) Any other scope, not specifically mentioned but required for satisfactory execution of clinical trials, shall be in Helsinki scope.

3.13) Overall Trial Management and Documentation

Overall Management and Documentation will be coordinated by the Clinical Research Coordinator.

3.14) Training of Site Staffs

In case required, Helsinki Clinical Solutions PVT LTD for their own studies would be obliged to provide protocol specific, site specific, IEC SOP and ICH GCP training to the site staff to conduct their study.


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3.15) Medical Records Storage

Helsinki Clinical Solutions will be responsible for the maintenance and storage of the Clinical Trial Medical Records and documents as per the guidelines of the Institutional Ethics Committee and the Regulatory authority. Helsinki Clinical Solutions will charge a professional storage fee for the medical records based on the requirement of the sponsor/CRO; Regulatory and site. The storage fee will be provided by the pharmaceutical company.

4) SCOPE OF SERVICE (Uttar Pradesh University of Medical Sciences)

Uttar Pradesh University of Medical Sciences will be responsible for the Institute authority activities required to conduct trial as per requirements of the Hospital/ Institute, IEC and Central Regulatory Guidelines. Activities are listed below.

- 4.1) Overseeing the clinical trials activity and ongoing clinical trial status directly or through representative.
- 4.2) Formation of an Independent Ethics Committee to oversee the clinical trial procedure.
- 4.3) **Uttar Pradesh University of Medical Sciences** will ensure the unbiased activity of Institutional Ethics Committee. No influence and decision- making activity should be proposed from Institute.
- 4.4) **Uttar Pradesh University of Medical Sciences** will allow access to pre- defined premises as required for specific Clinical Trial activity.
- 4.5) **Uttar Pradesh University of Medical Sciences** will provide facilities to conduct clinical trial at their facility like Diagnostic, Internet connection, study material storage area/space, with restricted access (Access for Helsinki Clinical Solutions Trial's staff), Investigational product storage area (2-8 degree).
Stationary, Computer/ Laptop and Printer including cartridges and printing papers shall be provided by Helsinki Clinical Solutions Sponsor at Uttar Pradesh University of Medical Sciences for studyspecific uses only.
- 4.6) To allow any regulatory audit by applicable regulatory authorities at any time to ensure compliance of any regulatory deficiency raised by such authorities in a reasonable period of time.
- 4.7) Ensuring access by HELSINKI CLINICAL SOLUTIONS PVT LTD SMO, monitors, auditors and regulatory authorities to the Principal Investigator and other project facilities, Hospital facilities including Pharmacy, ICU, OT, Diagnostic Centre , OPD and IPD, original study materials, drug records, subject records, case records and other records; subject to applicable laws and regulations; and providing appropriate working conditions for monitors, auditors and regulatory authorities to perform study related monitoring, audit and inspections with prior intimation only to access and review study documents.
Safe handling, storage, transportation and disposal of infectious materials and wastes involved in the Clinical Trial.
The Institution will allocate qualified and trained personnel (PI's, CO-I's only) and their fees shall be paid by Helsinki Clinical Solutions/ Sponsor, equipment, materials (except as otherwise may be provided herein) and facilities as are necessary or useful to perform the Clinical Trial.

- 5) Helsinki Clinical Solutions will be exclusive partner to Uttar Pradesh University of Medical Sciences for the purpose of conducting clinical trials at Uttar Pradesh University of Medical Sciences based on a detailed separate agreement with sponsor

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on mutually agreed terms.

6) Intellectual Property

6.1) Ownership: All intellectual property rights (IPR) arising from the collaboration, including but not limited to patents, copyrights, trademarks, trade secrets, and any other form of intellectual property, shall be owned as follows:

- **Pre-existing IP:** Each party shall retain ownership of any intellectual property they owned prior to this MOU or that they develop independently outside the scope of this collaboration.
- **Jointly Developed IP:** Any intellectual property jointly developed as a direct result of this collaboration shall be jointly owned by the SMO and the Institute. The ownership proportion will be agreed upon in subsequent agreements based on the level of contribution by each party.

6.2) Licensing: Each party grants the other a non-exclusive, royalty-free license to use, modify, and distribute the jointly developed IP solely for purposes related to the scope of this MOU, subject to any restrictions specified herein.

6.3) Confidentiality: The parties agree to keep confidential all information that is considered proprietary or confidential, as defined in the confidentiality agreements signed by both parties. This includes all data, know-how, results, or inventions that are not already in the public domain.

7) Commercialization: In the event that either party wishes to commercialize any jointly developed intellectual property, the parties agree to negotiate in good faith to enter into a separate agreement covering the terms and conditions of such commercialization.

8) Publication Rights: Both parties have the right to publish results from the collaboration. However, publications that disclose jointly developed IP must be reviewed and approved by both parties to protect proprietary information and intellectual property rights.

9) Financial Distribution

9.1) Helsinki Clinical Solutions PVT LTD will be responsible for the financial distribution to all parties including Uttar Pradesh University of Medical Sciences, Investigators, outside Diagnostics or Labs, any Third Parties and clinical trial staff. Helsinki Clinical Solutions Private Limited will coordinate, including with the Sponsor, and make necessary payment for all Clinical Trial Projects to all parties involved.

A Principal Investigator (PI) grant and pre-decided Institutional Over-Head [(Depending on the study Budget) excluding subject compensation, Subject travel reimbursement, Serious Adverse Event and Adverse Event reimbursement, hospitalization/Diagnostic charges] in any Study grant will go to the Hospital. This overhead will oblige the Hospital to provide Helsinki Clinical Solutions PVT LTD with the Clinical Research Room with optimum space (Minimum 100 Sqft), for IP and Pharmacokinetic (PK) sample storage facilities (-20- and -80-Degree Deep Freezer). The Pharmacokinetic (PK) Sample and Fridge Facilities will be provided/installed by Helsinki Clinical Solutions at Uttar Pradesh University of Medical Sciences, at their cost.


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Uttar Pradesh University of Medical Sciences
Safdar Enclave (U.P.)-206130



Other Hospital facilities will be used on basis of different study Protocols including but not limited to bed charges, various services, investigations, miscellaneous items etc.

10) Confidential Information

The Helsinki Clinical Solutions PVT LTD and Uttar Pradesh University of Medical Sciences shall not divulge to others during the term of this MOU period any technical information, market data or other confidential information received from the other party and will hold such information and data in confidence, except to the extent that it becomes generally available to the public or is received in good faith from a independent third party or is shown by written records to be in the recipient's possession prior to receipt from the other party.

11) Communication

All communication under this MOU shall be in writing and in English Language. All notices be served, either by hand delivery or by send by the same by registered post addressed to either party at the last known place of business or by facsimile/email and in providing the services of such notice, it shall be sufficient to show that the same has been received in person or property addressed by registered post.

12) Termination

1. This MOU shall not be terminated by either party without any prior notice, under the following Circumstances:

- i) Either one or both parties have becomes insolvent; or
- ii) Any party has been convicted of any crime which is likely to adversely affect the goodwill of other party, or
- iii) Any failure by the other party to comply with any of the provisions of the MOU; or
- iv) The Helsinki Clinical Solutions PVT LTD assigns the MOU to any third party without the consent in writing of Uttar Pradesh University of Medical Sciences , or
- v) If any of the representations of the statements etc. made by the Helsinki Clinical Solutions, in connection with this MOU are incorrect or are found to be incorrect.


2. The termination for reason stated above shall be without prejudice to other remedies that are available to the other party, under this MOU and/or Law.

Notwithstanding anything contained in this MOU, this MOU can be terminated by Uttar Pradesh University of Medical Sciences without assigning any reason, whatsoever, by giving 1 (one) month notice in writing to the Helsinki Clinical Solutions PVT LTD .

In event of MOU termination arising out of any terms stated above, Helsinki Clinical Solutions PVT LTD shall stop the performance of this MOU from the date of termination and hand over all the materials/facilities provided by Uttar Pradesh University of Medical Sciences. In such an event, Uttar Pradesh University of Medical Sciences shall get the payment against the services provided till the date of termination. No consequential damages shall be payable by Uttar Pradesh University of Medical Sciences to the Helsinki Clinical Solutions PVT LTD in the event of such termination.

13) Anti-Bribery Policy

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1. The Helsinki Clinical Solutions PVT LTD shall comply with the Anti-Bribery & Corruption ("AB&C") requirements as applicable to them. A, B & C is appended with this MOU.
2. Uttar Pradesh University of Medical Sciences shall have the right to initiate "Audit proceedings" against Helsinki Clinical Solutions PVT LTD to verify compliance with Anti-Bribery & Corruption requirements. Such audit may be carried out by Uttar Pradesh University of Medical Sciences or by a reputed agency to be appointed by Uttar Pradesh University of Medical Sciences at the sole discretion of Uttar Pradesh University of Medical Sciences. The Helsinki Clinical Solutions PVT LTD shall extend full cooperation for smooth completion of the audit.
3. Not with standing anything in this MOU, Uttar Pradesh University of Medical Science shall have the right to terminate the MOU forthwith in case, it is found that the Helsinki Clinical Solutions PVT LTD has failed to comply with A, B & C requirements

14) Arbitration

- 14.1) The Parties hereto shall endeavour to settle all disputes and differences relating to and/or arising out of the MOU amicably.
- 14.2) In the event of the Parties failing to resolve any dispute amicably the same shall be referred to Arbitration in accordance with the rules of Indian Arbitration and Conciliation Act, 1996 with all modifications and re-enactments thereto, as is prevalent in India. Each Party shall be entitled to nominate an Arbitrator and the two Arbitrators so nominated shall jointly nominate a third presiding Arbitrator. The Arbitrators shall give a reasoned award. The proper law for the purpose of Arbitration shall be Indian Laws.
- 14.3) The place of arbitration shall be **Saifai Etawah (U.P)**, India and the language of the arbitration shall be English.
- 14.4) The Parties further agree that any arbitration award shall be final and binding upon the Parties.
- 14.5) The Parties hereto agree that the Helsinki Clinical Solutions PVT LTD shall be obliged to carry out its obligations under the MOU even in the event a dispute is referred to Arbitration. It is further clarified that Uttar Pradesh University of Medical Sciences shall be entitled to get any sum or portion of Price, which has become due and payable, for any unfinished works/services or any subject matter under arbitration.

15) Governing Law and Jurisdiction

This Work Order shall be construed in accordance with and governed by the laws of India and in the event of any litigation the courts in **Saifai Etawah (U.P)**, India shall have exclusive jurisdiction



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SMO Name: Helsinki Clinical Solutions PVT LTD

Signature and date : Suraj Singh

Represented by (Name) : Mr. Suraj Singh

Title : Director
Helsinki Clinical Solutions Pvt Ltd
Address: 537 Kha/5/24 Faizullaganj Near Sita RamMandir
Lucknow -226020 Uttar Pradesh, India



Signature and date : Sunil Yadav

Represented by (Name) : Mr. Sunil Yadav

Title : Director
Helsinki Clinical Solutions Pvt Ltd
Address: 537 Kha/5/24 Faizullaganj Near Sita RamMandir
Lucknow -226020 Uttar Pradesh, India



Witness

Signature and date : Abhinav Verma

Represented by (Name) : Mr. Abhinav Verma

Title : Director

: Navkalyanam Social Development Foundation
Address: 59 Vishva Lamxi Nagar Ext. Krishna Nagar Mathura- 281004

Institutional Name : UTTAR PRADESH UNIVERSITY OF MEDICAL SCIENCE

Signature and date : Prabhat Kumar Singh

Represented by (Name): Dr. Prabhat Kumar Singh

Title : Vice Chancellor
Uttar Pradesh University of Medical Sciences
Safai, Etawah (U.P.)-206130

Witness

Signature and date : Dr. Kamal Pant

Represented by (Name) : Dr. Kamal Pant

Adv
11/09/24
KAMAL PANT
Advocate
Court Officer
Civil Court, AGRA
Notary Govt. Of India