Clinowell Research Services SMO

clinowellresearch@gmail.com
7666616212/7045778080
203, Plot no. 50 Om Mangalmurti chs , Sector 44, Seawoods Navi Mumbai Maharastra 400706

Memorandum of Understanding

This Agreement is made on **06 Apr 2024**, by and between **"Clinowell Research Services"** having its Office at 203, Plot no. 50 Om Mangalmurti chs , Sector 44, Seawoods Navi Mumbai Maharastra 400706, referred as a party- A **(here in after referred to as the "SMO")**

And

Mahatma Gandhi Mission (MGM) Medical College & Hospital, sector 1, Kamothe, Navi Mumbai, Maharashtra- 410209, India referred as a party-B **(here in after referred to as the "Institution")**

The two parties, in a spirit of business cooperation, agree to sign this contract and pledge to fulfil conscientiously all the obligations stipulated in it.

NOW, THEREFORE, in consideration of the promise and mutual covenants herein contained and for Other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, it is mutually covenanted and agreed by and between the parties here to as follows

MGM Medical College & Hospital appoints Clinowell Research Services As a site management organization on **Exclusive basis for period of 10 years w.e.f 08 Apr 2024** to 08 **Apr 2034. (Will be reviewed and updated accordingly**

Obligations of Clinowell Research Services:

Clinowell Research Services is a site management Organization based in NaviMumbai, Maharashtra providing end to end clinical research services to the Hospitals. Is and offers a complete range of Clinical Research in all therapeutic areas. We expertise in site Management Activities, Project Management, Medical Writing, Monitoring, Safety Reporting, Regulatory services, Potential Site selection, Faster patient Recruitment, Quality compliance & Maintenance, and Clinical Research Expertise in India

Clinowell Research Services is desirous of working with Hospital for the purpose of conducting ICH-GCP complaint phase 1.1V clinical trials for new mails for new drug & treatment.

Clinowell Research Services Shall play vital role in getting clinical trials to the hospital /Hospital from the sponsors and CRDs and execute them in Hospital

Clinowell Research Services will manage study Operations and study services as directed by study protocol for the duration of the clinical trial.

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Clinowell Research Services appoint project manager (PM) who will be responsible to coordinate and over-see the progress and management of CRC activities & trial ensure data quality, resolve screening, enrolment if any, follow up on past-monitoring action elements and study training investigator & sponsor/CRO on trial progress tor general issue as per needs and frequent discussion with

Clinowell Research Services will appoint Quality check (QC Experts) who will be responsible to ensure adherence to the protocol regulatory requirements record seeping and retention. Study co-ordination, project management and quality management will be done by Clinowell Research Services. Clinowell Research Services personnel, CRC PM. CC Experts will assist PI and the Site

Clinowell Research Services will bear all the administrative cost related to the various activities undertaken by PM, CRC or any other staff placed by Clinowell Research Services which includes telecommunication, travel cost, training cost at various centres across India or abroad.

Clinowell Research Services will be exclusively conducting/managing all trial at the Hospital during the tenure of this agreement. This agreement will last for 10 (ten) years and can be renewed further on mutual agreement.

Following activities will be carried out by appointed CRCs

1. Performing all the activities in strict adherence to the ICH-GCP guidelines, Schedule Y India GCP and Regulatory requirement
2. Preparation for site selection visit and Site Initiation Visit (SIV)
3. Communication & follow up with IRB/IEC Submission and Approval
4. Accurate and complete documentation of relevant EC documentation
5. Regulatory documents Collection
6. Patient Identification for assigned study form OPD or Hospital Database.
7. Maintenance and update of Trial Master File (TMF), site binders and relevant files
8. Preparation for site Monitoring Initiation Visit (SMV) and resolving all action items generated during Previous monitoring visits
9. Conduct Study according to International Conference of Harmonization (ICH) E6 and India Good Clinical Practice (GCP) regulation
10. Assisting Principal Investigator in administrating ICF and its procedures.
11. Ensure protocol & applicable regulatory guidelines compliance and adherence
12. Patient's pre-screening enrollment and recruitment
13. Preparing source notes and CRF filling
14. Communication with CRA/ Project Manager, PI, IRB/IEC, site for study updates.
15. Coordinate and schedule subject's regular follow up visits and procedures, maintain regular Telephonic contact with patients to preventing lost to follow up and missed visits.
16. Managing Clinical Trial Materials (CTM) maintenance, Accountability, distribution and logistics at site

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17. Coordinate all site-specific queries- medical, administrative, subject reimbursements and other study related activities
18. Reporting and coordinating all AE/SAEs according to their timelines as per regulatory norms
19. Filling up and maintaining trial related logs likes source documentation, drug dispensing logs, subject log, visit logs, Investigational product log, temperature log, SAE and EC communicational log.
20. Documentation of protocol deviation as appropriate and communicate any impacting subject safety to the ethics committee
21. Coordinate with central and local lab for logistics and sample flow
22. Attend study related meeting as appropriate
23. Preparing sites for Monitoring/Auditing visits coordinate close out visit and Archival at site
24. Any other required activities during the trials
25. Any other required activities during the trials
26. Communication with Investigators/Hospitals and conduct protocol specific feasibility
27. Other duties as requested by Clinowell Research Services Management

B. Hospital Permits

1. Hospital will give the space and required facilities to appointed CRC & Clinowell Research Services in order to perform clinical trials activities under respected PI.
2. Hospital will allow Clinowell Research services and Sponsors of Cllinical trials to acces the facility to verify source documents
3. Hospital will allow Clinowell Research Services to bring Sponsors of clinical trials to meet with PI/SITE representatives at a mutually convenient time.
4. Hospital shall permit Clinowell Research Services to exclusively manage all clinical trial commenced by Clinowell Research Services

C. Term of Agreement

The term of this Agreement shall be for a period of 10 years commencing on the effective date 8th April 2024. However, this Agreement shall be reviewed annually by both parties if needed.

D. Relationship of the parties

1. . Hospital and Clinowell Research Services are independent parties. Both parties agree that their relationship is that of an independent contractor and not employer and employee.
2. Neither party shall have express or implied rights nor authority to assume or create any obligation or responsibility on behalf of or in the name of the other party by reason of this Agreement, except as provided in this Agreement.

E. GCP, ICH and CFR compliance

Hospital agrees to comply with International Conference of Harmonization & Good Clinical Practices (ICH-GCP) and all India regulations, CDSCO requirement and circulars there under.

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F. Confidentiality

1. the parties here recognize and agree that due to the complex and competitive nature of the business, the confidential of information concerning both parties is of critical importance. Either party shall not, either during or after the term of this Agreement, disclose to any third party any confidential information and all Information or information relative to the work or the business of either party without the written consent of either party Clinowell Research Services agrees that it shall not during, or at any time after the termination of this Agreement, directly or indirectly disclose or use any information for any reason whatever, without the prior written consent of SITE.
2. 2. Hospital shall not disclose to any third party any and information about new studies received from Clinowell Research Services.

G. Indemnification

Hospital shall indemnify and hold harmless Clinowell Research Services against any losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of any act or omission by SITE, its agents, directors or employees, Clinowell Research Services shall indemnify and hold harmless hospital against any and all losses, claims, liabilities, damages and expenses of any nature, directly or indirectly arising out of act or commission by Clinowell Research Services, its agents, directors, or employees. In no event will either party be required to indemnify or hold harmless the other's negligence or gross negligence.

H. Compensation and Agreement

1. The Hospital, principal Investigator, Clinowell Research Services and Sponsor and/or CRO will enter into a quadripartite clinical trial agreement before/at the time of placement of each trial at the Hospital
2. All feasibilities and payments shall be routed through Clinowell Research Services and pricing while bidding for the trial shall be discussed mutually and final correspondence with the Sponsor/CRO also would be handled by Clinowell Research Services for smooth and hassle-free finalization of Clinical Trial Agreements
3. Getting payment from sponsor and giving to Hospital and/or Investigator is the responsibility of Clinowell Research Services.
4. Clinowell Research Services will be payee name for all trial related payment.
5. All payment shall be due and payable to the hospital on actual work i.e. number of subject randomized or visits completed.
6. The payment of remuneration shall be after deduction of all taxes under applicable laws.
7. All invoices will be requested from the hospital for study payment and all study related payment will be done to MGM Medical College & Hospital, in a period of 45 working days after receiving the payment from the sponsor/CRO.
8. **The details of study budget sharing in INR are as follow:**
    - **100%** study payment will be paid to Clinowell Research Services from Sponsor/ CRO for each study.
    - **60%** study payment will be paid to Hospital/Principal Investigator from Clinowell Clinical Research and Services

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- **40%** study payment fees will be paid to Clinowell Research Services.
- **100%** CRC fees will be paid to Clinowell Clinical Research and Services from sponsor/CRO.

- Subject Travel reimbursement amount will be paid to Hospital from Clinowell Research Services.
- Additional 30% Institutional overhead will be paid from Clinowell Research Services received from sponsor/CRO.
- Clinowell Research Services will pay Lab Cost, subject Hospitalization, SAE Medical Management charges at actual basis to Hospital/Principal Investigator received from sponsor/CRO.

(Note: Hospital/Principal Investigator should provide dedicated working space, Electricity, Internet connection facility to our study team.)

I. Termination of Agreement

1. This Agreement shall be terminated by mutual agreement by giving sixty (60) days prior written notice by either party after the completion of any ongoing trials.

J. Permission to use personal Information or Statement

For good consideration, the undersigned authorizes SMO and its assigns to use, publish or reprint in whole or part any basic information about my identity, practice, and participation in clinical research including any specific details of my clinical research that do not conflict with a previously contacted privacy agreement.

The two parties shall consult with each other and medicate any disputes which may arise about the contact. If all attempts fail the two parties can appeal to the organization of arbitration in judicial court of the state of Maharashtra India.

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1. Authorized Signature	2. Authorized Signature
Signature : [signature]	Signature : [signature] 3.5.24
Date: 3/5/24	Date:
Name: Dr. Nilchandani	Name: Dr Navsheli
Title: Prof & HOD of Pharmacology	Title:
Hospital Name: MGM Hospital & MC	Hospital Name: MGM Hospital & MC Navi Mumbai
Add: Mahatma Gandhi Mission(MGM) Medical college and Hospital Sector 1 Kamothe Navi Mumbai Maharashtra 410209	Add: Mahatma Gandhi Mission(MGM) Medical college and Hospital Sector 1 Kamothe Navi Mumbai Maharashtra 410209
Stamp: Prof. & Head Pharmacology M.G.M. Medical College, Kamothe, Navi Mumbai-410209	Stamp: Dean MGM Medical College & Hospital Kamothe, Navi Mumbai-410209

3. Authorized Signature	
Signature : [signature]	MGM MEDICAL COLLEGE NAVI MUMBAI 410209 KAMOTHE
Date: 3/5/24	
Name: Rohan Shetty	
Title: Director	
Clinowell Research Services Add: 203, Omnangal Murti Plot no.50 Sector 44Seawoods Navi Mumbai Maharastra 400706	
Stamp: Clinowell Research Services SMO	