



पश्चिमबङ्ग पश्चिम बंगाल WEST BENGAL

AP 018972

Service Agreement

This Service Agreement ("The Agreement") is made and executed on _____

Amongst:

Infoclin Consultancy; a company incorporated and registered under the Companies Act, 1956 and deemed to be existing under the Companies Act, 2013 with CIN # U24110TG1989PLC009723 and having its registered office 77/1Y/1, Ibrahimpur Road, Jadavpur, Kolkata-700032, West Bengal, India, (hereinafter called "SMO" which expression unless repugnant to the subject or context therein shall mean and include its assignees, affiliates, employees, subsidiaries, nominees, agents and successors-in-interest) of the First Part;

And

Mahatma Gandhi Mission's Medical College, a Medical College & Hospital situated at MGM Medical College, Sector 1, Kamothe, Navi Mumbai – 410209, Maharashtra, India (hereinafter referred to as "Institution", which expression shall unless repugnant to the context or meaning thereof shall mean and include its successors and permitted assigns) of the Second Part;

WHEREAS:

- A. The Institution is a Hospital and Research Institute based at Navi Mumbai.
- B. SMO represents that it has an expertise in providing Clinical Trial Services and is desirous of providing its services to the Institution for the Studies undertaken.
- B. The Institution has agreed to appoint SMO to provide the necessary professional services on the terms and conditions mentioned hereinafter.

NOW THIS AGREEMENT WITNESSETH AND IT IS HEREBY AGREED BY AND BETWEEN THE PARTIES HERETO AS FOLLOWS:

Article 1 : APPOINTMENT & SCOPE OF SERVICES

The Institution hereby appoints the SMO and SMO hereby accepts its appointment for providing professional services to the Institution relating to Clinical Trial Services for the Studies conducted at Institution premises as described hereunder (hereinafter referred to as "Services"):

- 1.1 The SMO shall assist Principal Investigator (PI) where authorized; in overall management of all site related activities as per the applicable ICH GCP, Country Regulatory Guidelines and study protocol.
- 1.2 The SMO will be responsible for scheduling patient visits, support Principal Investigator appointed on the Studies conducted at the Institution in subject screening and enrolment, timely completion of CRF data entry and query resolution, maintaining the clinical trial related documents in site file, preparing and assisting in Site feasibility, Site Initiation, Site Monitoring, Site Close out Visits and Quality Audit, Inspections Sponsor Visits etc.
- 1.3 The SMO shall coordinate submissions to Ethics Committee for Protocol, Adverse Events/Serious Adverse Events, periodic study status for review and maintaining all relevant communications. Transcribing source documents if required under supervision of PI/designated personnel, maintaining records of IP- Dispensing, Storage condition- Temperature and other ancillary supplies.
- 1.4 The SMO shall ensure to organize lab sample pick-up, coordinating with local laboratories (if applicable).
- 1.5 The SMO shall manage the payments for smooth conduct of study, releasing payments to laboratories and Site CRC salary as well as IOH.
- 1.6 The SMO shall designate a Study coordinator working under Principal Investigator's supervision.
- 1.7 The Medical Management, administration of IP and assessment of outcome will be the responsibility of Principal Investigator.
- 1.8 The SMO shall be a signatory to the Clinical Trial Agreements executed with Study Sponsors for the purpose of remittance of charges related to services provided for the Study.

Article 2 : DUTIES AND RESPONSIBILITIES OF SERVICE PROVIDER

- 2.1 SMO undertakes to safeguard the interests of the Institution in every respect and, in particular, to do everything in its power and do its best endeavor to perform its obligations under this Agreement with all due care and diligence. The employees and the personnel allocated by SMO to perform the Services shall exhibit highest professional and ethical standards.
- 2.2 SMO shall ensure that it is not under any contractual or statutory or other obligation or restriction which is inconsistent with its obligations under this Agreement.
- 2.3 SMO shall intimate the Institute by writing at least one month in advance if SMO desires to associate himself with any competitor of the Institute.
- 2.4 The Institute and/or its affiliate retain the right to audit the SMO's records relating to the Services and any financial records and/or payments issued by SMO on behalf of the Institute. Such audit will require reasonable prior written notice by the Institution.

Article 3 : FEES

In consideration of the due performance of its obligations under this Agreement, Institution agrees to receive research fees and overhead charges as per the Institute recommendations (if any) from the SMO. The fees shall be paid subject to deduction of tax at source at applicable rates under Income Tax Act, 1961 as amended from time to time. Any reimbursement of charges without original receipts/ bills/ supporting documents will be liable to deduction of tax at applicable rates under Income Tax Act, 1961 as amended from time to time.

SMO shall bear and pay all applicable taxes including Goods and Services Tax (GST) and other applicable taxes, if any. SMO shall ensure timely raising of tax invoice at or before the time of supply of service to the Sponsor/CRO.

SMO will raise the invoice quarterly basis (or as mentioned in the respective study agreement) to the Sponsor/CRO and pay to the respective parties mentioned in the CTA and other parties such as local lab, Ethics Committee, Supporting Staff, Logistics or transport vendor if any.

Article 4 : INDEMNITY

4.1 SMO covenants to observe and comply with all Central, State and Local regulations and all health and safety precautions in respect of the Services provided under this Agreement. SMO shall at all times comply with all applicable Laws and the Rules /Regulations / notifications / circulars issued from time to time in relation to the subject matter of this Agreement (all collectively referred as "Applicable Laws").

4.2 SMO is fully informed and aware of the fact that it is a criminal offence to bribe a public official in order to obtain business or other improper advantages in the conduct of business. SMO undertakes not to use bribing in order to obtain said business or other improper advantages. Institution reserves the right to terminate this Agreement without prior notice with immediate effect if it has reasonable grounds to believe that SMO is responsible for breach of this undertaking.

4.3 SMO shall indemnify and keep indemnified the Institution at all times from and against all actions, suits, proceedings, claims, demands, liabilities, penalties, losses costs and expenses of whatsoever nature made or suffered or incurred by the Institution whether by reason of or by virtue of (i) any non-performance or non-observance or non-compliance by SMO of any terms and conditions of this Agreement or of any of the Applicable Laws; (ii) any public liability claims, environmental damage and industrial accidents or (iii) willful misconduct or negligent acts or omissions on the part of SMO or its agents/ representatives.

Article 5 : TERM AND TERMINATION

5.1 Subject to the provisions of Articles 5.2 and 5.3, this Agreement shall remain in full force and effect for a period of **five (05) years** effective from _____, 2023 till _____.

5.2 Either party may terminate this Agreement at any time during its term by giving 30 days' prior written notice to that effect to the other party without being required to assign any reasons and without being liable to pay any compensation whatsoever for such earlier termination. However, Institution shall have the option to terminate this Agreement at any time with immediate effect without being required to assign any reasons and without being liable to pay any compensation whatsoever for such forthwith termination. On termination or expiration of this Agreement, SMO shall be required to return to the Institution all the papers and any assets and property of the Institution lying in the possession of SMO at the time of termination.

5.3 Notwithstanding anything contained hereinabove, Institution may at its option and by written notice to SMO terminate this Agreement forthwith in its entirety in any of the following cases:

- (i) If SMO applies for or is adjudicated bankrupt or a receiver is appointed to direct his business;
- (ii) If SMO fails or refuses to perform or fulfil any obligation, term or condition of the Agreement, Institution shall be entitled to send to SMO, a written notice notifying it of breach/failure and requiring the SMO to rectify/remedy the breach/failure within a period of 15 days from the date of receipt of notice. If the breach/failure is not rectified/remedied within 15 days, this Agreement shall automatically stand terminated and be cancelled without any further notice and without any obligation to pay any compensation to SMO.

5.4 The expiry or earlier termination of this Agreement shall not absolve either party from any liability which either party may have incurred under or by virtue of this Agreement prior to such expiration or termination.

5.5 Failure by either party to take any action or enforce its right of termination of this Agreement following any breach of any terms or conditions thereof, shall not be deemed to be a waiver of the rights accruing to the other by such breach or in continuation thereof or any future breach or non-compliance.

Article 6: MISCELLANEOUS

6.1 FORCE MAJEURE

Neither party to this Agreement shall be liable for failure to perform any of its obligations hereunder for reasons beyond its reasonable control including but not limited to acts of God, war, fires, floods, civil commotion, riots, earthquake, terrorism, strikes, lockouts not caused by the negligence or willful misconduct of the parties. The COMPANY may at its sole discretion terminate the Agreement forthwith if the conditions of force majeure continue for a period of more than one month.

6.2 INVALIDITY

Should one or more of the terms in the Agreement is construed to be or becomes entirely or partly inoperative or illegal ("ineffective term"), this shall not affect the validity of the remaining terms of this Agreement. In such case, the ineffective term(s) shall be replaced by mutually agreed valid and legal term(s) achieving to the extent possible the economic purpose of the ineffective term.

6.3 DELEGATION / ASSIGNMENT

SMO shall not be entitled to delegate or assign any of its duties and obligations under this Agreement to any third party without obtaining prior permission of the Institution to that effect. The Institution shall not be liable for any claims or dues of such representative/agent/associate. Similarly, the Institution will not take any responsibility for any sort of dispute or litigations between SMO and its appointed representative/agent/ associate.

The Institution is entitled to assign this Agreement or any of its rights, obligations or beneficial interests hereunder in whole or in part to any of its affiliate without obtaining the prior written consent from and after having given written notice thereof to SMO.

6.4 NOTICE

All approvals, consents, notices or other communication provided for in this Agreement shall be in writing in the English language and shall be delivered personally or sent by certified or registered airmail or courier or transmitted by telefax to their respective addresses as mentioned hereinabove or to such other address as may be subsequently indicated by the parties.

6.5 WRITTEN FORM & AMENDMENTS

This Agreement constitutes the entire understanding between the parties and supersedes any previous agreements in this regard.

Any amendments or modifications of this Agreement shall only be valid when in writing and signed by both parties. There are no representations, understandings or Agreements, oral or written, which are not included herein. The terms and conditions contained in this Agreement shall govern the transaction contemplated herein to the entire exclusion of any other terms or conditions contained in any purchase order, order acknowledgment, invoice, bill of lading or other transactional document) unless otherwise agreed herein. No amendment to this Agreement shall be effected by the acknowledgement or acceptance of purchase orders, shipping instruction forms, order confirmation forms or any other documents between the parties containing terms or conditions different from this Agreement.

6.6 GENERAL

- The execution of this Agreement and the performance of any of the provisions hereof shall not be construed to constitute or be deemed to establish a joint-venture or partnership or an agency (relationship of principal & agent) between the parties hereto.
- Failure by either party, at any time, to insist upon the strict compliance by the other party with the terms of this Agreement shall in no event be deemed as a waiver of its right to require strict compliance

with all terms hereof in any subsequent instance nor shall such failure prejudice any right of such party to terminate this Agreement and/or to pursue its other remedies.

- The headings of the several sections hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several sections hereof.
- All Appendixes/Annexures attached hereto or referred to in this Agreement are hereby incorporated and shall form an integral part hereof. Any capitalized terms used in these Appendixes/Annexures but not otherwise defined therein shall have the meaning as defined in this Agreement.

ARTICLE 7: DATA PROTECTION

7.1 SMO shall comply with obligations under all applicable data protection and privacy laws relating to Personal Data and/or Sensitive Personal Data including but not limited to the Information Technology Act, 2000 and rules framed under the Information Technology Act, 2000 (including Information Technology (Reasonable security practices and procedures and sensitive personal data or information Rules, 2011) or any other applicable statutory provisions. For the purposes of this clause Personal Data and Sensitive Personal Data shall have the meanings ascribed to it under the Information Technology (Reasonable security practices and procedures and sensitive personal data or information) Rules, 2011 as applicable and amended from time to time.

7.2 SMO confirms that in performing the Services if SMO has to pass certain Personal Data within its network of offices/affiliates and to certain other authorized representatives who will be subject to appropriate data protection standards. Irrespective of where SMO receives or holds Personal Data on Institution's behalf, SMO confirms that, acting as data processor SMO will take appropriate technical, physical and organizational/administrative measures to protect that Personal Data against accidental or unlawful destruction or accidental loss or unauthorized alteration, disclosure or access. SMO will use that Personal Data only for the purposes of providing Services as stated herein.

Article 8: APPLICABLE LAWS AND ARBITRATION

8.1 This Agreement shall be construed and governed in all respects by the **laws of India**.

8.2 All disputes or differences whatsoever arising between the parties hereto out of or relating to the construction, meaning or operation or effect of this Agreement or breach thereof shall be settled by arbitration in accordance with the Arbitration and Conciliation Act, 1996 and the award made in pursuance thereof shall be final and binding on the parties. The arbitration shall be conducted in English by a sole arbitrator and shall be governed by laws of India.

Article 9: STUDY GRANT/REMUNARATION

As per Annexure-A

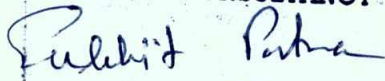
[Signature page follows]

IN WITNESS WHEREOF, the parties hereto have executed this Agreement, the day and the year first hereinabove written.

SIGNED & DELIVERED for

and on behalf of the SMO

by its authorized signatory

INFOCLIN CONSULTANCY

Proprietor

Name: Subhajit Patra

Title: Proprietor

Witness:

.....
Name:

Title:

SIGNED & DELIVERED for

and on behalf of Institute

by its authorized signatory


Dean

MGM Medical College & Hospital
Kamathyavi Mumbai-410209

Name: Dr. G.S. Narshetty

Title: Director/Head of Institute

24/01/2023

Witness:



.....
Name: Dr. P.N. Khandelwal

**Title: Professor & Head of
Pharmacology**

Annexure-A

Revenue sharing: Revenue sharing for clinical trials will be budgeted based on per patient costs. The revenue sharing for each study will be based on the model described below. **Clinical Trial Agreement (CTA)** will be mutually agreed and executed prior to the study initiation in consultation with Sponsor, Institute & Investigator.

• Particulars	• %
• Per patient cost	
• Institution Overhead	• 30%
• PI Fees	• Negotiations between Institution & SMO
• Co-I Fees	• Negotiations between Institution & SMO
• Research staff fees (CRC, Pharmacist, other staffs)	• Infoclin Consultancy
• Site Management Organization	• 40%
• Lab & Hospital charges	• As per actuals will be paid by Infoclin Consultancy

***Payee will be Infoclin Consultancy directly from Sponsor/CRO and will be responsible for disbursement to all the above-mentioned stakeholders.**

Payee Details:

Payee Name: Infoclin Consultancy

A/c no-50200044328167

Bank-HDFC

IFSC-HDFC0001231

Address-Jadavpur

PAN-ARYPP8894N

GST-19ARYPP8894N2Z0

Note: Any changes in above mentioned information will be notified to the concern authority on priority.