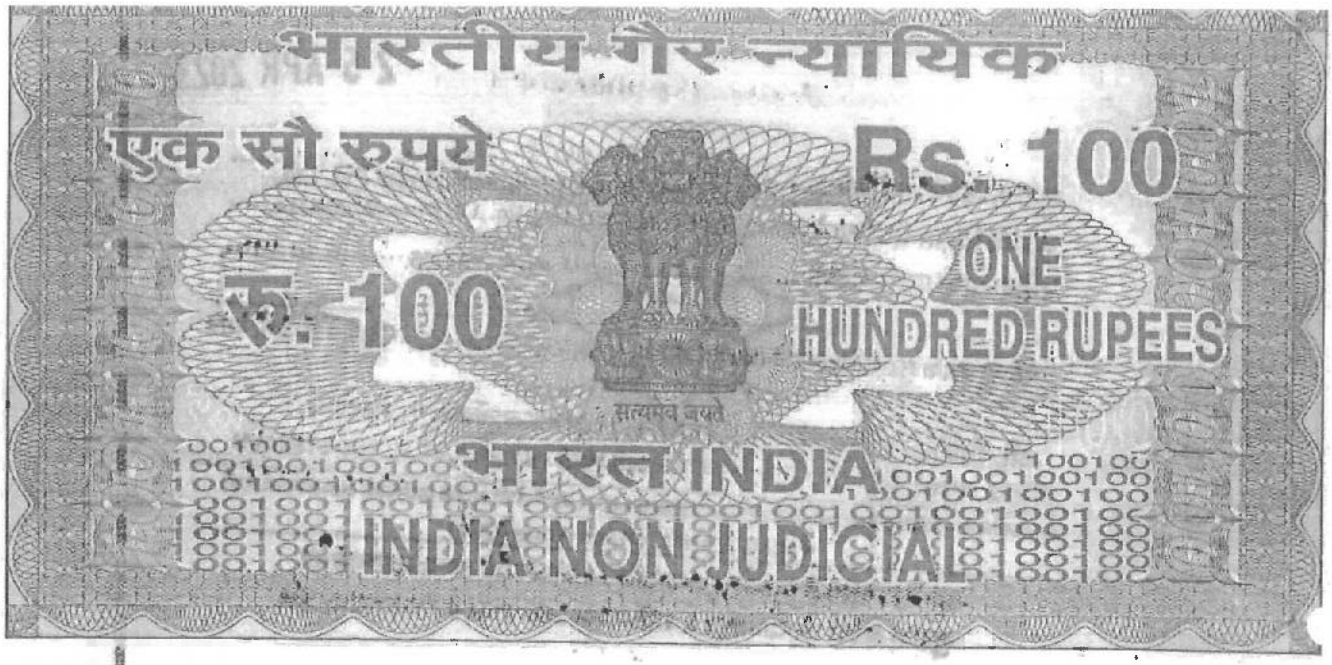


महाराष्ट्र MAHARASHTRA ◐ 2022 ◐ 47AA 927961

जिल्हा कोषागार कार्यालय, ठाणे
17 APR 2023
मुद्रांक प्रमाणक लिपीक / लिपीक

25 APR 2023

CLINICAL TRIAL AGREEMENT

THIS AGREEMENT IS MADE AND ENTERED INTO BY AND BETWEEN:

- **LABCORP DEVELOPMENT PVT. LTD.** a clinical research organization incorporated under the laws of India having its registered office at Building No. 1, Unit 601 Raheja Mindspace, Juinagar, MIDC Industrial area, shiravane Nerul Navi Mumbai 400706, Maharastra. engaged by the Sponsor for the purpose of assisting the Sponsor in administration, management and carrying out the clinical trials/studies in India (hereinafter referred to as the **"CRO"**);

AND:

- **Manipal Center of Clinical Research,** MAHE, having its Registered Office at Mezzanine Floor of old KMC Library Building, near KMC Dean Office, Kasturba Hospital, Manipal 576104 acting through its authorized signatory, Dr. B.S.Satish Rao , Director being authorised to sign this Agreement (hereinafter referred to as the "Institution" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns)
  (hereinafter referred to as the **"Institution"**)

- and -

- **Dr Veena Kamath**, Professor Department of Community Medicine, Kasturba Medical College, Manipal Academy of Higher Education having its registered office at manipal.edu Building, Madhavanagar, Manipal 576104, Karnataka (hereinafter referred to as the "**Principal Investigator**")

With each of the parties collectively or individually referred to as "Party" or "Parties"

AND RELATES TO THE FOLLOWING CLINICAL TRIAL:

Immunogenicity and Safety of an Investigational Quadrivalent Meningococcal Conjugate Vaccine when Administered Concomitantly with Routine Pediatric Vaccines in Healthy Infants and Toddlers in India and the Republic of South Africa
Code: MEQ00064

(hereinafter defined as the "**Clinical Trial**")

PREAMBLE

WHEREAS, Sanofi Pasteur Inc., having address at Discovery Drive, Swiftwater, PA 18370-0187,USA is the Sponsor, as defined in the ICH guidelines, of the above mentioned Clinical Trial and therefore wishes to perform this Clinical Trial; and

WHEREAS, the Institution and the Principal Investigator have capable personnel and the necessary expertise to organize and perform clinical trials in the field of vaccines; and

WHEREAS, the Institution and the Principal Investigator are willing to organize, conduct and perform this Clinical Trial on behalf of the Sponsor; and

WHEREAS, the Principal Investigator is responsible for the scientific supervision and direction of the Clinical Trial; and

WHEREAS, Sponsor has engaged Labcorp Development Pty. Ltd. ("CRO") and its affiliates as its clinical research organization for the purpose of assisting Sponsor in the administration, management and oversight of the Clinical Trial.

NOW THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each Party), the Parties hereby agree as follows:

ARTICLE 1 – DEFINITIONS

For the purposes of this Agreement the following words and phrases shall have the following meanings:

- "**Additional Personnel**" means any any individual or entity performing the Clinical Trial on behalf of the Principal Investigator and the Institution, including but not limited to co-investigator and/or any of Institution's employees, post-doctoral fellows, students and/or technical staff, associates, sub-investigators, biologists, assistants and nurses who may be involved in the Clinical Trial, other than the Principal Investigator. The Principal Investigator and the Institution shall cause the Additional Personnel to comply with the Agreement and shall be liable for any failure on the part of the Collaborators to comply with the Agreement.

- **"Affiliate(s)"** means, with respect to Sanofi Pasteur, (i) any Person of which the securities or other ownership interests representing fifty per cent (50%) or more of the equity or fifty per cent (50%) or more of the ordinary voting power or fifty per cent (50%) or more of the general partnership interest are, at the time such determination is being made, owned, Controlled or held, directly or indirectly, by Sanofi Pasteur, or (ii) any other Person which, at the time such determination is being made, is Controlling or under common Control with Sanofi Pasteur.

- **"Agreement"** means this Clinical Trial Agreement, all amendments and supplements to this Agreement and all schedules to this Agreement.

- **"Case Report Form" or "CRF"** means the form provided in the Protocol to be completed and returned to the Sponsor for each Subject participating in the Clinical Trial. This form might be (or not) an electronic form ("e-CRF") accessible through a web link which shall be communicated by the Sponsor to the Institution and the Principal Investigator. If the electronic data capture is used for the purpose of the Clinical Trial, then "Case Book" shall have the same meaning.

- **"Clinical Trial"** means the clinical trial above-mentioned in the Preamble of the Agreement.

- **"Confidential Information"** means any and all information disclosed or provided by the Sponsor (including through its CRO) or its Affiliates related to this Agreement or produced during the Clinical Trial by the Principal Investigator and any Additional Personnel, in any form, which is of a confidential and proprietary nature, including but not limited to any and all preclinical, clinical or formulation data, investigator brochures, case reports, source documentation, study protocols and SOPs (as defined hereafter). Results are Confidential Information.

- **"Control"** means, whether used as a noun or verb, the possession, directly or indirectly, of the power to direct, or cause the direction of, the management or policies of a Person, whether through the ownership of voting securities, by contract or otherwise.

- **"Enrollment Cap"** means that the Sponsor reserves the right to limit enrollment by giving written notice, or by giving notice by telephone followed by written notice, to the Institution and the Principal Investigator to cease further enrollment of Subjects in the Clinical Trial.

- **"GCP"** means the Good Clinical Practice, which is an international ethical and scientific quality standard, provide by the International Conference on Harmonization ("ICH"), for designing, conducting, recording and reporting trials that involve the participation of human subjects.

- **"Health Authorities"** means applicable health authorities, either governmental, regulatory or otherwise, including but not limited to the United States Food and Drug Administration ("FDA"), the European Medicines Agency ("EMA"), the French *"Agence Nationale de Sécurité des Médicaments et des produits de santé"* ("ANSM") and Health Canada.

- **"IEC/IRB"** means the Independent Ethics Committee / Institutional Review Board responsible for review and approval of the Protocol.

- **"Results"** means any inventions, discoveries, or innovations, products, processes, data, materials, documents, reports, results, Trial Site Data, formulations, technologies and compounds, whether patentable or not, arising, directly or indirectly, out of the performance of the Clinical Trial under this Agreement or using Clinical Trial funds or otherwise arising out of use of the Investigational Product as well as any intellectual property rights including any industrial property rights deriving therefrom.

- **"Investigational Product"** means the Sponsor's product Meningococcal Polysaccharide (Serogroups A, C, Y, and W) Tetanus Toxoid Conjugate Vaccine to be used in the Clinical Trial in accordance with the Protocol.

- **"Person"** means an individual, partnership, joint venture, trustee, trust, corporation, unincorporated organization or other entity or a government, state or agency, or political subdivision thereof.

- **"Personal Data"** means any and all data concerning an individual participating in the Clinical Trial whether as a Subject or as an investigator.

- **"Principal Investigator"** means the person who is named on the head of the Agreement and corresponds to the person who is named *"Investigator"* or *"Principal Investigator"* in the Protocol as defined in accordance with the ICH guidelines.

- **"Privacy Rules"** means any national and international standards of practice, including but not limited to the EU Data Protection Directive 95/46/EC (European Parliament) and the French Law Number 78-17 of 6 January 1978 referred to as the *"loi Informatique et Libertés"*, such as modified by the French law n°2004-801 of 6th August 2004, establishing a category of information regarding patients or Subjects, which may be used or disclosed to others in certain circumstances or under certain conditions.

- **"Processing"** means, in accordance with applicable rules and regulations, any operation or set of operations which is performed upon the Personal Data, whether or not by automatic means, such as collection, recording, organization, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction.

- **"Protocol"** means the last approved version of the protocol including any and all amendments, which will be considered as attached hereto upon completion, and is incorporated herein by reference. It is agreed that this Agreement shall be governed by the most recent version of the Protocol, and should this Agreement be executed prior to complete finalization of the Protocol, the last-dated version thereof will be considered to be incorporated by reference in place of any prior versions. In the event that there is a conflict between the terms of the Protocol and the terms of this Agreement, the terms of this Agreement will govern with respect to contract terms and conditions but the Protocol will govern with respect to the conduct of the Clinical Trial and with respect to serving the best interests of patient welfare.

- **"Public Presentation"** means, collectively or individually, any kind of disclosure in whatever form or support such as drafts of abstracts and/or manuscripts for publication (including slides and texts of oral or other public presentations).

- **"Related Person(s)"** means any Person(s) having a relationship with a Party whether as an employee, Additional Personnel, Affiliate, agent or representative.

- **"Subject"** means an individual who is selected in accordance with the terms of the Protocol to participate in the Clinical Trial.

- **"SOP(s)"** means the Sponsor's Standard Operating Procedure(s) as amended from time to time to be used for the purpose of the Clinical Trial.

- **"Trial Product"** means collectively the Investigational Product and any other product as concomitant or control products, as further detailed in the Protocol.

- "Trial Site" means the location(s) where the Clinical Trial activities are conducted by the Institution and/or the Principal Investigator.

- "Trial Site Data" shall mean the data obtained by the Principal Investigator and the Institution as a result of the performance of the Clinical Trial in the Trial Site.

ARTICLE 2 – SCOPE OF WORK

The Institution and the Principal Investigator shall conduct the Clinical Trial relating to the Investigational Product in accordance with the Protocol. Creation and modification of the Protocol shall be the sole responsibility of the Sponsor.

ARTICLE 3 - CLINICAL TRIAL APPROVALS

3.1 The Principal Investigator shall be responsible for having the Clinical Trial documents (such as Protocol, Sponsor informed consent form and/or site inform consent form, any advertisement(s) pertaining to the recruitment of Subjects in the Clinical Trial) approved by the IEC / IRB prior to the beginning of the Clinical Trial.

3.2 In the event the IEC/IRB requests that changes be made to the Protocol such as the informed consent form template, the Institution shall immediately inform Sponsor of the IEC/IRB's request in detail. Any modifications to the Protocol including the informed consent form template must be approved by the Sponsor before being implemented by Institution.

3.3 The Institution and the Principal Investigator shall not modify the Protocol without the prior written approval of the Sponsor.

3.4 The Sponsor shall be responsible, if applicable, for the submission of any investigational new drug (IND) application resulting from the Clinical Trial and the Parties agree to fully cooperate as necessary with the Sponsor and at Sponsor's expense, in the completion and filing of the IND.

ARTICLE 4 – ORGANIZATION OF THE CLINICAL TRIAL

4.1 The estimated time schedule of the Clinical Trial described in detail in the Protocol may be summarized as follows:

- Planned starting of the Subjects' recruiting process: **June 2023**
- Planned final report: **Q2 2025**

It is understood that the effective beginning of the Clinical Trial is dependent upon timely approval of key Clinical Trial documents and/or performance of preparatory activities by Sponsor and/or third parties (e.g. IEC/IRB or Health Authority) and/or availability of the Trial Product. Thus, any delay in this approval and/or the performance of those preparatory activities and/or availability of the Trial Product may have a cascade effect on the Clinical Trial initiation. The Principal Investigator and the Institution agree that any such delay shall not entitle them to any compensation or remedy.

4.2 It is estimated that the Principal Investigator participating in this Clinical Trial will enroll a target number of **46** Subjects in **6 MONTHS** in Cohort I and target number of **30** Subjects in **4 MONTHS** in Cohort II starting

from the first Subject recruited in the Clinical Trial. This target of recruitment can be modified only upon written agreement of the Sponsor.

If not achieved, the Sponsor might decide to reallocate the Subjects enrollment to another site and in this case, the rules set forth in section 4.2.1 of the Agreement will be applied.

For a multi-center Clinical Trial, the Sponsor may amend the number of Subjects to be recruited by the Principal Investigator and in this case the rules set forth in sections 4.2.1 and/or 4.2.2 of the Agreement will be applied.

4.2.1 if in the reasonable opinion of the Sponsor, recruitment of Subjects is proceeding at the Trial Site at a rate below than the rate required to enable the relevant timelines to be met, the Sponsor may by written notice (e-mail or letter) to the Institution require recruitment at the Trial Site to cease and the terms of the Agreement shall relate thereafter to the number of Subjects who have been accepted for treatment in the Clinical Trial at the date of such notice; or

4.2.2 if recruitment of Subjects is proceeding at the Trial Site a rate above than the rate required to meet the relevant timelines, the Sponsor may with the agreement of the Institution increase the number of Subjects to be recruited by the Principal Investigator.

For a multi-center Clinical Trial having a competitive enrollment, the Sponsor reserves the right to request the Principal Investigator to limit recruitment of further Subjects or cease the recruitment, notably if the global recruitment target for the Clinical Trial has been reached. In such event, the Sponsor will inform the Principal Investigator on interrupting the recruitment of any Subject who has not yet signed the informed consent form.

The Principal Investigator shall upon receipt of a written notice (e-mail or letter) for stopping recruitment, stop immediately further recruitment of Subjects. Payment shall only be made according to the number of Subjects recruited up to the date of receipt of the said notice of stopping. The Sponsor will neither take any responsibility, nor make any payment for the Subjects recruited after this date.

The Institution acknowledges that it is able to perform a competitive enrollment and has a capacity of recruitment of **46-(Forty Six)** Subjects within a period of **6 (Six)** months in Cohort I and **30-(Thirty)** Subjects within a period of **4 (Four)** months in cohort II.

4.3 It is agreed among the Parties that the Principal Investigator and the Additional Personnel shall attend the mandatory training session(s) organized in relation with the Clinical Trial.

The Parties agree to inform each other of the Clinical Trial performance and therefore agree to organize and to participate in meetings related thereto.

The Principal Investigator agrees to take the necessary time to meet with any person duly appointed by the Sponsor for monitoring the Clinical Trial.

4.4 If, at any time, Institution or Principal Investigator have reason to believe that the Clinical Trial will not be initiated or completed as per the schedule initially anticipated and agreed upon by the Parties, Sponsor will be advised immediately, in writing, of the reason(s) and length of additional time required to commence or complete work, and this Agreement may be terminated by Sponsor as provided in Article 13 hereafter.

ARTICLE 5 - OBLIGATIONS OF THE INSTITUTION AND/OR THE PRINCIPAL INVESTIGATOR

5.1 The Institution shall apply its best efforts to retain the services of the Principal Investigator.

In the event that the Principal Investigator leaves the Institution or is otherwise unable or unwilling to continue his/her tasks as Principal Investigator, the Institution shall so inform the Sponsor by written notice immediately, and the Parties shall apply their best efforts to appoint, within a reasonable time, a mutually acceptable substitute for the resigning Principal Investigator, which replacement shall have a similar background and also knowledge of the Clinical Trial.

Any successor to the Principal Investigator must be approved, in writing, by the Sponsor and such successor shall be required to agree to all the terms and conditions of the Protocol and this Agreement and to sign each such document as evidence of such agreement (although failure to so sign will not relieve such successor from abiding with all the terms and conditions of the Protocol and this Agreement).

5.2 The Institution shall ensure that the Principal Investigator and any Additional Personnel shall conduct the Clinical Trial in accordance with:

(a) the Protocol and all other terms of this Agreement;
(b) any and all applicable laws and regulations including in particular but not limited to those pertaining to (i) the conduct of clinical investigations among which the Helsinki Declaration as amended in Fortaleza (Brazil)(October 2013), the Public Health Service Act, the Food, Drug and Cosmetic Act, and the Code of Federal Regulations of the United States, if the Clinical Trial is performed in the USA and (ii) the transportation, storage, use, administration and disposal of drugs, vaccines/biologicals;
(c) those policies, standards, procedures, conventions and techniques that are of a high, recognized and acceptable professional standard in the scientific community, such as GCP;
(d) any and all Sponsor's requirements, directions or instructions, including but not limited to the SOPs.

5.3 The Institution and the Principal Investigator agree that the Subjects to be involved in the Clinical Trial will be selected pursuant to the criteria set forth in the Protocol and that they will be fully informed of the foreseeable consequences of their inclusion in the Clinical Trial and that they, or if appropriate, their parents having authority over them, have given written consent to their inclusion in the Clinical Trial.

Such informed consent shall be obtained by the Principal Investigator using the informed consent form template developed for the Trial Site. The Privacy Rules of each country shall be followed in order to obtain consent from Subjects as required throughout the Clinical Trial.

5.4 The Institution and the Principal Investigator shall have the following record keeping and reporting obligations:

(i) To prepare and maintain complete and accurate written records, accounts, notes, reports and data relating to the Clinical Trial under this Agreement.
(ii) To prepare and submit to the Sponsor (in a periodic and timely manner during the term of this Agreement) all raw data and other material called for in the Protocol, in the form of properly completed Case Report Forms or into an electronic database (i.e., remote data entry) supplied by the Sponsor, for each Subject. All Case Report Forms and the information and data stored in any electronic database shall be the exclusive property of the Sponsor.
(iii) To retain in a secure facility the essential documents as per GCP requirements (including but not limited to the original informed consent form signed by each Subject) and the supporting

documents relating to the Clinical Trial for the longest of those time periods (the "Retention Period"):
- Twenty-five (25) years after the signature of the final Study report or,
- Any longer period as required by applicable regulatory requirements.

The Principal Investigator and Institution should take measures to prevent accidental or premature destruction of these documents.

Following such Retention Period, as prior instructed by the Sponsor by written notice, Principal Investigator and/or Institution will either forward such records to Sponsor at Sponsor's expense, retain such records for an additional period of time at Sponsor's sole expense, to be negotiated in good faith, or destroy the records, and send Sponsor proof of such destruction. In any way, no document shall be destroyed without the prior written permission of the Sponsor.

The Institution and Principal Investigator shall ensure that all procedures defined in the Protocol are complied with, so that all data coming from the Trial Site are reliable and have been processed and recorded correctly (especially the randomization lists, and the blind character of the Clinical Trial as the case may be) and will ensure that the content of the CRF / e-CRF will accurately reflect source documents.

5.5 The Principal Investigator shall report any adverse experiences and adverse events observed in the Clinical Trial to the Sponsor. All adverse experience/event reports shall be prepared and collected by the Principal Investigator according to the procedures outlined in the Protocol.

5.6 The Institution and the Principal Investigator shall use their best efforts to complete expeditiously the Clinical Trial in accordance with the time-schedule provided for in the Protocol.

5.7 The Institution shall, on or before the signing date of this Agreement, supply the Sponsor with a complete list of its Additional Personnel who it anticipates will be involved in carrying out Institution's obligations under this Agreement, specifying the role each individual will play in carrying out these obligations. The Institution agrees to inform the Sponsor of any changes to such list and train new Additional Personnel to the specificities of the Clinical Trial.

5.8 The Institution and the Principal Investigator agree to inform the Sponsor of any cooperation or collaboration they would like to undertake regarding a therapeutic concept similar to the one studied according to the Protocol if such a project would compete with the Clinical Trial. The Sponsor will be entitled to terminate this Agreement if such a cooperation or collaboration is deemed by the Sponsor to be incompatible with its interests.

5.9 To comply with applicable Health Authorities' regulations, as well as the Sponsor's conflict of interest policies that require investigators conducting clinical trials to provide the Sponsor with information regarding certain types of relevant financial or business relationships between the Sponsor and the Principal Investigator, his/her spouse and dependent children, the Institution shall ensure that the Principal Investigator and Additional Personnel involved in this Clinical Trial at the Trial Site provide the Sponsor with the appropriate financial disclosures updated from time to time by the Principal Investigator. During the term of the Agreement and for one (1) year following termination or completion of the Clinical Trial, the Principal Investigator shall promptly notify Sponsor of any material change in the information disclosed on a previous form. By signing this Agreement, the Principal Investigator hereby consents to the use by the Sponsor of such information (including disclosure to Health Authorities, if necessary). The Institution understands that similar obligations exist for sub-investigator(s) and agrees to provide the Sponsor with similar disclosures from each sub-investigator before permitting them to participate in the Clinical Trial.

5.10 In the interest of transparency relating to the SPONSOR's financial relationships with Principal Investigator and Institution, the Sponsor may collect, publicly disclose, and communicate to relevant authorities/institutions, the funding, including payments made to the Principal Investigator / Institution/ Payee and payments made to individuals, and/or any direct or indirect advantages and/or or any related information or document associated with this Contract, if required by applicable law.

5.11 The Investigator represents and warrants to the Sponsor that he/she:

a) is not bound, at the date of signature of this Agreement, by any obligation or commitment to a third party, including any legal entity of which he/she is an employee or to which he/she refers, that could conflict with the terms of this Agreement and

b) will not knowingly enter into any agreement with a third party that would in any way prevent him/her from participating as an investigator in the Study or could conflict with the terms of this Agreement.

5.12 The Sponsor registers all its clinical trial protocols on the web site *http://ctri.nic.in*. If local regulations require the Clinical Trial to be registered locally, the Institution and the Principal Investigator are in charge of doing it and informing the Sponsor. The Sponsor shall support them by providing the required information.

ARTICLE 6 – TRIAL PRODUCT, EQUIPMENT AND DOCUMENT

6.1 The Trial Product, as well as the documents and the material necessary to conduct the Clinical Trial, as described in the Protocol, shall be supplied free of charge to the Institution by the Sponsor. In certain circumstances, the Sponsor (including through its CRO) might instruct the Institution to purchase part of the Trial Product and/or equipment. In such a case, the Sponsor will reimburse these expenses to the Institution at invoice value (all invoices are requested by the Sponsor prior to reimbursement).

The Institution shall inform the Sponsor on or before the signing date of this Agreement of the name and complete address to which the Trial Product shall be shipped by the Sponsor.

6.2 All the Trial Product, the document, the equipment and the material supplied pursuant to this Agreement shall remain at all times the property of the Sponsor and shall be used only and exclusively pursuant to the Agreement. It is understood that the Trial Product is provided by the Sponsor for the sole purpose of conducting the Clinical Trial.

THE SPONSOR MAKES NO WARRANTIES, EXPRESS OR IMPLIED, CONCERNING THE TRIAL PRODUCT OR ITS MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE, OTHER THAN FOR ITS USE IN THIS CLINICAL TRIAL.

All unused doses of Trial Product shall be promptly returned to the Sponsor upon the completion of the Clinical Trial as directed by the Sponsor, or upon earlier termination of this Agreement, unless written authorization to destroy the Trial Product is given by Sponsor. If authorization to destroy unused Trial Product is previously given in writing, the Institution shall provide the Sponsor with documentation as to the method of destruction. The Institution shall conform with all laws and regulations pertaining to the disposal of drugs, vaccines/biologicals during any destruction of unused quantities of the Product. Upon delivery, the Institution and the Principal Investigator shall be responsible for any improper administration, storage or handling of the Trial Product and for its use beyond its applicable expiration date.

6.3 If some products among the Trial Product were to be recalled, the Principal Investigator and the Institution commit to implement the Sponsor's instructions immediately and to quarantine the recalled product(s) at stake.

6.4 Upon request of the Sponsor (including through its CRO), the Principal Investigator or his/her designees shall submit e-CRFs. If needed, Sponsor will provide the Institution and/or the Principal Investigator with a computer and/or internet connection ("the Material") for the use and submission of e-CRFs for the Clinical Trial. The Principal Investigator or his/her designees shall be trained by Sponsor (including through its CRO) on the use of e-CRFs. Following the training process, the Principal Investigator or his/her designees shall sign an acknowledgment form which contains statements of understanding regarding the e-CRF process. The Principal Investigator and the Institution agree that any and all Material shall remain the sole property of the Sponsor. The Institution and the Principal Investigator shall (i) keep the Materials in a reasonably secure environment; (ii) take all reasonable precautions as are necessary to avoid any damage or loss of the Materials; and (iii) not use the Materials for any purpose other than performance of the Clinical Trial and their obligations required under the Protocol and the Agreement. The Institution and the Principal Investigator shall promptly return to the Sponsor any such Material when all e-CRFs for the Clinical Trial have been completed by the Principal Investigator.

ARTICLE 7 - AUDITS

7.1 During the Clinical Trial and for such additional period of time that records are required to be retained by law or otherwise, it is agreed that representatives of the Sponsor may (including through its CRO) arrange with the Principal Investigator or his/her designee, after having duly informed the Institution respecting at least seven (7) days prior notice:

(i) to examine and audit, at regular business hours, the locations where the Clinical Trial is performed;

(ii) subject to applicable patient confidentiality considerations, to inspect, audit, and to copy or have copied, all data and work product relating to the Clinical Trial conducted under this Agreement and to inspect and make copies of all data necessary for the Sponsor to confirm that the Clinical Trial is being conducted in conformance with the Protocol and in compliance with all applicable legal and/or regulatory requirements of any and all Health Authorities; and

(iii) to meet with any person involved in the Clinical Trial's performance.

7.2 The Institution agrees to assist the Sponsor and its CRO, to the extent deemed reasonable by the Sponsor, in facilitating the Sponsor's representatives' examination, inspection, auditing and copying of materials relating to the Clinical Trial and in order to enforce the rights granted to the Sponsor in this Article 7.

The Principal Investigator and the Institution agree to take any action, as reasonably requested by the Sponsor (including through its CRO), to properly correct or address any deficiencies noted during any audit and agree to cooperate with the Sponsor with respect to any action taken to address any such deficiencies.

7.3 If the need arises (or if the need be), the Institution agrees to notify Sponsor within twenty-four (24) hours in the event that a Health Authority notifies the Institution of a pending inspection/audit. In addition, the Institution will forward to Sponsor any written communication received as a result of the inspection/audit within twenty-four (24) hours of receipt of such communication and agrees to accept Sponsor's assistance in responding to any citations. Such responses shall be made within ten (10) business days of issuance of any citations or within any earlier deadline set by the issuing Health Authority. The Institution shall also provide the Sponsor with copies of any documents provided to any inspector or

auditor. In the event any applicable Health Authority requests or requires any action to be taken to address any citations, the Principal Investigator and the Institution agree, after consultation with the Sponsor, to take such action as necessary to address such citations, and agree to cooperate with the Sponsor with respect to any such citation and/or action taken with respect thereto.

7.4 It is expressly agreed between the Parties that the Sponsor will not compensate the Principal Investigator and/or the Institution for the audits, investigations and inspections and that the assistance and availability of the Principal Investigator or the Institution for the audits, investigations and inspections are included in the amount mentioned in Schedule A.

ARTICLE 8 - FINANCIAL PROVISIONS

The financial provisions applicable to the Agreement in consideration of the performance of the Clinical Trial are provided for in *Schedule A* and depicted in *Schedule B* attached hereto.

ARTICLE 9 - CONFIDENTIALITY

9.1 Before and during the course of the Clinical Trial, the Institution and the Principal Investigator may obtain, or have access to Confidential Information.

Except as expressly set forth in this Article, the Institution and the Principal Investigator shall each cause its Related Person(s) to keep the Confidential Information confidential, and the Institution and the Principal Investigator shall not disclose directly or indirectly, and shall cause its Related Persons not to disclose directly or indirectly, any Confidential Information to anyone, except that the foregoing restriction shall not apply to any information disclosed hereunder if such Confidential Information, as reasonably demonstrated by the Institution and/or the Principal Investigator:

(i) is generally available to the trade or public or becomes after the time of receipt by the Institution and/or the Principal Investigator part of the public domain, other than by reason of any breach or default by the Institution and/or the Principal Investigator or any of its Related Persons of a confidentiality obligation under this Agreement;

(ii) was already known to the Institution and/or the Principal Investigator at the time of disclosure by the Sponsor;

(iii) is disclosed to the Institution and/or the Principal Investigator or any of its Related Persons by a Third Party who has the right to disclose such information; or

(iv) based on such person's good faith judgment with the advice of counsel, is otherwise required to be disclosed in compliance with applicable legal requirements to a Health Authority.

Whenever the Institution and/or the Principal Investigator become aware of any state of facts which would or might result in disclosure of Confidential Information pursuant to subparagraph (iv) above, it shall, if possible, promptly notify the Sponsor prior to any such disclosure so that the Sponsor may seek a protective order or other appropriate remedy and/or waive compliance with the provisions of this Agreement.

In any event, if the Institution and the Principal Investigator are unable to promptly notify the Sponsor or if such protective order or other remedy is not obtained, or if the Sponsor waives compliance with the provisions of this Agreement, the Institution and the Principal Investigator will furnish only that portion

of the information which its counsel directs is legally required and will exercise reasonable efforts to obtain assurance that confidential treatment will be accorded the Confidential Information.

The Sponsor shall be entitled, in addition to any other right or remedy it may have, at law or in equity, to an injunction, without the posting of any bond or other security except as required by the relevant laws, enjoining or restraining the Institution and/or the Principal Investigator and any of its Related Persons from any violation or threatened violation of this Article.

9.2 The Institution and the Principal Investigator agree that no Confidential Information shall:

(i) be used in its own business except as necessary to the fulfillment of the rights and obligations of the Institution and the Principal Investigator under this Agreement;

(ii) be disclosed, assigned, licensed, sublicensed, marketed, transferred or loaned, directly or indirectly to any third party other than to Related Persons of the Institution and/or the Principal Investigator in accordance with the provisions of this Agreement, except as necessary to the fulfillment of the rights and obligations of the Parties under this Agreement;

(iii) be used or exploited by the Institution and the Principal Investigator or any of its Related Persons for its or their respective benefit or the benefit of any other relationships with customers of such Party and its Related Persons.

(iv) be used by the Institution and/or the Principal Investigator for obtaining intellectual property rights.

Without limiting the generality of the foregoing, the Recipient agrees that, it shall not (and shall not permit any of its Related Persons) at any time use any Confidential Information in the conduct of its business without the prior written consent of the Sponsor.

The obligations set forth in this Article shall extend to copies, if any, of Confidential Information made by the Institution and/or the Principal Investigator and/or its Related Persons and to documents prepared by such persons which embody or contain Confidential Information.

9.3 The Institution and the Principal Investigator shall deal with Confidential Information so as to protect it from disclosure with a degree of care not less than that used by it in dealing with its own information intended to remain exclusively within its knowledge and shall take reasonable steps to minimize the risk of disclosure of Confidential Information which shall include, without limitation, ensuring that only their respective Related Persons who have a *bona fide* "need to know" such Confidential Information for purposes permitted or contemplated by this Agreement shall have access thereto.

The Institution and the Principal Investigator shall notify all of its Related Persons who have access to Confidential Information of its confidentiality and the care therefore required, and shall obtain from any such Related Person an agreement of confidentiality incorporating the restrictions set forth herein.

9.4 The obligations set forth in the present article shall survive the termination of this Agreement for a period of **fifteen (15) years.**

9.5 Except as otherwise agreed to by the Parties in writing, the Institution and the Principal Investigator shall (and shall cause its Related Persons to), within thirty (30) days after the termination of this Agreement, return to the Sponsor or destroy all documents and tangible items then in its possession which it has received from the Sponsor or its Related Persons pertaining, referring or relating to the Sponsor's Confidential Information, as well as all copies, summaries, records, descriptions, modifications, and duplications that it, or any of its Related Persons has made from the documents or tangible items received from the Sponsor or Related Person; provided, however, that the Institution may retain one copy of each

document in its legal files solely to permit the Institution and the Principal Investigator to continue to comply with its obligations hereunder and, in addition, may upon notice to the Sponsor, retain in its legal files or in the office of outside legal counsel one copy of any document solely for use in any pending legal proceeding to which such document relates.

ARTICLE 10 – INTELLECTUAL PROPERTY RIGHTS AND PUBLICATION

In recognition of the importance of disseminating information relating to any novel or important observations or results that may arise from the Clinical Trial, and understanding that such need must be balanced with the Sponsor's obligations to maintain control over Confidential Information as well as to comply with all appropriate Health Authorities' rules and regulations, the Parties hereby agree to the following:

10.1 The Institution and the Principal Investigator agree that all Results, generated, directly or indirectly, during the course of or as a result of the Clinical Trial shall become automatically and immediately, once generated, the exclusive property of the Sponsor which can use and exploit them without any limitation whatsoever (domain, duration, territory, etc) and without any additional payment to the Institution or the Principal Investigator or any Additional Personnel.

For this purpose, the Principal Investigator and the Institution thus assign, and shall cause its Related Persons to assign to the Sponsor all intellectual property rights on the Results including in particular any and all rights any and all materials, once generated, created in relation to the Clinical Trial, and further agree to execute any documents or undertake any further actions requested by the Sponsor (including through its CRO) to evidence such transfer of title to such Results. The rights so assigned shall include, but not be limited to, rights of reproduction, adaptation, translation, exploitation and display, worldwide, in any form, on any medium and for the legal duration of protection of intellectual-property rights in the country of exploitation.

While such intellectual-property rights shall be assigned to the Sponsor, title to the documents or materials which are their medium or support shall simultaneously be assigned to the Sponsor or any Affiliate.
The Sponsor shall be under no obligation to patent, develop, market or otherwise use the Results of the Clinical Trial, issued under this Agreement.

10.2 The Sponsor acknowledges the importance of public disclosure/publication of information collected or generated by the Principal Investigator under the condition that public disclosure/publication takes place under the provisions of this article 10.

At the end of the Clinical Trial (whether prematurely or otherwise) the Principal Investigator and Sponsor shall co-operate in producing a report of the Clinical Trial detailing the methodology, Results and containing an analysis of the Results and drawing appropriate conclusions.

10.3 Subject to the terms and conditions of this clause 10.3 and the terms of any publication policy described in the Protocol, provided any such policy does not obstruct publication unreasonably, the Sponsor agrees that the Institution and the Principal Investigator have the right to publish or publicly present the data resulting from the performance of the Clinical Trial in the Trial Site (the "Trial Site Data").

The Principal Investigator and the Institution agree not to publish or publicly present the Trial Site Data without prior review by the Sponsor, as provided herein. Upon completion of the Clinical Trial, or when the Clinical Trial Results are considered as adequate in Sponsor's reasonable judgment, and subject to clause 10.4 hereof, the Principal Investigator may prepare the Trial Site Data for Public Presentation. The

Principal Investigator and the Institution further agree to provide ninety (90) days written notice to the Sponsor, including a complete copy of the intended Public Presentation, prior to submission for publication or presentation to permit the Sponsor to review a Public Presentation which reports any Results arising out of the Clinical Trial.

The Sponsor shall have editorial rights with respect to a Public Presentation and the right to review and comment on the content of the Public Presentation including in particular the Trial Site Data analysis to ensure notably but not limited to, that:

(i) the Principal Investigator and/or the Institution remove from the projected Public Presentation any Sponsor Confidential Information that are not Trial Site Data;;

(ii) the information contained in the Public Presentation is accurate; and

(iii) the Public Presentation is fairly balanced and in compliance with applicable Health Authorities' regulations as to its content and authorship.

The Principal Investigator and/or the Institution agrees that all reasonable comments made by the Sponsor in relation to a proposed publication or presentation will be incorporated into the Public Presentation.

If the Parties disagree concerning the accuracy and appropriateness of the Trial Site Data analysis and presentation, and/or confidentiality of Sponsor's Confidential Information, the Institution agrees to meet with Sponsor's representatives, prior to submission of a Public Presentation, for the purpose of making good faith efforts to discuss and resolve any such issues or disagreement.

10.4 To the extent that the Principal Investigator and Institution's participation in the Protocol is a part of a multi-center clinical trial, the Institution and the Principal Investigator agree that an initial Public Presentation of their results shall occur only together with the other sites unless specific written permission is obtained in advance from the Sponsor for Public Presentation of separate results. The Sponsor shall advise as to the implications of timing of any Public Presentation in the event the Clinical Trial is still in progress at sites other than the Principal Investigator's one and any institution or investigator participating in a multi-center clinical trial shall follow the Public Presentation review procedures set forth in Article 10.3 above.

10.5 The Institution and the Principal Investigator shall be aware that a Public Presentation of patentable subject matter prior to filing respective patent application will jeopardize such patent rights. Therefore, if the Sponsor believes there is a patentable subject matter contained in any Public Presentation submitted for review, the Sponsor shall promptly identify such subject matter to the Principal Investigator and the Institution and inform the Principal Investigator and the Institution that the said Public Presentation shall be delayed for ninety (90) calendar days and shall be entitled to make a reasoned request to the Principal Investigator and the Institution that Public Presentation be delayed for an additional ninety (90) calendar days, to enable the Sponsor to take steps to protect its proprietary information and/or intellectual property rights and know-how and the Principal Investigator and the Institution shall not unreasonably withhold their consent to such a request.

Furthermore, if the Sponsor requests and at the Sponsor's expense, the Institution and the Principal Investigator shall use their best efforts to assist the Sponsor in filing a patent application covering such subject matter prior to any publication.

10.6 The Sponsor will register the Clinical Trial, post results from the Clinical Trial, and update as necessary such registrations or postings, so as to comply with such laws, regulations, and corporate policies as may be applicable. The Sponsor registers all its clinical trial protocols on the web site http://clinicaltrials.gov.

If local regulations require the Clinical Trial to be registered locally, the Institution and the Principal Investigator are in charge of doing it and informing the Sponsor. The Sponsor shall support them by providing the required information.

To avoid any unnecessary duplication or confusion, neither the Institution nor the Principal Investigator shall register either the Clinical Trial or the results, on any publicly accessible database, unless required by law to do so, in which case Institution and Principal Investigator will so inform Sponsor to work in good faith to ensure that a single, harmonized registration is posted in full compliance with all applicable laws and regulations concerning such postings.

10.7 Unless it is an exploratory clinical trial, the Sponsor shall ensure that the results of the Clinical Trial will be published on a free, publicly accessible clinical trial results database within one (1) year after the Investigational Product is first approved and made commercially available in any country, or for a post-approval Clinical Trial, within one year of Clinical Trial completion. In respect of a Clinical Trial that is under review by peer-reviewed journals that prohibit disclosure of results pre-publication, the results will be posted at the time of publication, or as otherwise required by applicable law or regulation.

ARTICLE 11 – INDEMNIFICATION AND INSURANCE

11.1 In case of Study Subject injury or death due to participation in the Study, SPONSOR will, pay for the required medical management and compensation to the Study Subject or Study Subject's representative in accordance with the New Drugs and Clinical Trials Rules, 2019 ("New Rules").
For the avoidance of doubt, medical management has the same meaning as defined in the New Rules.
It being understood that the INVESTIGATOR and the INSTITUTION shall discharge its obligations in a professional and diligent manner as per applicable laws.

11.2 The SPONSOR certifies it has subscribed a liability insurance policy to cover its liability as required by applicable law. The SPONSOR will provide the INVESTIGATOR and/or the INSTITUTION with a certificate of insurance in the countries where this document is required.

11.3 The insurance subscribed by the SPONSOR does not release neither the INVESTIGATOR nor the INSTITUTION from their obligation to maintain their own liability insurance policy.

11. 4 The SPONSOR agrees to indemnify, hold harmless and defend the INVESTIGATOR, the INSTITUTION, and Collaborators (« Indemnities ») from and against any and all claims and suits, including reasonable attorneys' fees incurred in the defence thereof, arising out of an injury to a Subject (including death) caused by the administration of the IMP or the performance of any procedure required under the Protocol, except to the extent such claim or suit is attributable to:

i) a failure to adhere to the terms of this Contract, the Protocol or any written instructions from the SPONSOR regarding the administration of the IMP or the performance of any required procedure; or
ii) a failure to comply with any applicable laws, regulations and government requirements (including, without limitation, obtaining informed consents); or
iii) the negligence or willful malfeasance of the Indemnities.

11.5 The SPONSOR shall have no obligation under this Article, however, unless: (i) the SPONSOR is promptly notified of any such claim or suit; (ii) the Indemnities cooperate fully in the handling thereof; and (iii) the SPONSOR has sole control over the disposition of such claim or suit, including the selection of counsel and any settlement thereof, provided, however, that no settlement shall include an admission of liability

on the part of the Indemnities without their prior written consent, which consent shall not be unreasonably withheld.

11.6 The Sponsor shall indemnify, defend and hold harmless the Institution, its trustee, officers, directors, agents, Additional Personnel and the Principal Investigator (the "Indemnitee"), from and against any demands, claims, actions, proceedings or costs of judgments which may be made or instituted against any of them by reason of personal injury (including death) to any person, resulting from the use of the Trial Product in connection with the Clinical Trial.

Therefore, the Sponsor shall maintain, at its sole expense, policies of liability insurance. Such insurance policies shall provide broad form contractual liability coverage for the Sponsor's indemnification under this article 11 and shall also provide product liability and clinical trials liability coverage. The minimum amounts of insurance coverage required shall not be construed to create a limit of the Sponsor's liability with respect to its indemnification under this article 11. The Sponsor shall maintain the aforementioned insurance during the Clinical Trial. This obligation to maintain insurance shall survive the termination of this Agreement. The Sponsor shall provide the Institution with written evidence of such insurance upon the written request of the Indemnitee.

11.7 In the event a claim is made or an action is brought against the Institution and/or its trustees and/or its officers and/or its directors and/or its agents and/or its Additional Personnel and/or the Principal Investigator, the Institution and the Principal Investigator shall immediately report it to the Sponsor and shall assist the Sponsor and cooperate in the gathering of information with respect to the time, place and other circumstances of the event giving rise to the claim or action and in obtaining the names and addresses of the allegedly injured parties and available witnesses. The Principal Investigator and the Institution agree to cooperate with and to authorize the Sponsor to carry out the sole management and defense of such claim or action. Neither the Principal Investigator nor the Institution, its trustees, officers or Related Persons shall compromise or settle any claim or action without the prior written approval of the Sponsor.

11.8 Notwithstanding the foregoing, the Sponsor shall have no indemnification obligation or liability and the Institution and the Principal Investigator shall indemnify, defend and hold harmless the Sponsor, its Affiliates, officers, directors, agents and employees for loss or damage resulting from:

(i) failure of the Institution or the Principal Investigator or the Additional Personnel to adhere to the terms and provisions of the Protocol or any amendments thereto (including but not limited to the Principal Investigator's and the Institution's obligations with regard to adverse event reporting procedures as set forth in this Agreement and the Protocol (and any appendix or attachment to the Protocol)), or the Sponsor's written recommendations and instructions relative to the administration and use of any drug substances involved in the Clinical Trial, including but not limited to the Trial Product, any comparative drug and any placebo;

(ii) failure of the Institution or the Principal Investigator or the Additional Personnel to comply with any applicable Health Authorities' requirements, law, rules or regulations applicable to the performance of its obligations under this Agreement;

(iii) failure of the Institution or the Principal Investigator or the Additional Personnel to render professional service or to conduct the Clinical Trial in accordance with GCP and current medical practice; or

(iv) any negligent act or omission or willful misconduct by the Principal Investigator, the Institution, its trustees, officers, directors, or Related Person who rendered services under this Agreement.

11.9 The Institution shall secure and maintain in full force and effect through the performance of the Clinical Trial (and following termination of the Clinical Trial to cover any claims arising from the Clinical Trial) insurance coverage for:

(i) medical professional and/or medical malpractice liability (including coverage for the Principal Investigator);
(ii) general liability (including coverage for the Clinical Trial site); and
(iii) worker's compensation coverage,

in amounts required by applicable federal, provincial or state laws and appropriate to the conduct of Institution's business activities and the services contemplated by the Clinical Trial.

Upon request of the Sponsor (including through its CRO), copies of certificates evidencing such insurance coverage will be made available to the Sponsor and the Institution shall provide thirty (30) days' prior written notice to the Sponsor in the event of cancellation or any material change in such insurance.

ARTICLE 12 – TERM

This Agreement shall become effective on **04 May 2023** and shall remain in full force and effect until completion of the Clinical Trial and delivery of the final report, which for reference only, is expected by **Q2-2025**.

ARTICLE 13 – TERMINATION

13.1 The Sponsor may terminate this Agreement at any time by giving thirty (30) days written notice to the Institution. In the event thirty (30) days is determined by the Institution to be insufficient notice based upon evaluation of risks to enrolled Subject(s) then receiving the Trial Product, the Parties will cooperate to safely withdraw Subjects from the Clinical Trial over a mutually agreeable period of time but in no event shall the Sponsor's obligation to supply the Trial Product hereunder extend beyond a reasonable period. Notwithstanding the foregoing, in the event the Sponsor believes that immediate termination is necessary due to its evaluation of risks to enrolled Subject(s), the Sponsor may terminate this Agreement immediately.

The Sponsor reserves the right not to perform the Clinical Trial. In such a case, the Agreement shall be considered as automatically terminated upon the Sponsor's formal notice to both the Institution and the Principal Investigator.

13.2 Notwithstanding any other provision hereof, the Sponsor shall be entitled to terminate this Agreement for any Material Breach, which shall be defined as:

(i) The Institution and/or the Principal Investigator's failure to comply with their obligations, responsibilities and the terms and conditions of this Agreement including the Protocol;

(ii) The Institution and/or the Principal Investigator's failure to comply with: (a) their obligations for keeping the Sponsor informed of all necessary and relevant information in connection with the Protocol; (b) any applicable law, rule or regulation relevant to the Clinical Trial; or (c) the work to be performed under this Agreement; or

(iii) A breach by the Institution, the Principal Investigator, or their Related Persons of the confidentiality provisions of this Agreement.

13.3 Upon termination, for any reason:

(i) the Institution shall return to the Sponsor all unused materials, including but not limited to, the Trial Product and any clinical supplies (unless written authorization to destroy them is given by the Sponsor, in which case the Institution shall comply with the applicable provisions of Article 6 hereof);

(ii) except in the event of termination because of a Material Breach by the Institution, and unless otherwise specified in writing between the Parties, the total sums payable by the Sponsor pursuant to this Agreement shall be equitably pro-rated for actual work performed in accordance with the Protocol to date of notice of termination with any unexpended portion of funds previously paid by the Sponsor to the Institution being refunded to the Sponsor;

(iii) in the event of termination as a result of a Material Breach, the Parties agree to make a good faith effort to reach agreement to compensate the Institution for actual work performed in accordance with the Protocol to date of notice of termination; and

(iv) the Principal Investigator shall return to Sponsor all Confidential Information (as defined in Article 9 hereof) owned or controlled by the Sponsor and in the possession of the Institution or its Related Persons;

(v) the Principal Investigator must submit to the Sponsor the Case Report Forms for all the work in progress as of the effective date of termination.

13.4 The termination of this Agreement shall not relieve either Party of its obligations set out in Sections 5.3, 5.4, 5.5 and Articles 6, 7, 9, 10 and 11 of this Agreement.

13.5 Upon receipt of notice of Enrollment Cap, the Institution and the Principal Investigator agree to enroll no further Subjects in the Clinical Trial, and the funds payable pursuant to this Agreement shall be adjusted to reflect only the number of Subjects actually enrolled and the number of visits and technical procedures actually performed prior to receipt of such notice. The Institution and the Principal Investigator, as the case may be, shall refund to Sponsor any funds received in advance from Sponsor that are in excess of the adjusted funding.

ARTICLE 14 – DATA PROTECTION AND TRANSPARENCY

14.1 For the purpose of this Section 14, "Personal data" means any information relating to an identified or identifiable natural person ("Data Subject"); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person.

14.2 The Principal Investigator, the Institution and Sponsor will comply with Schedule C "Data Processing Agreement".

14.3 Principal Investigator and Institution shall inform the Collaborators that:

- For the purposes of the implementation of the Clinical Trial as described in the Protocol, their Personal Data will be collected and processed by the Sponsor, acting as the Data Controller (as defined under the General Data Protection Regulation (EU) 2016/679).

- Within the framework of the Clinical Trial, and only for the purposes described below, the following categories of personal data might be collected and processed by the Sponsor: (i) their name, surname, contact details, age, where deemed necessary, their professional identification number (i.e. RPPS) (ii) where strictly necessary, bank account details, (iii) information on their education – qualification(s), (iv) information on their professional life including but not limited to their specialty or academic activities, (v) amount of allowances and remuneration received, and (vi) information on their participation to the Clinical Trial, including quality events, adverse events reports, history of access and connections to the medical data of persons taking part in the research.

- Their Personal Data will be collected and processed on the basis of: (i) this Contract, and (ii) legal obligation(s) SPONSOR has to comply with.

- Their Personal Data will be collected and processed for the following purposes: (i) for the purpose of carrying out the Clinical Trial in compliance with applicable requirements, including but not limited to regulatory and transparency requirements, (ii) for the purpose of publishing the results of the Clinical Trial, where relevant, and (iii) or the purpose of identifying them for further study projects for which their participation might be of interest for them and Sponsor.

- Unless Principal Investigator and Additional Personnel have agreed to be recontacted for other studies by separate agreement, their Personal Data will not be retained longer than necessary to achieve the above-mentioned purposes. In any case, their Personal Data will be deleted after the Retention Period.

- For the purposes set forth above, Sponsor may communicate and/or disclose their Personal Data (i) to Sponsor's affiliates, partners, and successors (ii) to contract research organizations, including but not limited any service provider working on the Clinical Trial under the responsibility of the Sponsor, and (iii) to regulatory authorities and ethics committees or on a public repository and websites as required to comply with legal or regulatory requirements or judicial or administrative orders.

- For the purpose of raising awareness on the Clinical Trial to general public and referral of potential Clinical Trial participants, Sponsor may communicate and/or disclose their Personal Data on sanofistudies.com.

- In accordance with the rights granted to them by law, they are entitled to: (i) access upon request, their Personal Data; (ii) request a rectification of their Personal Data if they are inaccurate, incomplete or obsolete; (iii) obtain the deletion of their Personal Data unless otherwise required by applicable law (iv) obtain a limitation of the processing of their Personal unless otherwise required by applicable law, (v) directly send an information request to Sponsor's Data Protection Officer should any difficulty arise, and/or (vi) lodge a complaint with Sponsor's lead authority, the "Commission Nationale de l'Informatique et des Libertés" or to any competent local Regulatory Authority".

14.4 The Parties acknowledge and agree that certain information related to this Agreement, including but not limited to, Principal Investigator's, Institution and Sponsor's name, the amount of the remuneration as well as the purpose of this Agreement, may be communicated to any relevant authorities/institutions and/or publically disclosed by the Sponsor and/or by its Affiliates and/or by relevant authorities/institutions to the extent required by local laws and regulations and/or Codes of Practice applicable to the pharmaceutical industry. In this context, by signing this Agreement, the Principal Investigator acknowledges that the collection, the processing and the transfer of his/her Personal Data, together with the amount paid under this Agreement, could be necessary for the performance of the Agreement and hereby gives his/her consent thereto to the maximum extent required.

14. Sanofi Data Protection Officer contact is Sanofi DPO - 54 rue La Boétie - 75008 PARIS – France, or by e-mail : privacy-office-global@sanofi.com.

ARTICLE 15 – NOTICES

All notices required or permitted to be given under this Agreement shall be in writing and may be effectively given if delivered personally or if sent by prepaid registered mail, or by facsimile addressed in the case of the Sponsor to:

- **Sanofi Pasteur Inc.**
  Discovery Drive
  Swiftwater, Pennsylvania 18370
  USA
  Attention: General Counsel

  with a copy to:
  Attention: Oscar Borg Oliver
  Email ID:Oscar.Borg-Olivier@sanofi.com

or in the case of the Institution to:

- **Manipal Centre for Clinical Research, MAHE**

  Mezzanine Floor of old KMC Library Building,
  Near KMC Dean Office,
  Kasturba Hospital,
  Manipal 576104
  Attn: Dr. BS Satish Rao
  Email ID: rao.satish@manipal.edu

For the Principal Investigator

- **Name: Dr.Veena Kamath**
  Email ID: veenak@manipal.edu

Any such notice shall be deemed to have been given and received when actually received. Either Party may change its address for service from time to time by notice given in accordance with the foregoing.

ARTICLE 16 – REPRESENTATION AND WARRANTIES

16.1 Representations and Warranties by the Sponsor: as of the signing date of the Agreement, the Sponsor represents and warrants to the Institution and the Principal Investigator, and acknowledges that the Institution and the Principal Investigator are relying on such representations and warranties in entering into this Agreement, that:

(a) the Sponsor is a company duly organized and validly existing under the laws of France; and

(b) the Sponsor has no commitments or agreements with any Person which interfere with or preclude the diligent and complete fulfillment of their obligations under this Agreement;

(c) the Sponsor has all necessary corporate power and authority to enter into this Agreement and to carry out its obligations under this Agreement, and the execution, performance and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement have been duly authorized by all necessary corporate action on the part of the Sponsor;

(d) this Agreement has been duly authorized, executed and delivered by the Sponsor and constitutes a legal, valid and binding obligation of the Sponsor enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, moratorium or similar laws, or general equitable principles, whether considered in an action at law or in equity;

16.2 Representations and Warranties by the Institution: as of the signing date of the Agreement, the Institution represents and warrants to the Sponsor, and acknowledges that the Sponsor is relying on such representations and warranties in entering into this Agreement, that:

(a) the Institution is a corporation duly incorporated and validly existing under the laws of India;

(b) the Institution has no commitments or agreements with any Person which interfere with or preclude the diligent and complete fulfillment of its obligations under this Agreement;

(c) the Institution has all necessary corporate power and authority to enter into this Agreement and to carry out its obligations under this Agreement, and the execution, performance and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement have been duly authorized by all necessary corporate action on the part of the Institution;

(d) this Agreement has been duly authorized, executed and delivered by the Institution and constitutes a legal, valid and binding obligation of the Institution enforceable in accordance with its terms, except as enforceability may be limited by applicable bankruptcy, insolvency, moratorium or similar laws, or general equitable principles, whether considered in an action at law or in equity;

(e) the Principal Investigator is an employee of the Institution.

16.3 Representations by the Principal Investigator: The Principal Investigator represents to the Sponsor and the Institution, as of the signing date of the Agreement, and acknowledges that the Sponsor and the Institution are relying on such representations in entering into this Agreement, that Principal Investigator has no commitments or agreements with any Person which interfere with or preclude the diligent and complete fulfillment of his/her obligations under this Agreement.

The Principal Investigator represents and warrants that neither he/she nor any Additional Personnel involved in conducting the Clinical Trial, has been debarred, excluded, disqualified or restricted in their ability to practice medicine, participate in a clinical trial, or perform services in connection with the evaluation of a pharmaceutical product under any laws, regulations or professional code of conduct, including but not limited to the United States Code of Federal Regulations ("U.S.C." or "CFR") title 21 section §335a and section §312.70.

The Principal Investigator shall immediately notify Sponsor should he/she or any Additional Personnel involved in conducting the Clinical Trial, be so debarred, excluded, disqualified or restricted, or should a procedure or action be initiated against any of them that could result in their being so debarred, excluded, disqualified or restricted, at any time during the term of this Agreement and during the twelve months following the expiration or termination of the Agreement.

ARTICLE 17 – ETHICAL CONDUCT

17.1 The Parties will conduct themselves and undertake the arrangements contemplated by this Agreement in a manner which is consistent with good business ethics and all applicable anti-bribery legislation (national and foreign), including but not limited to the OECD Convention dated 17th December 1997 on combating bribery of public officials in international business.

17.2 The Institution and the Principal Investigator, as well as any Additional Personnel, shall not make, promise or offer to make any payment or transfer anything of value (directly or indirectly) to (i) any individual, (ii) corporation, (iii) association, (iv) partnership, or (v) public body, (including but not limited to any officer or employee of any of the foregoing) who, acting in their official capacity or of their own accord, are in a position to influence, secure or retain any business for (and/or provide any financial or other advantage to) the Sponsor by improperly performing a function of a public nature or a business activity with the purpose or effect of public or commercial bribery, acceptance of or acquiescence in extortion, kickbacks or other unlawful or improper means of obtaining or retaining business.

17.3 The Institution shall have and maintain in place, throughout the term of this Agreement, its own anti-bribery policies and procedures to ensure compliance with these anti-bribery requirements (including but not limited to relevant and regular anti-bribery training to employees and an anti-bribery monitoring process) and shall enforce them where appropriate. The Institution shall ensure notably that the Principal Investigator and any Additional Personnel have been informed about:

→ the Sanofi Code of Conduct and anti-bribery policy are available at
- site http://www.codeofethics.sanofi/
- http://www.sanofiaventisgroup.ethicspoint.com

and shall further ensure that the Principal Investigator and any Additional Personnel will perform the Clinical Trial and behave in such way that enables the Sponsor to abide by its undertakings as set forth in those Sanofi codes.

The Institution and the Principal Investigator shall immediately notify the Sponsor if, at any time during the term of this Agreement, its circumstances, knowledge or awareness changes such that it would not be able to repeat the warranties set out in this Article 17 at the relevant time.

Violation Reporting of Sanofi's Code of Conduct & Anti-Bribery Policy: The Principal Investigator and the INSTITUTION recognize that Sponsor is committed at all times to uphold ethical policies in the conduct of its business, and it hereby undertake to comply with Sanofi's Code of Conduct and Anti-Bribery Policy. Sanofi's Code of Conduct and Anti-Bribery Policy is available on the site http://www.codeofethics.sanofi/ for any further references. If you have a concern, or believe in good faith that a law, regulation, provision of an industry code of conduct or any of the principles of Sanofi's Code of Ethics has been or is about to be violated, including but not limited to Anti-Bribery provisions, you may raise a concern on http://www.sanofiaventisgroup.ethicspoint.com.

The Principal Investigator and the Institution represent and warrant that neither he/she/it nor any of their personnel are officials, agents, representatives or employees of any government or political party or any

international public organization where they may be in a position of official government authority able to use that position to help the Sponsor obtain or maintain business or obtain a business advantage.

The Principal Investigator and the Institution further represent and warrant that they have not made and agree that they shall not make any payment or any offer or promise for payment, either directly or indirectly, of money or other assets, or transfer anything of value, to government or political party officials, officials of international organizations, candidates for public office, or representatives of other businesses or persons acting on behalf of any of the foregoing for the purpose of influencing decisions or actions or where such payment or advantage would constitute violation of any applicable anti-bribery legislation, regulations and/or codes, both national and foreign, including but not limited to, the US Foreign Corrupt Practices Act and the UK Bribery Act (hereinafter and above designated by "Anti-Bribery Provisions").

ARTICLE 18 - BENEFIT, ASSIGNMENT & TRANSFER

This Agreement shall benefit and be binding upon all of the Parties hereto, and their respective successors and assigns. This Agreement is concluded by the Sponsor *intuitu personae*. Hence the Principal Investigator and the Institution shall not be allowed to transfer totally or partially, directly or indirectly, the obligations the Sponsor charged them with, nor to subcontract them without the prior written consent of the Sponsor, which consent may be reasonably withheld.

In this latter case, the Principal Investigator and the Institution shall be fully responsible for the part of the obligations so subcontracted and warrants to the Sponsor that such part of the obligations shall be rendered under conditions consistent in all respect with the terms and conditions set forth herein. For sake of clarity, such consent from the Sponsor will not relieve the Institution and the Principal Investigator from any liability or obligation under this Agreement and Institution and Principal Investigator will remain liable *vis-à-vis* the Sponsor for the acts, omissions, defaults or negligence of its sub-contractors.

However, the Sponsor shall be entitled to assign and transfer to one of its Affiliates or successors this Agreement, without the prior written consent of the other Party, with notice thereafter to the other Party, by reason of any merger, acquisition, partnership, license agreement or otherwise, provided that the assignee is subject to the terms and obligations provided in this Agreement.

ARTICLE 19 - LAW

This Agreement shall be governed by and construed in accordance with the laws of India exclusive of its conflicts of laws principles. All and any dispute arising in connection with the interpretation or execution of this Agreement shall be settled by the competent courts of Mumbai (India).

ARTICLE 20 - PUBLICITY

No Party shall use the name of any other Party (or the name of any of the Sponsor's divisions or Affiliates) for promotional purposes without the prior written consent of the Party whose name is proposed to be used. No news release, publicity or other public announcement, either written or oral, regarding this Agreement or performance hereunder or results arising from the Clinical Trial, shall be made by the Institution or the Principal Investigator without the prior written approval of the Sponsor.

ARTICLE 21 - INDEPENDENT CONTRACTOR

Each Party acknowledges that it is an independent contractor. For greater certainty, the relationship between Sponsor, on the one hand, and Institution and Principal Investigator, on the other hand, shall not constitute a partnership, joint venture or agency. No Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which will be binding on the other, without the prior consent of the other Party to do so.

ARTICLE 22 – COUNTERPARTS

This Agreement may be executed in one or more counterparts which, together, shall constitute one and the same Agreement.

ARTICLE 23 - AGREEMENT MODIFICATIONS

The provisions of this Agreement, may not be altered, amended or modified except by written agreement signed by both Parties.
The Parties acknowledge and agree that the schedule of the present clinical trial agreement may be subject to amendments and/or update and in such a case, the last-dated version approved in written by a representative of all Parties will be considered to be incorporated therein by reference in place of any prior versions.

ARTICLE 24 - SEVERABILITY

If any term or condition of this Agreement (the deletion of which would not adversely affect the receipt of any material benefit by either Party hereunder) shall be held to be illegal, invalid or unenforceable by a court of competent jurisdiction, the remaining terms and conditions of this Agreement shall not be affected thereby and such terms and conditions shall be valid and enforceable to the fullest extent permitted by law.

ARTICLE 25 - NO WAIVER

Failure on the part of the Sponsor to exercise or enforce any right conferred upon it hereunder shall not be deemed to be a waiver of any such right nor operate to bar the exercise or enforcement thereof at any time or times thereafter.

ARTICLE 26 - FORCE MAJEURE

Noncompliance by any Party with the obligations of this Agreement due to force majeure, (laws or regulations of local government, war and/or civil commotion in the country of Clinical Trial's performance, destruction of facilities and materials necessary for the Clinical Trial's performance, fire and/or flood and/or earthquake and/or storm and/or shortage of materials and/or failure of public utilities or common carriers directly impacting the Clinical Trial's performance) 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, provided it first notifies the other Party in writing of such prevention and that it uses its best efforts to cause the event of the force majeure to terminate, be cured or otherwise ended.

ARTICLE 27 - SUPERIORITY

In the event of any inconsistency between the body of this Agreement and any schedules thereto, the provisions of the body of the Agreement shall prevail.

IN WITNESS WHEREOF, the Parties hereto have executed this Agreement as of the date first above written.

PRINCIPAL INVESTIGATOR

Name: Dr. Veena Kamath
Title: Principal Investigator
Date:

PROFESSOR
COMMUNITY MEDICINE DEPT.
KASTURBA MEDICAL COLLEGE
MANIPAL - 576 104

INSTITUTION

Name: Dr. BS Satish Rao
Title: Director, Manipal Center for Clinical research, MAHE, Manipal
Date:

Director - Research, MAHE
Office of Directorate of Research
Manipal Academy of Higher Education
MANIPAL - 576 104, KARNATAKA, INDIA

LABCORP DEVELOPMENT PVT. LTD.

DocuSigned by:
shekar dawkhar
Signer Name: shekar dawkhar
Signing Reason: I have reviewed this document
Signing Time: 04 May 2023 | 2:08:34 AM EDT
0484509F3B21B9777A5C86F67261

Name: Shekar Dawkhar
Title: Senior Costing Director
Date: 04 May 2023

Labcorp Drug Development India Pvt. Ltd.

SCHEDULE A
- FINANCIAL CONDITIONS -

1- Clinical Trial Costs:

For sake of clarity, the Parties hereby agree that:

(i) **"Evaluable Subject"** shall mean a Subject per Protocol for the primary endpoint of the Clinical Trial

(ii) **"Estimated Budget"** shall mean the estimated total amount of ***INR 81,03,621.50/- (Eighty-One Lakhs Three Thousand Six Hundred Twenty Once and Fifty paise only.)*** to be paid by the Sponsor (including through its CRO, audits and inspections compensation as referred to under Article 7.4) to the Institution, split as follows:

- Site-Startup Cost: (fixed amount): ***INR 60,000/- (Sixty Thousand Only)***
- Subjects costs (estimated total amount):***INR 79,08,621.50/- (Seventy-Nine Lakhs Eight Thousand Six Hundred Twenty Once and Fifty paise only.)***
- Site Close Out Cost: (fixed amount): ***INR 50,000/- (Fifty Thousand Only)***
- The SPONSOR will pay one-time sum of @ ***INR 85,000 /- (Eighty-Five Thousand only***) after the Study Closure to INVESTIGATOR / PAYEE for archival and document storage for a period of 25 (Twenty-Five) years from the date of site closure.

based on the following:

(iii) **"Actual Budget"** shall mean the real amount to be paid by the Sponsor (including through its CRO) to the Institution, i.e. the Estimated Budget reviewed according to actual (i) number of Subjects and visits per Subject performed, (ii) associated work per Subject carried out, and (iii) activities performed and related costs.

(iv) **"Contracted Currency"** shall mean the __INR_____ used for invoice's and payment's purpose.

(v) **"Domestic Currency"** shall mean the__INR___ used for the purpose of the calculation of the above-mentioned Clinical Trial Costs.

(vi) **"Foreign Currency Exchange"**: The Parties acknowledge that, due to fluctuations in exchange rates between Contracted Currency and Domestic Currency, the payments to be made by the Sponsor (including through its CRO) to the Institution may be greater or lesser than estimated by the Parties on the date of execution of this Agreement.

Prior to the payment of the last milestone, "balance of the Actual budget ", the Parties agree to examine the variation between the Foreign Currency and the Domestic Currency.

If the Exchange Parity has fluctuated by more than 10% [Option: 7% if not accepted by PI], upwards or downwards compared to the Reference Exchange Rate as determined below, the Parties agree to adjust the payment to be made to the Institution either upwards or downwards in the same magnitude as the currency exchange variation:

- If the difference is in favor of the Institution then, the Institution shall reduce invoice such difference to the Sponsor.
- If the variation is in favor of the Sponsor, the Institution will reflect that difference from the payment of the last milestone.

For the purposes of this Agreement, Reference Exchange Rate shall be the exchange rate as published by the European Central Bank in its web site called:
http://www.ecb.int/stats/exchange/eurofxref/html/index.en.html

To determine the variation of the exchange rate, the Parties agree to use the exchange rates as published on the month of the last invoice to be sent by the Institution.

All the payments to the Principal Investigator / Institution/Payee shall be done in Indian Rupees (INR) only. Accordingly, section (vi) is not applicable to the Agreement.

2- Payments:

Payments by the Sponsor (including through its CRO) to the Institution shall be made as follows:

- Upon signing of the Agreement by both parties and after receipt of Sanofi Pasteur Purchase Order number: INR 60,000(Sixty Thousand Only), corresponding to the Site start up fees.
- First Subject enrolled in Visit 1 of cohort I at the Trial Site: 05% of Estimated total subject cost
- First Subject enrolled in Visit 1 of cohort II at the Trial Site: 05% of Estimated total subject cost
- Last Subject enrolled in Cohort II Visit1 at the Trial Site: 40% of Actual Budget (minus the 10% of the Estimated Budget already paid)
- Last Visit Last Subject: 20% of the Actual Budget.
- Database clean: 20% of Actual Budget.
- End of statistical analysis and in no case no later than 3 months after database clean: the balance of the Actual Budget.

  However, if less than 90% of the Subjects enrolled are considered as Evaluable Subjects, the balance will not be paid to the Institution.

- Study patient travel reimbursement at the rate of **INR 1000/-** will be reimbursed to the site. Study patient travel reimbursement will only be paid by Labcorp if a third party vendor is not involved. Study patient names and any personal information must be removed and redacted from any expense supporting documentation (receipts and tickets etc.) submitted to Labcorp. Invoices shall be generated and submitted to Labcorp on quarterly basis. The invoice generated for patient travel reimbursement shall include the patient study number and visit details along with the details mentioned in section 3.5.

3- Payment terms:

3.1- Invoices must be issued to the CRO in accordance with the payment schedule defined in above section 2.

3.2- Payments of any and all amounts due by the CRO will be made only upon receipt of the proper and detailed corresponding original invoices by the Institution (CRO's payment terms: 45 days' net from the receipt of correct invoice's), in the Contracted Currency by bank transfer to the following Institution's bank account opened in the country in which the Institution is located.

For Payments related to INSTITUTION / INVESTIGATOR

Bank Name & Branch:	State Bank of India Madhuvan Seria, Ground Floor, Near SmrithiBhavan, Tiger Circle, Manipal, Karnataka 576104
Bank IFSC	SBIN0004426
Account No.:	32152923733
PAYEE:	Manipal University Research Unit
PAN No.:	AAETM8695B
GST No.:	29AAETM8695B1Z4

3.3- To be paid, any invoice must be approved in advance by Satyanarayana Peesapati, Regional Study Manager-Clinical Development

An electronic draft of any invoice in a pdf format must thus be sent in advance for review and validation by email to

To: Ruchi Chakraborty
Email: ruchi.chakraborty@covance.com
Subject: MEQ00064_Site invoice for processing

3.4- Once validated in accordance with above section 3.3, the original paper version of the invoice shall be addressed to the CRO to the following address:

- If shipped by normal mail (by post):

LABCORP DRUG DEVELOPMENT INDIA PRIVATE LIMITED
Building No. 1, Unit 601, Raheja Mindspace, Juinagar, MIDC Industrial Area, Shiravane Nerul,
Navi Mumbai 400706, Maharashtra

3.5- To be paid the original invoice must reference the following:

- Complete Institution's Name, Address and Phone Numbered
- Invoice date
- Invoice number
- Sanofi Pasteur Purchase Order Number – E003102537

- Payment amount and currency
- Payment term /due date
- CRO contact name
- Clinical Trial Code and Complete description of service rendered
- Method of payment: (Wire)
- Wiring instructions, including bank name, address, account number
- Intracommunity VAT number if applicable [For European third party in European countries only]

Sanofi Pasteur/ CRO may reserve the right to send back to the Institution any invoice that would not mention any and all of the above-mentioned references.

4- Miscellaneous:

4.1- Each Party will bear its own costs (legal, tax, accounting and other fees) incurred with the drawing up and execution of the Agreement.

4.2- If relevant, the Institution shall be liable to pay any and all amounts to others involved in the Clinical Trial, and especially the Additional Personnel.

4.3- The Parties agree that the excess and/or unutilised amount lying with the PAYEE/PRINCIPAL INVESTIGATOR/ INSTITUTION under this Agreement, at the request of the SPONSOR and/or as agreeable to the PAYEE/INVESTIGATOR /INSTITUTION at its/their discretion from time to time, be returned to the SPONSOR and/or be utilized towards Subjects' academic, educational or research purposes including setting up a library, recreational centre for Subject care.

5- Taxes:

5.1 The PAYEE will bear the responsibility for the déclaration of these sums and for the payment of all taxes and social contributions on the fees it will receive hereunder.

5.2 Taxes, as applicable, will be paid on generation of valid invoice showing the amount of tax to be charged before any payment is made under this Agreement.

5.3 Each payment made shall be inclusive of all applicable taxes and duties except for Goods and Service Tax ("GST") which shall be reimbursed by the SPONSOR to the Payee against presentation by the Payee of all relevant documentation. The party who makes a taxable service under or in connection with this Agreement shall be entitled to recover such taxes that it is required by law to collect from the other party to whom the services are made by issuing a valid tax invoice in the format prescribed under the relevant law.

Notwithstanding anything contrary stated herein in this Agreement, the other party to whom the services are made shall not be under any obligation to make any payment until the receipt of the tax invoice. In addition, if the PAYEE fails to upload its return on GSTN portal and is unable to pay GST within prescribed time period, the Payee shall indemnify the Sponsor such GST amount along with applicable interest.

- A Subject is considered as having completed the Study when he/she has completed the specified Study period, and is evaluated as per the Protocol.
- In case of Subjects recruited but not having completed the Study, the amount to be paid will be calculated according to the fees of the visits actually performed by these Subjects. No payment will be made for an ineligible Subject incorrectly randomized into the Study or in case the Subject did not complete the Study due to negligence, malpractice, breach of Protocol, willfully wrong act or omission on the part of the Principal Investigator/Institution.

-SCHEDULE 'B' BUDGET -

MEQ00064_Budget sheet for Dr.Veena Kamath			
Per subject Cost - Cohort 1_Group 1a			
Visit	Investigator Grant	Institutional Overhead @ 30%	Total
V1	21,130	6,339	27,469
C1	950	285	1,235
V2	6,002	1,801	7,803
V3	6,002	1,801	7,803
V4	6,001	1,800	7,801
C2	950	285	1,235
V5	6,000	1,800	7,800
V6	7,500	2,250	9,750
Per subject total grant			70,896
Target subjects to be enrolled			3
Grand Total Group 1a (A)			212,687
Per subject Cost - Cohort 1_Group 1b			
Visit	Investigator Grant	Institutional Overhead @ 30%	Total
V1	17,330	5,199	22,529
C1	950	285	1,235
V2	7,998	2,399	10,397
V3	7,996	2,399	10,395
V4	7,996	2,399	10,395
V5	10,000	3,000	13,000
C2	950	285	1,235
V6	11,500	3,450	14,950
Per subject total grant			84,136
Target subjects to be enrolled			9
Grand Total Group 1b (B)			757,224
Per subject Cost - Cohort 1_Group 1c			
Visit	Investigator Grant	Institutional Overhead @ 30%	Total

V1	17,330	5,199	22,529
C1	950	285	1,235
V2	8,260	2,478	10,738
V3	8,303	2,491	10,794
V4	8,225	2,468	10,693
V5	8,225	2,468	10,693
V6	9,000	2,700	11,700
C2	950	285	1,235
V7	10,000	3,000	13,000
Per subject total grant			**92,616**
Target subjects to be enrolled			**12**
Grand Total Group 1C (C)			**1,111,391**

Per subject Cost - Cohort 1_Group 2			
Visit	Investigator Grant	Institutional Overhead @ 30%	Total
V1	17,330	5,199	22,529
V2	10,801	3,240	14,041
C1	950	285	1,235
V3	8,000	2,400	10,400
V4	8,225	2,468	10,693
V5	8,225	2,468	10,693
V6	9,000	2,700	11,700
C2	950	285	1,235
V7	10,000	3,000	13,000
Per subject total grant			**95,525**
Target subjects to be enrolled			**24**
Grand Total Group 2 (D)			**2,292,607**

Per subject Cost - Cohort 2_Group 5a			
Visit	Investigator Grant	Institutional Overhead @ 30%	Total
V1	17,330	5,199	22,529
C1	950	285	1,235
V2	9,500	2,850	12,350
V3	9,500	2,850	12,350
C2	950	285	1,235

V4	8,300	2,490	10,790
V5	8,300	2,490	10,790
V6	8,300	2,490	10,790
V7	9,500	2,850	12,350
C3	950	285	1,235
V8	9,318	2,795	12,113
V9	8,360	2,508	10,868
Per subject total grant			118,635.40
Target subjects to be enrolled			5
Grand Total Group 5a (E)			593,177
Per subject Cost - Cohort 2_Group 5b			
Visit	Investigator Grant	Institutional Overhead @ 30%	Total
V1	17,330	5,199	22,529
C1	950	285	1,235
V2	9,500	2,850	12,350
V3	9,500	2,850	12,350
C2	950	285	1,235
V4	8,300	2,490	10,790
V5	8,300	2,490	10,790
V6	8,300	2,490	10,790
V7	9,500	2,850	12,350
V8	950	285	1,235
C3	9,318	2,795	12,113
V9	8,360	2,508	10,868
Per subject total grant			118,635.40
Target subjects to be enrolled			15
Grand Total Group 5b (F)			1,779,531
Per subject Cost - Cohort 2_Group 6			
Visit	Investigator Grant	Institutional Overhead @ 30%	Total
V1	17,330	5,199	22,529
C1	950	285	1,235
V2	9,500	2,850	12,350

V3	9,500	2,850	12,350
C2	950	285	1,235
V4	8,000	2,400	10,400
V5	8,000	2,400	10,400
V6	8,000	2,400	10,400
V7	8,155	2,447	10,602
V8	9,690	2,907	12,597
C3	950	285	1,235
V9	8,360	2,508	10,868
Per subject total grant			**116,200.50**
Target subjects to be enrolled			**10**
Grand Total Group 6 (G)			**1,162,005**
Estimated Total Subject Cost (A+B+C+D+E+F+G)			**7,908,621.50**

Fixed Payment		
Sr. No.	**Clinical trial set up costs**	**Amount**
1	Site-Start Up Fees	60,000
2	Site close out Fee	50,000
3	Archiving Cost for 25 yrs	85,000
Total Fixed Cost (H)		**195,000**

Estimated Total site level study budget	**8,103,621.50**
Above budget is excluding of subject travel reimbursement	

SCHEDULE C
- DATA PROCESSING AGREEMENT "DPA" -

This DPA details Sponsor, Institution and Investigator's respective roles and obligations regarding the processing of Personal Data under the Contract.

1. Definitions

1.1. Under this DPA, the Parties agree that the terms ***"Controller"***, ***"Data Subject"***, ***"Personal Data"***, ***"Personal Data Breach"***, ***"Processor"***, and ***"Supervisory Authority"*** shall have the meaning assigned to them in the General Data Protection Regulation (EU) 2016/679 ("GDPR").

1.2. ***"Applicable Data Protection Law"***: means, (i) in any case the GDPR; (ii) the French regulation on the protection of Personal Data as applicable to any Processing performed by and on behalf of the SPONSOR; and (iii) as the case may be, any other law or regulation applicable to the Processing of Personal Data.

1.3. ***"Approved Sub processor"*** means any natural or legal person engaged by Investigator or Institution, for the performance of any Processing under the Contract.

1.4. ***"Patient Medical Files"*** means any file other than clinical trial database and the Study File as defined in the current Good Clinical Practices and ICH Guidelines in which Institution and/or Investigator record the demographic, medical and treatment information about a Data Subject. It may be paper based and/or electronic records.

1.5. ***"Processing"***: means any operation or set of operations performed on Personal Data or on sets of Personal Data under the Contract, whether or not this processing is performed by automated means, including the collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction of Personal Data.

2. Role of the Parties

2.1. Sponsor shall be deemed as a Controller and Institution and/or Investigator as Processor(s) for any Processing of Personal data performed in accordance with the Protocol for the purpose of conducting the Study (**"Study Purpose"**).

2.2. It is agreed between the Parties that Institution and/or Investigator shall be deemed as independent controller(s) for (i) the Processing of Personal Data collected or generated in the course of the Study for the purpose of exercising independent medical judgment outside the Protocol requirements, (ii) for the retention and further use of Patient Medical Files and (iii) for meeting its confidentiality obligations and the obligations imposed on Institution and/or Investigator by applicable laws and regulations in the area of clinical trials (together **"Study Participant Care Purpose"**). For any Processing performed for the Study Participant Care Purpose, Institution and/or INVESTIGATOR shall process Personal Data in compliance with applicable data protection law and intellectual property and confidentiality sections of the Contract.

Institution and/or Investigator shall be solely responsible for the implementation of such Processing including, notably, to ensure that it has a legal ground to implement such Processing.

3. Obligations of the Parties

3.1. Processor expressly agrees that, for the Study Purpose:

a. it shall process Personal Data in accordance with the provisions of (i) the Contract and, in particular, this DPA, (ii) the Protocol as amended from time to time by Sponsor, (iii) the Informed Consent Form, as drafted and communicated by the Sponsor and as applicable (iv) any instructions from the Controller. All these documents define notably the scope, modalities and means of the Processing for the Study Purpose, as well as categories of Data Subjects concerned by such Processing

b. it shall process any data defined as personal data under Applicable Data Protection Law in compliance with such law.

3.2. In this respect Processor shall:

a. comply for any Processing with the instructions from any Supervisory Authority. If such instructions are contradictory to the provisions of this DPA, Processor shall inform in advance the Controller provided it is authorized to do so – in which case the Parties shall negotiate in good faith a review of this agreement to ensure it complies with such instructions;

b. immediately inform the Controller of its inability or the inability of any of its Approved Subprocessor, to comply with Processor obligations under Applicable Data Protection Laws or this DPA for whatever reason, with due justification as to the nature, cause and expected consequences of such inability.

c. maintain (i) all relevant documentation to be able to demonstrate its compliance with Applicable Data Protection Laws and with the provisions of this DPA, and (ii) a record of all categories of Processing activities carried out under the Contract. Such records of Processing activities shall contain, at least, its legal designation and the names and contact details of its representatives (including, for instance, its data protection officer, if any), the categories of processing activities carried out, the transfers of personal data to a third party country and the technical and organizational security measures it has implemented. It shall make such records of Processing activities available upon request to any competent Supervisory Authority and/or to the Controller;

d. immediately inform the Controller if it has reason to believe that all or part of the Processing infringes Applicable Data Protection Law or any relevant applicable law. In such a case, Controller and Processor shall cooperate in good faith to determine whether the Processing must be regarded as a breach of Applicable Data Protection Law, and whether, as a result, the Processing should be suspended, amended and re-initiated or alternatively if the Processing - as well as the Contract and this DPA - shall be terminated;

e. only disclose or permit the disclosure of Personal Data to Approved Subprocessor or collaborators who are (i) properly trained on the Processing of Personal Data and (ii) subject to confidentiality and data protection obligations at least as stringent as those contained in the Contract and this DPA, or as required by applicable Supervisory Authorities. Processor shall be responsible for any breach of this DPA by its Approved Subprocessors or Collaborators;

f. where it intends to transfer Personal Data in the context of the Agreement outside of the region where it is originally collected or hosted, (i) ensure that the transfer is governed by relevant safeguards, as defined by Applicable Data Protection Law, to maintain an adequate protection of Personal Data in compliance with Applicable Data Protection Law(s) and (ii) obtain, as applicable, any relevant consents, authorizations or permits from Data Subjects or competent Supervisory Authorities.

g. process and retain the Personal Data only for the period set out in Article 5.4 of the Agreement and in any event for no longer than any statutory or professional retention periods under any Applicable Data Protection Law or other mandatory laws or regulations;

h. provide Controller with the name of its representative for the Processing of Personal Data (for example: the name of the data protection officer);

3.3. It is also agreed between the Parties that Investigator and/or Institution shall never disclose, whether directly or indirectly, any directly identifying Personal Data, such as names, address and contact details, to Sponsor. Investigator and/or Institution shall be responsible to put in place all relevant technical and organizational measures and procedures to ensure such disclosures will not happen.

3.4. For the Study Purpose, the Parties agree that Investigator shall be responsible to provide all Data Subjects with all necessary information regarding the Processing, in compliance with article 3 of the Agreement.

3.5. When collecting the Personal Data from the Data Subjects, Investigator and Institution shall ensure that the Personal Data is accurate and shall maintain them up to date.

3.6. Institution and Investigator shall be responsible to ensure that Data Subjects can exercise effectively their rights regarding the Processing of their Personal Data for Study Purpose. As a consequence, Institution undertakes to implement all adequate technical and organizational measures designed to ensure that it can and will, on behalf of Sponsor, address all requests from Data Subjects for the exercise of the rights set out below within a maximum duration of 1 (one) month. Notwithstanding the above, Institution will forward any inquiries which cannot be answered or processed to the SPONSOR so that Sponsor can answer to the data subjects through Institution. The communications between Institution and Sponsor will be done in a pseudonymized form using the study-specific identification number. In addition, Institution and/or Investigator shall promptly inform the Sponsor of any objection to the Processing that may affect the use of the Personal Data under the Agreement, or of any claim regarding the Processing of Personal Data carried out within the framework of the Agreement, including allegation that the Processing is carried out in violation of the rights of the Data Subjects. Institution shall maintain a register of these requests and provide it to Sponsor upon to Sponsor(s)'s request.

3.7. In the event of a Personal Data Breach that compromises the security, privacy, confidentiality or integrity of Personal Data, Investigator and/or Institution, when it suffered or committed the Personal Data Breach, shall comply with Applicable Data Protection Law and at its own costs:

- notify without undue delay and in any case within twenty-four (24) hours of becoming aware of it, Sponsor about the Personal Data Breach and detail in the notification the nature of the Personal Data Breach, the categories and approximate number of Data Subjects concerned, the categories and approximate number of Personal Data records concerned and the likely consequences of the Breach,
- after investigating the causes of such Personal Data Breach, take such actions to minimize the effects of any Personal Data Breach,
- shall record all information relating to the Personal Data Breach, including the results of its own investigations and investigations by authorities,
- take all measures as necessary to prevent future Personal Data Breach.

3.8. Upon request, Processor shall provide reasonable assistance to allow Controller to develop a data protection impact assessment, notably by providing clear, complete and accurate information about the Processing to the Sponsor/Party handling the DPIA.

3.9. For the Study Purpose, Sponsor shall be the main point of contact to answer any queries or requests for information by competent Supervisory Authorities. In the event of such queries, requests for information or investigations from competent Supervisory Authorities, Institution and Investigator shall immediately inform Sponsor and consult with SPONSOR about the best course of action. As far as possible, Institution and Investigator shall submit any intended filing, declaration or statement to Sponsor for advice prior to its communication to any Supervisory Authority.

4. **Security measures**

4.1. Processor shall take, implement and maintain during the entire term of the Agreement, all appropriate technical and organizational security measures which shall ensure the confidentiality, integrity, availability and resilience of its Processing systems and service. To that end, the Controller will define, implement and monitor the application of a security and confidentiality policy. Regarding the technical and organizational measures designed to mitigate the risks, this policy shall at least describe:

- measures to ensure the physical security of equipment and premises and the provisions made for file backup;
- conditions of access to data, in particular the management of access rights, identification and authentication measures, procedures;
- measures ensuring traceability of access to medical information and connection history;
- security measures to be implemented for data transfer.
- research data must not be entered, even temporarily, on any tools other than those used for the processing;

4.2. In the event of direct data entry by clinical research professionals or on the premises of a data processor, the remote data entry tool must be secured, in particular by user authentication and encryption of data flows.

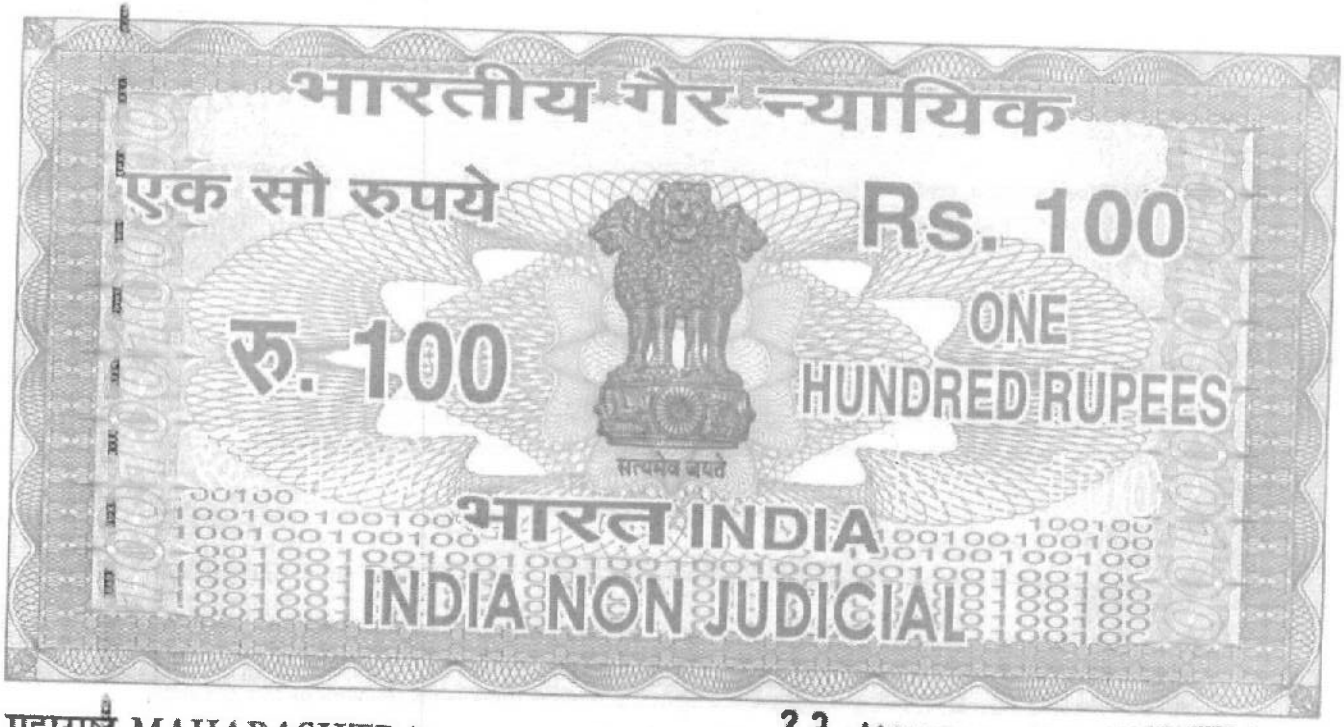
5. **Liability**

5.1. Processor shall be fully accountable and liable in the event of any breach of its obligations under this DPA and/or non-compliance with the Applicable Data Protection Law.

5.2. Each Party (the "Indemnifying Party") agrees to indemnify, defend, and hold harmless the other Party, its affiliates, trustees, officers, employees, agents, and successors (hereinafter referred to collectively as "Indemnitee(s)") from and against any claim, demand, proceeding, action, liability, suit, expense, fine, penalty, damage, loss and/or cost (including without limitation legal and other professional advisers fees) resulting or arising from any claims, actions, demand or suits from a Data Subject, a Third Party and/or a Supervisory Authority (collectively "Claim") that are incurred by or suffered by, made or instituted against the Indemnitees, and which arise out of, result from or are based on (i) the Indemnifying Party failure to adhere to and comply with the terms of this DPA, (ii) the Indemnifying Party failure to comply with the Applicable Data Protection Law, or (iii) the Indemnifying Party gross negligence or willful misconduct, for a Processing activity for which it is responsible as per this DPA. If Controller and Processor both contributed to the failure that gave rise to the same Claim, their liability shall be shared pro rata their contribution. When their respective contribution cannot be determined, their liability shall be shared in equal parts.

5.3. Use of a Subprocessor shall not release Processor from its obligations under this DPA. Processor remains solely responsible for the work and activities of its Subprocessors, and Processor shall be held liable for the acts and omissions of any of its Subprocessor(s) to the same extent as if the acts or omissions were performed by said Party.

5.4. This section prevails over the provisions relating to liability and/or indemnification in the Agreement and as the case may be, any separate letter of indemnification.



महाराष्ट्र MAHARASHTRA ◐ 2023 ◐ 23 JAN 2024 86AA 261258

जिल्हा कोषागार कार्यालय, ठाणे
8 JAN 2024
मुद्रांक प्रमुख लिपीक / लिपीक

AMENDMENT N°01

TO THE CLINICAL TRIAL AGREEMENT

BY AND BETWEEN:

- **FORTREA DEVELOPMENT PVT. LTD.** a clinical research organization incorporated under the laws of India having its registered office at Building No. 1, Unit 601 Raheja Mindspace, Juinagar, MIDC Industrial area, shiravane Nerul Navi Mumbai 400706, Maharastra. engaged by the Sponsor for the purpose of assisting the Sponsor in administration, management and carrying out the clinical trials/studies in India (hereinafter referred to as the "**CRO**");

AND:

- Manipal Center of Clinical Research, MAHE, having its Registered Office at Mezzanine Floor of old KMC Library Building, near KMC Dean Office, Kasturba Hospital, Manipal 576104 acting through its authorized signatory, Dr. B.S.Satish Rao , Director being authorised to sign this Agreement (hereinafter referred to as the "Institution" which expression shall mean and include unless repugnant to the context, its successors and permitted assigns)

(hereinafter referred to as the "**Institution**")

- and -

- **Dr Veena Kamath**, Professor Department of Community Medicine, Kasturba Medical College, Manipal Academy of Higher Education having its registered office at manipal.edu Building, Madhavanagar, Manipal 576104, Karnataka (hereinafter referred to as the **"Principal Investigator"**)

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With each of the parties collectively or individually referred to as "Party" or "Parties"

AND RELATES TO THE FOLLOWING CLINICAL TRIAL:

Immunogenicity and Safety of an Investigational Quadrivalent Meningococcal Conjugate Vaccine when Administered Concomitantly with Routine Pediatric Vaccines in Healthy Infants and Toddlers in India and the Republic of South Africa
Code: MEQ00064

(hereinafter defined as the **"Clinical Trial"**)

PREAMBLE

By this amendment (the **"Amendment"**), the Parties wish to complete and modify the clinical trial agreement effective as of 06th February 2024 signed between the Parties (as well as any previous amendments) (hereinafter the **"Agreement"**).

NOW THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration (the receipt and sufficiency of which are acknowledged by each Party), the Parties hereby agree as follows:

ARTICLE 1: PURPOSE OF THE AMENDMENT

The Sponsor wishes to entrust the Institution and the Principal Investigator with the performance of additional services. The Parties have agreed on the additional services to be performed by the Institution and the Principal Investigator, as summarized below and listed in Appendix 1 attached hereto.

Additional Services: the Parties hereby agree and acknowledge that article 4.2 first paragraph of the Agreement shall be amended as follows:
- to increase the number of Subject from **46** Subjects to **96** Subjects in **6 MONTHS** in Cohort I and target number of **30** Subjects to **60** Subjects in **4 MONTHS** in Cohort II starting from the first Subject recruited in the Clinical Trial.

The Institution acknowledges that it is able to perform a competitive enrollment and has a capacity of recruitment of **96** Subjects within a period of **6** months in Cohort I and **60** Subjects within a period of **4** months in cohort II.

WHEREAS, Fortrea was formerly known as Labcorp Drug Development India Private Limited and changed its name to Fortrea Development India Private Limited through an amendment to its organizational documents and this Notice reflects the new party name following the name change;

NOW THEREFORE, Fortrea hereby inform you in lieu of the Novation Notice shared with site in Oct 2023, as follows:

1. References to Fortrea's former company name are amended to refer to the new company name following its name change in the Agreement which is currently in force.

2. Each word and term used in this Notice, but not defined, has the meaning specified in the Agreement unless a clear contrary interpretation otherwise applies.

3. Pursuant to certain clause of the Agreement, the Parties have agreed to vary the terms agreed in the Agreement by the terms set out in this Notice.

4. Notices to Fortrea under the MSA shall be sent to:

   Fortrea Development India Pvt Ltd

   Building No. 1, Unit 601, Raheja Mindspace,
   Plot Nos. Gen/2/1/D,E&F, MIDCTTC Industrial Area,
   Shiravane, Nerul,
   Navi Mumbai 400706, Maharashtra

With a copy to:
General Counsel
8 Moore Drive, Durham, North Carolina, USA 27709

ARTICLE 2: DURATION

This Amendment is effective as of 06th February 2024 and shall remain in force until completion of the Clinical Trial and delivery of the final report, which for reference only, is expected by Q2, 2025.

ARTICLE 3: FINANCIAL CONDITIONS

The new financial provisions applicable to the Agreement as amended by this Amendment in consideration of the performance of the Clinical Trial together with the Additional Services are provided for in **Appendix 1** and depicted in **Appendix 2** attached hereto. It modifies and replaces the Schedules A and B attached to the Agreement.

ARTICLE 4: MISCELLANEOUS

All provisions of the Agreement not modified by this Amendment shall continue to be binding on the Parties.

IN WITNESS WHEREOF, the Parties hereto have caused this Amendment to be duly executed on their behalf in three counterparts, each of which shall be deemed to be an original.

PRINCIPAL INVESTIGATOR

Name: Dr Veena Kamath
Title: Principal Investigator
Date: 19/MAR/2023

INSTITUTION

Name: Dr. BS Satish Rao
Title: Director, Manipal Center for Clinical Research, MAHE, Manipal
Date: 09/APR/2024

Director - Research, MAHE
Office of Directorate of Research
Manipal Academy of Higher Education
MANIPAL - 576 104, KARNATAKA, INDIA

FORTREA DEVELOPMENT PVT. LTD.

Name: Shekhar Dawkhar
Title: Senior Costing Director
Date: 8-MAR-2024

Fortrea Development India Private Limited

APPENDIX 1

New Financial Conditions of the Clinical Trial

1- Clinical Trial Costs:

For sake of clarity, the Parties hereby agree that:

(i) "**Evaluable Subject**" shall mean a Subject per Protocol for the primary endpoint of the Clinical Trial

(ii) "**Estimated Budget**" shall mean the estimated total amount of ***INR 1,60,36,943.00/- (One Crore Sixty Lakhs Thirty Six Thousand Nine Hundred and Forty three rupees only)*** to be paid by the Sponsor (including through its CRO, audits and inspections compensation as referred to under Article 7.4) to the Institution, split as follows:

- Site-Startup Cost: (fixed amount): ***INR 60,000/- (Sixty Thousand Only)***
- Subjects costs (estimated total amount):***INR 1,58,41,943.00/- (One Crore Fifty eight Lakhs Forty one Thousand Nine Hundred and Forty three rupees only)***
- Site Close Out Cost: (fixed amount): ***INR 50,000/- (Fifty Thousand Only)***
- The SPONSOR will pay one-time sum of ***@ INR 85,000 /- (Rupees Eighty five Thousand only)*** after the Study Closure to INVESTIGATOR / PAYEE for archival and document storage for a period of 25 (Twenty-Five) years from the date of site closure.

based on the following:

(iii) "**Actual Budget**" shall mean the real amount to be paid by the Sponsor (including through its CRO) to the Institution, i.e. the Estimated Budget reviewed according to actual (i) number of Subjects, number of subjects randomized into the cohort and visits per Subject performed(ii) associated work per Subject carried out, and (iii) activities performed and related costs.

(iv) "**Contracted Currency**" shall mean the __INR_____ used for invoice's and payment's purpose.

(v) "**Domestic Currency**" shall mean the__INR___ used for the purpose of the calculation of the above-mentioned Clinical Trial Costs.

(vi) "**Foreign Currency Exchange**": The Parties acknowledge that, due to fluctuations in exchange rates between Contracted Currency and Domestic Currency, the payments to be made by the Sponsor (including through its CRO) to the Institution may be greater or lesser than estimated by the Parties on the date of execution of this Agreement.

Prior to the payment of the last milestone, "balance of the Actual budget ", the Parties agree to examine the variation between the Foreign Currency and the Domestic Currency.
If the Exchange Parity has fluctuated by more than 10% [Option: 7% if not accepted by PI], upwards or downwards compared to the Reference Exchange Rate as determined below, the Parties agree to adjust the payment to be made to the Institution either upwards or downwards in the same magnitude as the currency exchange variation:

- If the difference is in favor of the Institution then, the Institution shall reduce invoice such difference to the Sponsor.
- If the variation is in favor of the Sponsor, the Institution will reflect that difference from the payment of the last milestone.

For the purposes of this Agreement, Reference Exchange Rate shall be the exchange rate as published by the European Central Bank in its web site called:
http://www.ecb.int/stats/exchange/eurofxref/html/index.en.html

To determine the variation of the exchange rate, the Parties agree to use the exchange rates as published on the month of the last invoice to be sent by the Institution.

All the payments to the Principal Investigator / Institution/Payee shall be done in Indian Rupees (INR) only. Accordingly, section (vi) is not applicable to the Agreement.

2- Payments:

Payments by the Sponsor (including through its CRO) to the Institution shall be made as follows:

- Upon signing of the Agreement by both parties and after receipt of Sanofi Pasteur Purchase Order number: INR 60,000(Sixty Thousand Only), corresponding to the Site start up fees.
- First Subject enrolled in Visit 1 of cohort I at the Trial Site: 05% of Estimated total subject cost
- First Subject enrolled in Visit 1 of cohort II at the Trial Site: 05% of Estimated total subject cost
- Last Subject enrolled in Cohort II Visit1 at the Trial Site: 40% of Actual Budget (minus the 10% of the Estimated Budget already paid)
- Last Visit Last Subject: 20% of the Actual Budget.
- Database clean: 20% of Actual Budget.
- End of statistical analysis and in no case no later than 3 months after database clean: the balance of the Actual Budget.

However, if less than 90% of the Subjects enrolled are considered as Evaluable Subjects, the balance will not be paid to the Institution.

- Study patient travel reimbursement at the rate of **INR 1000/-** will be reimbursed to the site. Study patient travel reimbursement will only be paid by Fortrea if a third party vendor is not involved. Study patient names and any personal information must be removed and redacted from any expense supporting documentation (receipts and tickets etc.) submitted to Fortrea. Invoices shall be generated and submitted to Fortrea on quarterly basis. The invoice generated for patient travel reimbursement shall include the patient study number and visit details along with the details mentioned in section 3.5.

3- Payment terms:

3.1- Invoices must be issued to the CRO in accordance with the payment schedule defined in above section 2.

3.2- Payments of any and all amounts due by the CRO will be made only upon receipt of the proper and detailed corresponding original invoices by the Institution (CRO's payment terms: 45 days' net from the receipt of correct invoice's), in the Contracted Currency by bank transfer to the following Institution's bank account opened in the country in which the Institution is located.

For Payments related to INSTITUTION / INVESTIGATOR

Bank Name & Branch:	State Bank of India Madhuvan Seria, Ground Floor, Near SmrithiBhavan, Tiger Circle, Manipal, Karnataka 576104
Bank IFSC	SBIN0004426
Account No.:	32152923733
PAYEE:	Manipal University Research Unit
PAN No.:	AAETM8695B
GST No.:	29AAETM8695B1Z4

3.3- To be paid, any invoice must be approved in advance by Shailender Rathore, Clinical Project Leader and Yuvadee Yaiprayoon, Clinical Study Manager- Clinical Development

An electronic draft of any invoice in a pdf format must thus be sent in advance for review and validation by email to

To: Shailender Rathore
Email: shailender.rathore@fortrea.com
Subject: MEQ00064_Site invoice for processing

3.4- Once validated in accordance with above section 3.3, the original paper version of the invoice shall be addressed to the CRO to the following address:

- If shipped by normal mail (by post):

FORTREA DRUG DEVELOPMENT INDIA PRIVATE LIMITED
Building No. 1, Unit 601, Raheja Mindspace, Juinagar, MIDC Industrial Area, Shiravane Nerul, Navi Mumbai 400706, Maharashtra

3.5- To be paid the original invoice must reference the following:

- Complete Institution's Name, Address and Phone Number
- Invoice date
- Invoice number
- Payment amount and currency
- Payment term /due date
- CRO contact name
- Clinical Trial Code and Complete description of service rendered
- Method of payment: (Wire)
- Wiring instructions, including bank name, address, account number
- Intracommunity VAT number if applicable [For European third party in European countries only]

Sanofi Pasteur/ CRO may reserve the right to send back to the Institution any invoice that would not mention any and all of the above-mentioned references.

4- Miscellaneous:

4.1- Each Party will bear its own costs (legal, tax, accounting and other fees) incurred with the drawing up and execution of the Agreement.

4.2- If relevant, the Institution shall be liable to pay any and all amounts to others involved in the Clinical Trial, and especially the Additional Personnel.

4.3- The Parties agree that the excess and/or unutilised amount lying with the PAYEE/PRINCIPAL INVESTIGATOR/ INSTITUTION under this Agreement, at the request of the SPONSOR and/or as agreeable to the PAYEE/INVESTIGATOR /INSTITUTION at its/their discretion from time to time, be returned to the SPONSOR and/or be utilized towards Subjects' academic, educational or research purposes including setting up a library, recreational centre for Subject care.

5- Taxes:

5.1 The PAYEE will bear the responsibility for the déclaration of these sums and for the payment of all taxes and social contributions on the fees it will receive hereunder.

5.2 Taxes, as applicable, will be paid on generation of valid invoice showing the amount of tax to be charged before any payment is made under this Agreement.

5.3 Each payment made shall be inclusive of all applicable taxes and duties except for Goods and Service Tax ("GST") which shall be reimbursed by the SPONSOR to the Payee against presentation by the Payee of all relevant documentation. The party who makes a taxable service under or in connection with this Agreement shall be entitled to recover such taxes that it is required by law to collect from the other party to whom the services are made by issuing a valid tax invoice in the format prescribed under the relevant law.

Notwithstanding anything contrary stated herein in this Agreement, the other party to whom the services are made shall not be under any obligation to make any payment until the receipt of the tax invoice. In addition, if the PAYEE fails to upload its return on GSTN portal and is unable to pay GST within prescribed time period, the Payee shall indemnify the Sponsor such GST amount along with applicable interest.

- A Subject is considered as having completed the Study when he/she has completed the specified Study period, and is evaluated as per the Protocol.
- In case of Subjects recruited but not having completed the Study, the amount to be paid will be calculated according to the fees of the visits actually performed by these Subjects. No payment will be made for an ineligible Subject incorrectly randomized into the Study or in case the Subject did not complete the Study due to negligence, malpractice, breach of Protocol, willfully wrong act or omission on the part of the Principal Investigator/Institution.

APPENDIX 2 - BUDGET

MEQ00064_Budget sheet for Dr.Veena Kamath

Per subject Cost - Cohort 1_Group 1a			
Visit	**Investigator Grant**	**Institutional Overhead @ 30%**	**Total**
V1	21,130	6,339	27,469
C1	950	285	1,235

V2	6,002	1,801	7,803
V3	6,002	1,801	7,803
V4	6,001	1,800	7,801
C2	950	285	1,235
V5	6,000	1,800	7,800
V6	7,500	2,250	9,750
Per subject total grant			**70,896**
Target subjects to be enrolled			**6**
Grand Total Group 1a (A)			**425,373**

Per subject Cost - Cohort 1_Group 1b			
Visit	**Investigator Grant**	**Institutional Overhead @ 30%**	**Total**
V1	17,330	5,199	22,529
C1	950	285	1,235
V2	7,998	2,399	10,397
V3	7,996	2,399	10,395
V4	7,996	2,399	10,395
V5	10,000	3,000	13,000
C2	950	285	1,235
V6	11,500	3,450	14,950
Per subject total grant			**84,136**
Target subjects to be enrolled			**18**
Grand Total Group 1b (B)			**1,514,448**

Per subject Cost - Cohort 1_Group 1c			
Visit	**Investigator Grant**	**Institutional Overhead @ 30%**	**Total**

V1	17,330	5,199	22,529
C1	950	285	1,235
V2	8,260	2,478	10,738
V3	8,303	2,491	10,794
V4	8,225	2,468	10,693
V5	8,225	2,468	10,693
V6	9,000	2,700	11,700
C2	950	285	1,235
V7	10,000	3,000	13,000
Per subject total grant			**92,616**
Target subjects to be enrolled			**24**
Grand Total Group 1C (C)			**2,222,782**

Per subject Cost - Cohort 1_Group 2

Visit	Investigator Grant	Institutional Overhead @ 30%	Total
V1	17,330	5,199	22,529
V2	10,801	3,240	14,041
C1	950	285	1,235
V3	8,000	2,400	10,400
V4	8,225	2,468	10,693
V5	8,225	2,468	10,693
V6	9,000	2,700	11,700
C2	950	285	1,235
V7	10,000	3,000	13,000
Per subject total grant			**95,525**
Target subjects to be enrolled			**48**

Grand Total Group 2 (D)	4,585,214

Per subject Cost - Cohort 2_Group 5a			
Visit	Investigator Grant	Institutional Overhead @ 30%	Total
V1	17,330	5,199	22,529
C1	950	285	1,235
V2	9,500	2,850	12,350
V3	9,500	2,850	12,350
C2	950	285	1,235
V4	8,300	2,490	10,790
V5	8,300	2,490	10,790
V6	8,300	2,490	10,790
V7	9,500	2,850	12,350
C3	950	285	1,235
V8	9,318	2,795	12,113
V9	8,360	2,508	10,868
Per subject total grant			118,635.40
Target subjects to be enrolled			10
Grand Total Group 5a (E)			1,186,354

Per subject Cost - Cohort 2_Group 5b			
Visit	Investigator Grant	Institutional Overhead @ 30%	Total
V1	17,330	5,199	22,529
C1	950	285	1,235
V2	9,500	2,850	12,350

V3	9,500	2,850	12,350
C2	950	285	1,235
V4	8,300	2,490	10,790
V5	8,300	2,490	10,790
V6	8,300	2,490	10,790
V7	9,500	2,850	12,350
V8	950	285	1,235
C3	9,318	2,795	12,113
V9	8,360	2,508	10,868
Per subject total grant			**118,635.40**
Target subjects to be enrolled			**30**
Grand Total Group 5b (F)			**3,559,062**
Per subject Cost - Cohort 2_Group 6			
Visit	**Investigator Grant**	**Institutional Overhead @ 30%**	**Total**
V1	17,330	5,199	22,529
C1	950	285	1,235
V2	9,500	2,850	12,350
V3	9,500	2,850	12,350
C2	950	285	1,235
V4	8,000	2,400	10,400
V5	8,000	2,400	10,400
V6	8,000	2,400	10,400
V7	8,155	2,447	10,602
C3	950	285	1,235
V8	9,690	2,907	12,597

C4	950	285	1,235
V9	8,360	2,508	10,868
Per subject total grant			**117,435.50**
Target subjects to be enrolled			**20**
Grand Total Group 6 (G)			**2,348,710**
Estimated Total Subject Cost (A+B+C+D+E+F+G)			**15,841,943.00**
Fixed Payment			
Sr. No.	**Clinical trial set up costs**		**Amount**
1	Site-Start Up Fees		60,000
2	Site close out Fee		50,000
3	Archiving Cost for 25 yrs		85,000
Total Fixed Cost (H)			**195,000**
Estimated Total site level study budget			**16,036,943.00**
Above budget is excluding of subject travel reimbursement			