CLINICAL TRIAL AGREEMENT

This Clinical Trial Agreement ("**Agreement**"), made and effective as of the dated signature at the end of this Agreement ("**Effective Date**"), is by and among;

CBCC Global Research ("**CBCC**"), an Indian Company having its principal place of business at 2nd floor, SKODA House, Opp. L.J. Campus, S. G. Highway, Ahmedabad – 382210, India represented by Dr. Sandeep Singh.

And

Dr. Mohd. Haseeb Mohd. Najeeb ("**Principal Investigator**"), having his principal business address at Mahatma Gandhi Mission's (MGM) Medical College & Hospital, N-6, Cidco, Aurangabad, 431003, Maharashtra, India.

And

Mahatma Gandhi Mission's (MGM) Medical College & Hospital ("**Institution**") having its principal business address at Mahatma Gandhi Mission's (MGM) Medical College & Hospital, N-6, Cidco, Aurangabad, 431003, Maharashtra, India.represented by Dr Rajendra Bohra.

And

Grapecity Research Solutions LLP ("**SMO**") having its principal business address at Shree Prasad, Block No D-2, Prakash Housing Society, Kalewadi Phata, Thergaon, Pune 411033, Maharashtra, India represented by Dr Sunil Chaudhary

PREAMBLE

WHEREAS, CBCC has been contracted by Tergene Biotech Pvt. Ltd. (A Subsidiary of Aurobindo Pharma Ltd.) ("**Sponsor**"), having its principal business address at Suite 121 & 122, Building 450, Genome Valley, Turkapally (V), Shamirpet (M) RR Dist, Hyderabad 500078, India to perform one or more of Sponsor study related duties and functions for the clinical trial entitled as "A Phase 3, Observer blind, Randomized, Active-Controlled Trial Evaluating the Immunologic Non-inferiority, Safety and Tolerability of a 15-valent Pneumococcal Conjugate Vaccine Compared to a 13-valent Pneumococcal Conjugate Vaccine in Healthy Infants Given with Routine Pediatric Vaccinations" (the "**Clinical Trial**" or "Study" as used throughout this Agreement) according to Protocol Number "**CBCC/2020/029**" ("**Protocol**"), and which term shall include any amendments made to the Protocol from time to time across India.

Hereinafter, the Institution, the Principal Investigator, SMO, CBCC are individually referred to as the "**Party**" or collectively referred to as the "**Parties**".

Study vaccine will be referred to as "**Investigational Product**" hereinafter.

Whereas Principal Investigator is appropriately qualified and experienced and working at the Institution and the Principal Investigator has the authority and desire to conduct the Study at the Institution,

Whereas the Institution has adequate infrastructure to conduct the Study and allows the Principal Investigator and CBCC to conduct the Study.

NOW THEREFORE, the undersigned Parties have agreed upon the rights and obligations set forth below, which shall apply between them in connection with the performance of the Clinical Trial.

1. SCOPE OF WORK

This Agreement allows the Parties to specify distinct Clinical Trial activities to be performed by the Principal Investigator and Institution for the Clinical Trial.

CBCC on behalf of Sponsor hereby declares that all the necessary permissions and licenses required under the provision of relevant acts and rules namely Drug & Cosmetics Act and Drug & Cosmetic Rules 1945 and their subsequent amendments (including New Drugs and Clinical Trials Rule, 2019) are obtained by them prior to starting subject enrollments in the Clinical Trial.

The Principal Investigator hereby confirms that he has read and understood the aforementioned Clinical Trial Protocol, inclusive of all amendments and appendices.

1.1 Clinical Trial Conduct

a) The Principal Investigator shall conduct the Clinical Trial at the Institution according to the Protocol provided to the Principal Investigator, which may be amended from time to time in writing by CBCC; which is hereby incorporated by reference (**Schedule I**) in this Agreement.

b) In the event of a conflict between the terms of this Agreement and the Protocol, the terms of the Protocol shall govern for any matter regulated by applicable laws and regulations and, as to all other matters, this Agreement shall govern.

c) The Institution will allocate qualified and trained personnel, equipment, materials (except as otherwise may be provided herein) and facilities as are necessary or useful to perform the Clinical Trial.

d) In performing the Clinical Trial, each Party shall fully comply with all applicable laws and regulations, and all terms and conditions of the Protocol and this Agreement.

e) Principal Investigator and the Institution agree that in performing their obligations under this Agreement, they shall comply with all the applicable laws, rules, regulations guidelines and standards, without limitation to the relevant ICH GCP guidelines and standards and all applicable laws relating to confidentiality and privacy, prescribed under the Directives of the Institutional Ethics Committee.

f) The Principal Investigator and the Institution will, during the Term, be granted role specific access to a third-party data management platform (the "**Platform**") and shall be responsible for and required, as part of their services, for inputting all correct and applicable information relating to the Study into such Platform within the required deadlines and in accordance with any Platform access or use requirements as may be specified from time to time by CBCC and/or the third party management Platform provider. CBCC will have the delegated responsibility from the Sponsor for the supervision and on-site and/or remote monitoring of the Principal Investigator and the Institution and for ensuring the data integrity of the inputted clinical site data entered into the Platform.

1.2 Principal Investigator

a) The work to be performed hereunder shall be performed solely by or under the supervision of the Principal Investigator:

- The Principal Investigator shall take primary responsibility for performing the Clinical Trial at the Institution according to the Protocol, the Good Clinical Practice Guidelines ("**GCP**"), the terms of this Agreement, and the current standard of care of Institution customary in the area of clinical research for the pharmaceutical industry ("**Standard of Care**") along with all applicable statutory provisions;
- The Principal Investigator shall ensure that the standard operating procedures have been documented and are in compliance with GCP and applicable regulations.
- The Principal Investigator represents and warrants that he is:
  - (i) Qualified by training and experience to perform the Clinical Trial and has special expertise in the field of clinical research relating to the Clinical Trial;
  - (ii) Has provided CBCC with a true and correct copy of Principal Investigator's current curriculum vitae (CV) and medical registration certificate.

b) If the Principal Investigator is unable to continue with the Clinical Trial or if the Institution is moving or closing down, the Principal Investigator and the Institution shall promptly notify CBCC in writing within 15 days and propose a substitute in place of the Principal Investigator or the new location of the site. CBCC, upon consultation with the Sponsor shall have the right to either approve any such substitute or terminate this Agreement within 30 days upon receipt of notification from the Principal Investigator if the proposed substitute is not acceptable to the Sponsor, in the Sponsor's sole discretion. If accepted by the Sponsor, the substitute Principal Investigator will sign this Agreement for approval and will become a party to this Agreement.

c) During the performance of the Clinical Trial, the Principal Investigator is responsible for, including but not limited to the following aspects:

- Provision of required study documents (e.g. curriculum vitae(s), Investigator Undertaking, medical registration certificates, and/or other relevant documents evidencing qualification of Investigator (s) and sub-Investigator (s), confirmation of adequate site facilities, etc.);
- Progress reporting (including recruitment figures) to the Ethics Committee and CBCC on a regular basis;
- Resolve any queries that are identified or generated between the Study Case Report Forms and the subject's medical records within 07 days;
- Ensuring access by monitors, auditors and regulatory authorities to the Principal Investigator and other project facilities, original study materials, drug records, subject records, case records and other records, subject to applicable laws and regulations; and providing appropriate working conditions for monitors, auditors and regulatory authorities to perform study–related on-site and/or remote monitoring, audit and inspections with or without prior intimation to access and review study documents;
- To allow any regulatory inspection by DCGI or any applicable regulatory authorities within 5 years of submission of the dossier and ensure compliance of any regulatory deficiency raised by such authorities in a reasonable period of time. If the Principal Investigator is to submit any information to such regulatory authorities' agencies, such submission shall not be made without CBCC's prior review and written approval, and any changes (other than entry of required information) also shall be subject to such prior written approval;

- Safe handling, storage, transportation and disposal of infectious materials and wastes involved in the Clinical Trial;
- Ensures a complete and final delegation log containing all study staff members and duties delegated by the Principal Investigator;
- Inform the Ethics Committee of the study updates and study closure;
- Maintenance of Investigational Product accountability records, study documents including Investigational Product acknowledgement receipts, study supply receipts, payment receipts, EC approvals etc;
- Handling and storage of the Investigational Products (as hereinafter defined) according to the Protocol;
- Storage of the Investigator site file containing Essential Documents (As per ICH-GCP) and all the Clinical Trial related data for a period of 5 years after completion of the Study. Charges for archival shall be borne as mentioned under **Schedule-II**. The Principal Investigator and/or the Institution shall inform CBCC in writing in the event of relocation or transfer of archiving responsibilities. On completion of the archival period, the Principal Investigator/Institution must notify, in writing, CBCC for further management of Study documents and follow CBCC's instructions. CBCC, in turn, will obtain confirmation from Sponsor on further management of Clinical Trial documents. CBCC on behalf of Sponsor may direct the Principal Investigator/Institution either to forward the documents to a third-party location identified by CBCC at CBCC or Sponsor's cost or to destroy the documents at the site, subject to any retention obligations imposed by applicable law on the Principal Investigator/Institution. The record of either a third party archival or destruction must be maintained at the Institution and a copy be forwarded to CBCC.
- The Principal Investigator is responsible for training and supervision of sub-Investigators and other site Study team member on the procedures specified in the Protocol to ensure scientific, technical and ethical conduct of the Clinical Trial. In case of any personnel changes, the Principal Investigator is responsible for notifying CBCC of such change in a timely manner.
- The Principal Investigator shall participate in teleconferences required by CBCC/Sponsor to update the Investigational Product information and resolve issues, if any;
- It shall be the duty of Principal Investigator to report all serious adverse events as per applicable local country regulatory requirement;

- Principal Investigator/Institute will inform CBCC about any inspection(s) from any regulatory authorities for the Study within 24 business hours of their notification. CBCC in turn will promptly notify Sponsor of inspection by regulatory authorities;
- The Principal Investigator shall provide adequate medical care to the Study Subject(s) (as defined in Clause 1.7) in case of any adverse events during the Subject's participation in the Clinical Trial.

1.3 Ethics Committee Approval

The Principal Investigator shall ensure that Ethics Committee is registered under CDSCO as per applicable local country regulatory requirement. The Principal Investigator shall also ensure that prior to enrolling any Subjects in the Clinical Trial, the Ethics Committee has approved in writing the conduct of Clinical Trial at the Institution under the supervision of the Principal Investigator. If the Ethics Committee alters or withdraws its approval of the Clinical Trial in any manner, or of the participation of the Principal Investigator or any Co-Investigators in the Clinical Trial, the Principal Investigator shall promptly notify CBCC/Sponsor in writing. The Principal Investigator shall comply with the terms and conditions laid down in the Ethics Committee approval.

1.4 Communication and Reporting to Competent Authorities

CBCC shall assume responsibility for interaction with and reporting to the Indian regulatory authority and the Ethics Committee as required and/or permitted by applicable laws and guidelines. The Principal Investigator retains responsibility for standard Clinical Trial-related communication and reporting to the Ethics Committee in accordance with standard procedure of the Ethics Committee, Indian Good Clinical Practice guidelines and all other applicable regulatory requirements.

1.5 Informed Consent

a) The Principal Investigator shall ensure that adequate information is given to the subject's parents (or legal guardian or legal representatives, if applicable) both in oral and written form in a language that they fully comprehend and in a manner that is non-technical. Principal Investigator will allow CBCC to monitor the signed informed consent forms during on-site and/or remote monitoring visits or audits.

b) The Principal Investigator shall ensure the Audio-visual recording of informed consent process.

c) The Principal Investigator shall ensure that the written Informed Consent is signed, dated and obtained from each subject's parent in this Clinical Trial. The signed and dated consent must be obtained prior to the first procedure set forth in the Protocol and subject's parents (or legal guardian or legal representatives, if applicable) will be allowed sufficient time to decide whether or not they wish to make an informed decision about their infant's participation in the Clinical Trial.

d) The Principal Investigator shall keep the original Informed Consent Form in the Study Subject's permanent records held by the Institution and hand over a copy to the subject's parent (or legal guardian or legal representatives, if applicable).

e) The Principal Investigator shall ensure that the Study Subject information sheet and the Informed Consent Form has been approved by the Ethics Committee and it shall be furnished to the Licensing Authority appointed by the Central Government to perform the duties of the licensing authority.

f) The Principal Investigator shall be responsible for responding to all subject's parents (or legal guardian or legal representatives, if applicable) questions relating to the Study.

1.6 Study Team

The Principal Investigator may appoint other individuals as Co-investigators who are appropriate to assist in the conduct of the Clinical Trial in accordance with the Protocol, provided that (i) the Principal Investigator shall be required to act in accordance with proper professional judgment in making all such appointments; and (ii) the Principal Investigator shall be responsible for all acts, omissions or breaches of this Agreement by such Co-investigators. The Principal Investigator shall be responsible for leading the team of Co-investigators, who in all respects shall be bound by the same obligations as the Principal Investigator, and the Principal Investigator shall keep all Co-investigators informed in detail about all such obligations as they may exist from time to time. The Principal Investigator may also appoint other staff such as site coordinator, phlebotomist etc. for Study related activities. Further, the Principal Investigator shall be responsible for ensuring that the Co-investigator and all staff and personnel within the Institution who participate in the Clinical Trial, have read and understood the Protocol and they are qualified, experienced and trained for conducting the Clinical Trial.

1.7 Study Subject Enrollment

a) The Principal Investigator shall not start enrolling Study Subjects prior to receiving written approval from the Ethics Committee (or equivalent) as well as written authorization from CBCC to do so. The Principal Investigator shall use his best efforts to promptly enroll Study Subjects in the Clinical Trial who meet the eligibility criteria set forth in the Protocol ("**Study Subjects**"), consistent with Standard of Care.

b) CBCC on behalf of Sponsor reserves the right to limit the recruitment of further Study Subjects or to cease the recruitment at the site, for reasons relating to the appropriate management of the Clinical Trial, including, without limitation, where the applicable national recruitment targets for the Clinical Trial have been reached. Upon receipt of written notice from the CBCC to cease recruitment, the Principal Investigator shall immediately cease further recruitment of Study Subjects.

1.8 Investigational Product

a) The Sponsor/CBCC or designee shall be responsible for providing the Principal Investigator the Investigational Products and the recommended vaccines as per the national immunization schedule free of charge to conduct the Clinical Trial at the Institution. The Investigational Products provided hereunder are investigational in nature and are not covered by any valid market authorization. The Sponsor/CBCC or designee shall be responsible for providing the supportive Clinical Trial supplies required for the Clinical Trial to be conducted at the site.

b) The Principal Investigator shall:

- not distribute the Investigational Products to any other person or entity,
- allow access of the Investigational Products to personnel within the Institution having a "need to access",
- use the Investigational Products only on Study Subjects under the Principal Investigator's supervision,
- not analyze, decompose, amend or modify the properties of the Investigational Products, and
- along with Institution shall not use the Investigational Product past the labeled expiration date.

c) The Institution and/or the Principal Investigator shall promptly provide to CBCC all required documentation with respect to the usage and the return of the Investigational Product. After completion or premature termination of the Clinical Trial, the Institution and/or the Principal Investigator shall return unused Investigational Product pursuant to the procedures provided by CBCC and/or Sponsor to the CBCC and/or Sponsor.

1.9 Monitoring, Inspections and Audits of Study

The Principal Investigator and the Institution shall permit Sponsor, CBCC and/or CBCC designee(s)/representative access to the Institution, during regular business hours with reasonable prior notice, to monitor the conduct of the Clinical Trial as well as to audit records, case report forms ("**CRF**"), Data and other information and documents relating to the Clinical Trial, in order to verify Principal Investigator's compliance with his obligations. If any governmental entity/regulatory agency should audit or inspect the Institution during the conduct of study, the Principal Investigator and/or the Institution shall provide CBCC and the Sponsor with immediate notice and shall provide an opportunity for the Sponsor and CBCC or their designee to be present during such governmental audit or inspection. The Institution agrees to co-operate and provide all reasonable assistance with any on-site and/or remote monitoring and/or auditing activity. No such on-site and/or remote

monitoring and/or auditing by the Sponsor and/or CBCC will relieve the Principal Investigator of any of his obligations hereunder.

In the event of inspection by regulatory agency in respect of Clinical Trial, Principal Investigator will cooperate with regulatory agency and CBCC representatives in the conduct of inspections and will ensure that Study Records are maintained in a way that facilitates such activities. Principal Investigator will promptly resolve any discrepancies that are identified between the Study Case Report Forms and the subject's medical records. Principal Investigator will promptly forward to CBCC copies of any inspection findings that Principal Investigator receives from a regulatory agency. Principal Investigator will also provide CBCC with an opportunity to prospectively review and comment on any Principal Investigator responses to regulatory agency inspections.

1.10 Adverse Events & Compensation

a) The Principal Investigator shall ensure that Adverse Events and Serious Adverse Events ("**AE/SAE**") whether expected or unexpected are reported in writing to CBCC, the Institution, the Sponsor, regulatory and the Ethics Committee in a timely manner and as defined in the Protocol or equivalent. The Principal Investigator shall strictly adhere to applicable local country regulatory requirement. and provisions of ICH-GCP. The review of Serious Adverse Events shall be undertaken by CBCC in close coordination with the Principal Investigator.

b) "Serious Adverse Event" as used in this clause refers to an experience which results in death, is life-threatening, requires in-patient hospitalization or prolongation of existing hospitalization, results in persistent or significant disability / incapacity, or is a congenital anomaly/birth defect.

c) "Unexpected" as used in this clause, refers to conditions or developments not previously submitted to governmental agencies or encountered during clinical studies of the Investigational Product, and conditions or developments occurring at a rate higher than shown by information previously submitted to governmental agencies or encountered during clinical studies of the Investigational Product or, if applicable, conditions or developments not identified in the approved Investigational Product information circular, and includes any other meaning under applicable law.

d) The Principal Investigator shall also comply with the compensation requirements as per applicable local country regulatory requirement. In case of an injury occurring to the Study Subject during the Clinical Trial, CBCC on behalf of the sponsor shall provide free medical management as long as required or until

such time it is established that the injury is not related to the Clinical Trial, whichever is earlier, in accordance with the applicable local country regulatory requirement.

e) The Sponsor/CBCC confirms that only the Sponsor/CBCC and neither the Principal Investigator nor the Institution is responsible for the costs of diagnosis, care and treatment of any undesirable side effects, adverse reactions, illness or injury to Study Subjects in the Clinical Trial which in the reasonable judgment of the Principal Investigator are determined to result from subject's participation in the Clinical Trial, except for such costs that arise directly from:

- the negligent activities, reckless misconduct or intentional misconduct of the Principal Investigator or his staff, or the Institution or its staff; or
- their failure to adhere to the terms of the Protocol.

This clause is not intended to create any third-party contractual benefit for any participants in the Clinical Trial.

1.11 No Reimbursement for Sponsor Paid Drug or Services

The Principal Investigator and the Institution agree that if the Investigational Product and/or other services are paid for or provided without charge by the Sponsor or CBCC, the Principal Investigator, the Institution and/or any other vendor subcontracted or engaged by the Principal Investigator/Institution shall not separately bill or seek reimbursement for such Investigational Product and/or services from any third party including, without limitation, the Study Subject, any private provider of Insurance or state program.

1.12 Deviation to Protocol

The Principal Investigator shall not deviate from the approved Protocol except when necessary to eliminate immediate hazards to the subjects or when the change(s) involves only logistical or administrative aspects of the trial (e.g., change of telephone number(s)). Any deviation and the reason(s) for such deviation to the Protocol shall be recorded and reported by the Principal Investigator to CBCC and to the Ethics Committee.

2. COST AND PAYMENT

2.1 Consideration

a) In consideration of the services provided under this Agreement, CBCC shall pay the Institution and/or the Principal Investigator and/or SMO on a per subject basis as set forth in the Payment **Schedule II** of this Agreement. The per subject fee structure detailed in **Schedule II** of this Agreement shall remain unchanged for the duration of the Study, unless otherwise agreed in writing by all Parties. All payments

towards the Principal Investigator and the Institution services shall be payable in Indian Rupees and will be paid within forty-five (45) days of receipt and approval of an invoice. CBCC or the Sponsor shall not be obligated to any person or entity to pay any amounts not explicitly set forth in **Schedule II** of this Agreement. The Principal Investigator and the Institution shall be jointly and severally responsible for the payment of any or all taxes that may apply to any payment it receives, including without limitation, for paying any value-added tax, sales tax, or similar tax imposed by the taxation authorities in any jurisdiction. The Parties hereto agree that CBCC will pay a sum for every complete and evaluable Trial Subject as defined in the payment schedule for "Per Subject Fee". The "Per Subject Fee" is a fixed fee per Trial Subject which includes all costs [and honoraria] including but not limited to:

- All Study related activities such as all Study visits and CRF completion,
- Principal Investigator and other site staff as well as Study coordinator time and effort,
- All diagnostic tests and other investigations (except those arising from any Adverse Event(s) and/or Serious Adverse Event(s))
- Hospitalization cost (except those arising from any Adverse Event(s) and/or Serious Adverse Event(s))
- Study Subject conveyance/Compensation,
- All overhead costs if any

b) A "complete and evaluable Study Subject" is defined as follows:

- All procedures must be performed according to the Protocol
- A Study Subject will only be included according to the inclusion/exclusion criteria
- All data are documented accurately and completely

c) All payments will be on a *pro rata* basis. For Study Subjects who do not complete the Clinical Trial (Screen failure, early termination, drop–out, etc.), the payment schedule will be evaluated according to the number of days/visits completed by such Study Subject. If site does not recruit any subjects, no payment shall be made to site.

d) The Institution shall generate invoice/request for payment on a monthly basis or as required according to the actual work performed (after source data verification and CRFs review for completed visits). The final payment and Archival Fees will be made by CBCC at the time of site close out visit or immediately after site close out visit or as agreed.

e) Other Parties appointed by the Principal Investigator (such as, Radiology, Local Laboratory etc.) will be managed and paid by the Principal Investigator.

f) The Ethics Committee fee will be paid by CBCC and is separate from the Per-Subject fee.

g) Screen Failure Subject's visits will be paid ONLY if the Subject's screen failure is based on results or reports of laboratory investigations, SAE, or in case a Subject withdraws consent.

h) If a Study Subject was randomized in the Study deviating from the Protocol inclusion and exclusion criteria (without waiver, if applicable) then payment will not be made for such wrong randomization and subsequent visits, however, screening visit can be paid in such an event and only if performed according to the Protocol.

i) Trial Subject's conveyance will be paid by CBCC and is included in Per Subject Fees.

j) CBCC will manage reimbursement for medical management expenses towards AE/SAE, and SAE compensation payment, with the prior written approval from the Sponsor.

2.2 The Institution and the Principal Investigator shall review the payment details generated by CBCC that shall accompany each payment and shall inform CBCC in writing in accordance with the instructions provided in the payment details of any discrepancies that may exist in the payment(s) received and the payment(s) expected. At the completion of the Study, the Institution and the Principal Investigator shall ensure that any such discrepancies that may exist are brought to the attention of CBCC no later than one month after the Study database is locked. The Parties shall work diligently and in good faith to resolve any such discrepancies.

2.3 Overpayment

If, at the date of Study termination, the total amount paid to the Principal Investigator/Institution exceeds the amount to which the Principal Investigator/Institution is entitled, the Principal Investigator/Institution shall return the overpayment to CBCC within forty-five (45) days following termination of the Study, completion of the remaining CRFs, final reconciliation of any remaining amounts due, and the return to CBCC of all items provided which will be listed separately.

2.4 Reasonable Efforts

The Principal Investigator and/or the Institution shall use all reasonable endeavors to enroll maximum eligible Subjects in the study. Recruitment in the study shall be competitive among participating sites.

2.5 Relationship of Parties

CBCC shall be responsible for all payments to the Principal Investigator/Institution pursuant to this Agreement. Such responsibility is subject to receipt of funds from the Sponsor provided the responsibility for such payments is agreed to in the Master Services Agreement entered into by the Sponsor and CBCC (the "**MSA**"). In all other

events where such payments have not been agreed in the MSA, CBCC shall be solely responsible for all payments to the Principal Investigator/Institution.

2.6 Institution Payment for Investigational Products and Other Expenses

The Institution acknowledges that the Investigational Product being investigated in the Clinical Trial is being provided by the Sponsor free of charge, for exclusive use on Study Subjects.

3. REPORTS, ACCESS

3.1 Access to the Principal Investigator

The Sponsor and CBCC shall have reasonable access (at mutually agreeable times and locations) to the Principal Investigator for the purpose of discussing progress reviews, internal reporting and other matters related to the Clinical Trial, including on-site and/or remote monitoring at intervals specified in the monitoring plan agreed by CBCC and the Sponsor.

3.2 Records and Reports

a) The Institution and/or the Principal Investigator shall prepare and maintain complete, accurately written records, accounts, medical notes, reports, and data including all supporting documentation for each Study Subject ("**Source Documents**") in accordance with all applicable laws. The Principal Investigator shall complete all CRFs and submit to CBCC all additional documentation for each Study Subject as required by the Protocol and shall promptly resolve all data queries from the Sponsor and CBCC. The Principal Investigator shall ensure that any data or supportive documentation provided to the Sponsor and CBCC does not include any information that would personally identify a Study Subject.

b) Study Subjects CRFs and all other records and reports relating to the Clinical Trial shall be available for inspection or copying by the Sponsor and CBCC, as soon as reasonably possible. The Institution shall allow access of original Study Subject medical records, and any documentation related to the Clinical Trial, for on-site and/or remote monitoring by the Sponsor and CBCC or their representative, possible audit or inspection by the Sponsor, CBCC, relevant competent authorities and other regulatory agencies.

c) All records and reports required by this Agreement, or prepared in connection herewith such as the Investigator Site File containing essential documents and source data must be maintained by the Institution and the Principal Investigator in a secure place at the Institution/Principal Investigator's cost for a period of at least five (5) years after the later of:

- the termination or expiration of this Agreement;
- the completion of the Clinical Trial; or

- as required by the applicable laws.

d) In the event that the Principal Investigator is to destroy the Investigator Site File or source data, the Principal Investigator shall inform CBCC and the Sponsor in writing prior to destruction to confirm it is acceptable for them to be destroyed.

4. CONFIDENTIAL INFORMATION

4.1 Definition of Confidential Information

a) The term "Confidential Information" shall include, but is not limited to reports, notes, analyses, memoranda, models, prototypes, drawings, plans, diagrams, photographs, test results, formulae, algorithms, research records, laboratory results, clinical results, laboratory methods and procedures, clinical methods or procedures, whether such information is communicated to recipient orally, in writing or any other hard copy such as computer discs or is learned by recipient or prepared by recipient in the course of or after the end of its relationship with the provider.

b) Confidential Information does not include information which:

- prior to or subsequent to the time of disclosure, Confidential Information is independently known to the recipient, as evidenced by written documentation;
- prior to or subsequent to the time of disclosure, Confidential Information has legitimately entered the public domain, as evidenced by written documentation;
- subsequent to the time of disclosure, Confidential Information becomes or is made available to the recipient by a third party having the lawful right to do so, as evidenced by written documentation;
- is independently developed by the recipient or its agents or employees by persons who did not receive the Information, as evidenced by written documentation; and
- is disclosed to others by the Provider without restrictions concerning disclosure and/or commercial use.

4.2 Term of Confidentiality

Each Party agrees that during the Term of the Agreement, and for a period of ten (10) years thereafter, (i) it will not use Confidential Information owned by any of the other Parties except for the purpose of carrying out this Agreement; (ii) it will maintain the Confidential Information in confidence and not disclose the same to anyone other than to their respective employees and agents who have a need to know the Confidential Information for the purpose of completing the Clinical Trial and provided the disclosing party advises all employees and agents having access to any Confidential Information of its confidential nature and the recipient's obligations under this

Agreement; (iii) it will safeguard all Confidential Information by using a reasonable degree of care that is not less than the degree of care used by the recipient in safeguarding its own Confidential Information.

4.3 Use of Confidential Information

a) Each Party agrees to keep the disclosed Confidential Information in strict confidence and not to disclose or otherwise use the Confidential Information for any other purpose. Accordingly, the recipient agrees to treat the Confidential Information, which it receives as it would its proprietary information and to take all reasonable precautions to prevent the unauthorized disclosure to any third party of the Confidential Information, which it received hereunder.

b) All tangible or hard copies containing the Confidential Information, which is or will be in the possession of any recipient hereunder, shall be returned to the disclosing Party at the first request.

c) The Confidential Information shared with any recipient hereunder will not be disclosed to any other Parties without prior written permission of the disclosing Party.

d) The recipient will not develop any modification, improvement, alteration, technology, idea, concept or design based on the information disclosed without the prior written consent of the disclosing Party;

5. DATA PROTECTION

Each of the parties agrees and ensures that required and appropriate measures shall be taken for protection of personal data and privacy.

6. INVENTIONS AND PATENT RIGHTS

6.1 Disclosure of Inventions, Reports and Results

The Institution and the Principal Investigator shall promptly and fully:

a) disclose to the Sponsor/CBCC in writing all improvements, developments, discoveries and inventions, whether or not patentable, conceived or first reduced to practice, either alone or with others, in connection with the performance of the Clinical Trial or relating to the Investigational Product and/or Confidential Information ("**Inventions**"); and

b) Disclose and deliver to the Sponsor/CBCC all results of the Clinical Trial ("**Results**") and all reports, records and other materials prepared by the Institution or the Principal Investigator, either alone or with others, in connection with or relating to the Investigational Product or Confidential Information ("**Reports**").

6.2 Ownership of Inventions, Reports and Results

All Inventions, Reports and Results are, and shall always be, the exclusive property of the Sponsor. All rights, title and interest of the Institution and the Principal Investigator in and to such Inventions, Reports and Results shall be automatically assigned to and shall belong exclusively to the Sponsor without any additional compensation than the ones listed in **Schedule II** of this Agreement. The Institution and the Principal Investigator, to the extent necessary (and at Sponsor's expense) will execute such documents as are reasonable and customary to perfect in and transfer to the Sponsor the ownership rights of the Institution and the Principal Investigator. Notwithstanding the foregoing, the Institution and the Principal Investigator shall have the right to publish the Results in accordance with clause 7 of this Agreement.

7. PUBLICATIONS

7.1 The data and Results from this Clinical Trial are the property of the Sponsor. As the Clinical Trial is a multi-Centre study, the Parties agree that, consistent with international standards for scientific and medical publications, the data from all centers will be analyzed collectively and reported as such (which including the Results and Reports shall be hereinafter the "**Study Outcome**"). CBCC, the Institution and the Principal Investigator (including its affiliates, employees, agents, authorized sub-contractors and consultants as applicable) shall not make any publications of the Study Outcome or refer to in whole or in part of the Study Outcome without first obtaining the prior written consent of the Sponsor and shall not use the Sponsor's name in connection with any publication without the Sponsor's prior written consent.

7.2 Sponsor shall have the right to access and use all data, results and the Study Outcome generated during the Clinical Trial. The Clinical Trial site will not use the clinical related data without the written consent of Sponsor for any other purpose than for Clinical Trial completion. The Principal Investigator, CBCC, the Institution shall properly refer to the Sponsor in all publications or presentations resulting from the performance of the Clinical Trial and provided the provisions of Clause 7.1 have been adhered to. No Party may use the name of any other Party in any advertising or other form of publicity without the written permission of the Party whose name is to be used.

8. INDEMNITY AND INSURANCE

8.1 Sponsor Indemnification

CBCC on behalf of Sponsor shall indemnify the Principal Investigator and the Institution, (including the Principal Investigator's and the Institution's affiliates, contractors, agents, fellows, employees and servants) (collectively "**Investigator Indemnitees**") for any damages and liabilities, including reasonable attorney's fees incurred by the Investigator Indemnitees as a result of any claim(s), lawsuit(s), loss(es) action(s), demand(s) or

judgment(s) against them arising out of the performance of the Investigational Product pursuant to the Protocol ("**Claims**"); provided however the CBCC/Sponsor will not be responsible for and assumes no liability for any claims, lawsuits, losses, actions, demands or judgments to the extent arising from any of the following:

a) the negligence or willful misconduct of any Investigator Indemnitees or any Investigator Indemnitees failure to adhere to:
   - the terms of the Protocol and/or this Agreement including any amendments thereto; or
   - applicable international, provincial, or local laws; or
   - the written instructions relative to the use of the Investigational Product

b) in no event shall the collective, aggregate liability (including without limitation, contract, tort or breach of statutory duty) of the Sponsor under this Agreement exceed the amount of fees paid to the Investigator Indemnitees under this Agreement.

8.2 Institution Indemnification

The Institution shall indemnify, defend and hold harmless the Sponsor and CBCC (including the Sponsor's and CBCC's affiliates, contractors, agents, fellows, employees and servants) (collectively "**Sponsor Indemnitees**") from any and all losses, injuries, harm, costs or expenses, including without limitation, reasonable attorney's fees, incurred by the Sponsor Indemnitees that arise from the negligence or willful misconduct by Investigator Indemnitees and/or any Investigator Indemnitees failure to adhere to the terms of the Protocol and/or this Agreement, or applicable international, provincial or local laws or the written instructions relative to the use of the Investigational Product. The Principal Investigator and the Institution shall carry professional Indemnity Insurance and such other insurance required to indemnity under this clause, for the Term of this Agreement and for a reasonable period (which is not less than 1 year) after termination or expiration thereof. The Principal Investigator and the Institution shall provide the copy of insurance as and when required by CBCC and the Sponsor.

8.3 Serious Adverse Event Reimbursement

Notwithstanding any other terms contained in this Agreement, the Sponsor/CBCC will reimburse the Institution for any reasonable, necessary and properly documented medical expenses directly related to a Study Subject's AE and/or SAE in accordance with the provisions of Clause 1.10.

9. DEBARMENT

Debarment and Exclusion: The Institution and the Principal Investigator certify that they are not debarred or restricted from conducting clinical research and will not use in any capacity the services of any person debarred

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or restricted from conducting clinical research under applicable law with respect to services to be performed under this Agreement. The Institution and the Principal Investigator further certify that they are not subject to a government mandated corporate integrity agreement and have not violated any applicable anti-kickback or false claims laws or regulations. During the Term of this Agreement and for three (3) years after its termination, the Principal Investigator and the Institution will notify CBCC and the Sponsor promptly in writing to the extent possible within two (2) business days if either of this certification needs to be amended in material issues related to the medical licensure of any associated researchers. The Institution and the Principal Investigator will cooperate with CBCC and /or Sponsor regarding any responsive action necessary.

10. TERM AND TERMINATION

10.1 Term

This Agreement shall, subject to the early termination provisions as specified hereunder, have a term of three (3) years from the Effective Date unless extended or terminated earlier by mutual written agreement of the Parties (the "**Term**") Notwithstanding the foregoing, all obligations which are by their nature continuing, including, without limitation, such obligations contained in Clauses 4 through 8, the effect of termination provisions of this Clause 10 and Clauses 12 and 14 shall survive the expiration or termination of this Agreement.

10.2 Early Termination

a) CBCC may terminate this Agreement during the Term with or without cause upon providing written notice to the other Parties.

b) CBCC may terminate this Agreement for a breach of this Agreement upon thirty (30) days' written notice specifying the nature of the breach. "Breach" shall be defined as failure to comply with any material provision of this Agreement. If such breach has not been substantially cured within the thirty (30) day period, CBCC may terminate this Agreement. In the event of termination, the Parties shall promptly meet to prepare a close-out schedule, and the Principal Investigator/Institution shall cease performing all work not necessary for the orderly close-out of the Clinical Trial or required by applicable laws or regulations. CBCC may terminate this Agreement immediately upon provision of written notice if any of the Parties becomes insolvent or files for bankruptcy.

c) The Institution or the Investigator may also terminate this Agreement, if in its reasonable judgment such termination is necessary to protect the health, safety and welfare of any Study Subject, by giving 24 hours written notice of termination to the other Parties.

d) In addition to the early termination rights as set out above, if applicable, CBCC or the Sponsor reserves the right to terminate the Clinical Trial by the provision of immediate notice in the case of (i) below and by thirty (30) days' notice in the case of (ii) and (iii) below to the other Parties where such termination is necessary if:

(i) In the interest of subject safety;
(ii) In order to comply with the requirements of any government agency, board, or department; and
(iii) In order to comply with the decision of the Independent Ethics Committee (IEC).

In the event of any early termination by CBCC, except in the event of early termination pursuant to Clause 10.2(b), CBCC shall reimburse the payee designated in **Schedule III** of this Agreement for all contractual commitments and financial obligations reasonably and necessarily incurred by the Institution in performing this Agreement prior to such termination and to the extent such financial obligations or contractual commitments cannot be cancelled by the Principal Investigator/Institution and the Principal Investigator and Institution shall cease incurring any further costs.

e) Upon receipt of a notice of termination, the Principal Investigator and the Institution shall immediately cease:

- enrolling Study Subjects in the Clinical Trial; and
- Conducting procedures in connection with the Clinical Trial, to the extent medically advisable, on Study Subjects.

Such termination shall not commence until Study Subjects can be transitioned out of the Clinical Trial without suffering any adverse medical effects. Unless otherwise directed by the Sponsor/CBCC, the Institution and the Principal Investigator shall immediately return:

- all Results, Reports and Inventions; and
- all unused Investigational Products to the Sponsor/CBCC if the Clinical Trial is terminated, suspended, discontinued or completed; unless the return of Investigational Product would jeopardize the rights, safety, or welfare of a Study Subject.

11. COVENANTS AND WARRANTIES

11.1 The Institution and the Principal Investigator represent and warrant that the services covered by this Agreement are not in violation of any other agreement with other Parties or of any restrictions of any kind to which either is bound.

11.2 The Institution and the Principal Investigator each represent and warrant that:

a) they have not been found by the relevant national and/or international competent authority officials to have violated any statutes, rules, or regulations concerning the conduct of clinical investigations; and

b) they have not been terminated from any investigation or research project for reasons other than completion of the research project.

The Institution and the Principal Investigator agree that if any of the events listed in a), or b) above should occur or have occurred, they shall notify the Sponsor/CBCC in writing of any such occurrence that occurred prior to the Effective Date, and no later than three (3) business days of each such occurrence that occurs after the Effective Date.

12. NO WARRANTIES

CBCC, Principal Investigator and the Institution makes no warranties, express or implied, as to any matter whatsoever, including, without limitation, the results of the Clinical Trial or any invention, process or Investigational product, whether tangible or intangible, conceived, discovered, or developed under this Agreement. The provisions of this clause shall survive termination of this Agreement.

13. FORCE MAJEURE

A Party shall be excused from performing its obligations under this Agreement to the extent its performance is delayed or prevented by any cause beyond such Party's reasonable control, including but not limited to, acts of God, fire, explosion, disease, weather, war, insurrection, civil strike, riots, terrorism or government action (a "**Force Majeure Event**") provided the affected Party gives the other Party prompt written notice of the occurrence of any Force Majeure Event and the nature and the extent to which the affected Party will be unable to perform its obligations under this Agreement. The affected Party agrees to use commercially reasonable efforts to correct the Force Majeure Event as quickly as possible, to perform its obligations under this Agreement to the extent feasible given the Force Majeure Event, and to give the other Party prompt written notice when it is again fully able to perform its obligations. Performance shall be excused only to the extent of and during the reasonable continuance of such Force Majeure Event, provided that either Party may terminate this Agreement if such Force Majeure Event continues for a period of forty-five (45) days or more. Any deadline or time for performance specified in this Agreement or the Protocol which falls due during or subsequent to the occurrence of a Force Majeure Event shall be automatically extended for a period of time equal to the period of the Force Majeure Event.

14. MISCELLANEOUS

14.1 Unless otherwise specified, this Agreement, together with the **Schedules** of this Agreement, embodies the entire understanding among the Parties with regards to the subject matter hereof, and any prior or contemporaneous agreements between the Parties relating to the subject matter hereof, either oral or written, are hereby superseded.

14.2 No amendments or changes to this Agreement, including without limitation, changes to the **Schedules** of this Agreement, shall be effective unless made in writing and signed by the authorized representatives of the Parties.

14.3 This Agreement shall be governed by the applicable laws of India.

14.4 If any provision of this Agreement is determined to be unenforceable or prohibited by any applicable laws, such provision shall be ineffective only to the extent of such unenforceability or prohibition without invalidating the remainder of such provision or the remaining provisions of this Agreement. This Agreement shall be binding upon and shall inure to the benefit of the Parties hereto and the successor to substantially the entire business and assets of the respective Parties hereto.

14.5 This Agreement shall not be assignable by any Party without the prior written consent of the other Parties, except that Sponsor/CBCC may assign some or all of its rights and obligations under this Agreement to any of its affiliated entities.

14.6 Notice

a) All notices, requests, demands or other communication required or permitted to be given under this Agreement shall be in writing, in English language (including by courier and/or email) and shall be effective upon delivery to the intended Party (whether by personal delivery or registered post or courier of international repute or email) at the address, and shall be marked to the attention of the person, indicated hereunder, unless the contrary is proved, be deemed to be delivered and duly served at the time of delivery, if made or delivered by hand, with acknowledgement of receipt thereof; on the 5th (fifth) business day after the date of posting by registered post or courier; or when dispatched and a receipt of delivery confirmation is received, if made or delivered by email:

If to **CBCC**, at:

Address: 2nd Floor, Skoda House, Opp. LJ Campus, SG Highway, Sarkhej, Ahmedabad – 382210, India.

E-mail Address: sandeep.singh@cbcc.global

Kind Attention: Dr. Sandeep Singh

Phone No.: +91 97264 34201/02/03

If to **Principal Investigator**, at:

Address: Mahatma Gandhi Mission's (MGM) Medical College & Hospital, N-6, Cidco, Aurangabad, 431003, Maharashtra, India.

E-mail Address: mohdhaseeb181@gmail.com

Kind Attention: Dr. Mohd Haseeb Mohd Najeeb

Phone No.: +91 9890057325

If to **Institution**, at:

Address: Mahatma Gandhi Mission's (MGM) Medical College & Hospital, N-6, Cidco, Aurangabad, 431003, Maharashtra, India.

E-mail Address: rajbohra@msn.com

Kind Attention: Dr. Rajendra Bohra

Phone No.: +91 9225304660

If to **SMO**, at:

Address: Grapecity Research Solutions LLP, Shree Prasad, Block No D-2, Prakash Housing Society, Kalewadi Phata, Thergaon, Pune 411033, Maharashtra, India

E-mail Address: drsunilchaudhary07@gmail.com

Kind Attention: Dr Sunil Chaudhary

Phone No.: +91 9890840086

b) If any notices, requests, demands or other communication required or permitted to be given under this Agreement is received by the intended Party (as aforesaid) after the normal business hours or on a non-business day, then the same shall, unless the contrary is proved, be deemed to be delivered and duly served on the succeeding business day.

c) Any change to the particulars of any Party, as set out above (i.e., the address, the e-mail address and the phone number), shall also be notified to all the other Parties in the manner mentioned herein, otherwise, such changes shall not be effective and binding on such other Parties.

14.7 The headings in this Agreement are intended solely for convenience or reference and shall be given no effect in the construction or interpretation of this Agreement. This Agreement may be executed and delivered in one or more counterparts, each of which when executed and delivered shall be deemed to be an original but all of which when taken together shall constitute one and the same Agreement.

14.8 The Principal Investigator and the Institution may not assign this Agreement to any other Party, nor may it subcontract any of its services hereunder, without CBCC's and Sponsor's prior written consent. Any attempted assignment without CBCC's and Sponsor's prior written consent shall be null and void and shall, for the avoidance of doubt, constitute a material breach of this Agreement.

14.9 This Agreement may be executed by the Parties and transmitted in a scanned version, with the same effect as if the Parties had delivered an executed original Agreement. Each of the Parties may request, at its own election, an original copy of the Agreement. None of the Parties shall be bound to this Agreement until all of the Parties have executed an original or scanned pdf version counterpart.

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date.

CBCC- Representative:

Name: DR. SANDEEP SINGH

Signature: _____ Date: 25/Mar/2021

Principal Investigator:

Name: DR. MOHD HASEEB MOHD NAJEEB

Dr. Mohd Haseeb
MBBS MD (Paed)
Reg. No. 2004/02/0721
Consulting Paediatrician and Neonatologist

Signature: _____ Date: 6.4.2021

Institution Representative:

Name: DR. RAJENDRA BOHRA

DEAN
MGM'S MEDICAL COLLEGE
AURANGABAD

Signature: _____ Date: 06/04/21

Title: Dean

SMO Representative:

Name: DR SUNIL CHAUDHARY

Signature: _____ Date: 06/04/21

Title: Director

Schedule I – Protocol

Study Title: A Phase 3, Observer blind, Randomized, Active-Controlled Trial Evaluating the Immunologic Non-inferiority, Safety and Tolerability of a 15-valent Pneumococcal Conjugate Vaccine Compared to a 13-valent Pneumococcal Conjugate Vaccine in Healthy Infants Given with Routine Pediatric Vaccinations

Study Number: CBCC/2020/029

Schedule II: Study Budget

Visit Type	Study Procedures			End of Study Assessment	Total
Days	**Day 1**	**Day 29**	**Day 57**	**Day 85**	
Investigator	3000	3000	3000	5000	14000
Study Coordinator	1700	1700	1700	2500	7600
Patient Reimbursement	1000	1000	1000	1000	4000
Total	**5700**	**5700**	**5700**	**8500**	**25600**
				Institutional Overhead (25%)	5400
				Total Cost Per Completed Patient (Including Institutional Overhead)	**31000**
				Applicable GST (18%)	5580
				Total Amount Payable to Site for Completed Patient (Including Institutional Overhead and GST)	**36580**

Notes:

Investigator fees will be paid for Day 1, which includes the Audio-video recording of ICF process and completion of day 1 procedure after confirming the eligibility.

Subject will be observed for any immediate reactions for at least 60 minutes after vaccination

All the recommended vaccines provided by the sponsor as per the national immunization schedule.

Archival Cost of **INR 25,000/-** will be paid at the time of site close out visit for archival of study documents for 5 years.

Schedule III - Payee Details

Study Title : A Phase 3, Observer blind, Randomized, Active-Controlled Trial Evaluating the Immunologic Non-inferiority, Safety and Tolerability of a 15-valent Pneumococcal Conjugate Vaccine Compared to a 13-valent Pneumococcal Conjugate Vaccine in Healthy Infants Given with Routine Pediatric Vaccinations.

Protocol Number : CBCC/2020/029

Investigator : Dr. Mohd. Haseeb Mohd. Najeeb

Site Address : Mahatma Gandhi Mission's (MGM) Medical College & Hospital, N-6, Cidco, Aurangabad, 431003, Maharashtra, India.

Payment Details

Payee Name (or institution) (title, first name, last name if payee)	Grapecity Research Solutions LLP
Payee Address	Grapecity Research Solutions LLP , Shree Prasad, Block No D-2, Prakash Housing Society, Kalewadi Phata, Thergaon, Pune 411033, Maharashtra, India
Bank Name and Address	ICICI Bank Gulmohar Park, Plot no 1 A, ITI road, Aundh, Pune 411007, Maharashtra, India.
Bank Account Number	007305009846
SWIFT/IFSC code	ICIC0000073
PAN details of Payee	AAPFG8186L
GST Number of Payee	27AAPFG8186L1ZH
Contact person for payments	Dr Sunil Chaudhary

Note: All the payments made to the payee are subject to withholding Tax (Tax Deducted at Source (TDS) as applicable from time to time and CBCC will deduct the tax at the time of making payments.