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INDIA NON JUDICIAL

Government of Karnataka

Rs. 100

e-Stamp

Certificate No.	:	IN-KA20776184896805T
Certificate Issued Date	:	11-Jun-2021 02:29 PM
Account Reference	:	NONACC (FI)/ kacrsfl08/ PADMANABHANAGAR3/ KA-BA
Unique Doc. Reference	:	SUBIN-KAKACRSFL08106820259860 63T
Purchased by	:	IQVIA RDS INDIA PRIVATE LIMITED
Description of Document	:	Article 12 Bond
Description	:	CLINICAL TRIAL AGREEMENT
Consideration Price (Rs.)	:	0 (Zero)
First Party	:	IQVIA RDS INDIA PRIVATE LIMITED
Second Party	:	ADICHUNCHANAGIRI HOSPITAL AND RESEARCH CENTRE
Stamp Duty Paid By	:	IQVIA RDS INDIA PRIVATE LIMITED
Stamp Duty Amount(Rs.)	:	100 (One Hundred only)

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AMARAJYOTI CO-OPERATIVE SOCIETY LTD * DRB-3/R&G/02/42156/2017-18 * BANGALORE

Please write or type below this line

CLINICAL TRIAL AGREEMENT

The Clinical Trial Agreement ("**Agreement**") is made by and between:

- **Adichunchanagiri Hospital & Research Centre** having a place of business at B G Nagara, Nagamangala Taluk, Mandya District, Karnataka 571-448 (the "**Institution**"), and
- **Dr. Ravi B Nagarajaiah** having a place of business at Adichunchanagiri Hospital & Research Centre, B G Nagara, Nagamangala Taluk, Mandya District, Karnataka 571-448 (the "**Investigator**"), and;

- **IQVIA RDS (India) Private Limited,** (formerly **Quintiles Research (India) Private Limited**), having a place of business at Omega Embassy Tech Square Marathahalli- Sarjapur Outer Ring Road, Kadubeesanahalli Bangalore- KA- 560103, India ("**IQVIA**").

Each a "**Party**" and together the "**Parties**".

Protocol Number:	BECT/COVID-19-PHASE-III/069
Protocol Title:	A Prospective, multicentre, Phase II Seamlessly Followed by Phase III Clinical Study to Evaluate the Immunogenicity and Safety of Biological E's CORBEVAX Vaccine for Protection Against COVID-19 Disease When Administered to COVID-19-Negative Adult Subjects.
Protocol Date:	13 May 2021
Sponsor:	Biological E. Limited
Country where Site is Conducting Study	India
Investigator:	Dr. Ravi B Nagarajaiah
Key Enrollment Date:	**30 Calendar Days after Site Initiation Visit (being the date by which Site must enrol at least one (1) subject as more specifically set out in section 1.8 "Key Enrollment Date" below)**
IRB/IEC	Institutional Ethics Committee Adichunchanagiri Hospital & Research Centre) B G Nagara, Nagamangala Taluk, Mandya District, Karnataka 571-448. Contact Person: Mr. Kumaraswamy Contact No: +919739099397

The following additional definitions shall apply to this Agreement:

Protocol: the clinical protocol referenced above as it may be modified from time to time by the Sponsor (defined below).

Case Report Form or **CRF**: case report form (paper or electronic) to be used by Site to record all of the Protocol-required information to be reported to Sponsor on each Study Subject (defined below).

Study: the clinical trial that is to be performed in accordance with this Agreement and the Protocol for purposes of gathering information about the compound/medical device identified in the Protocol.

Study Subject: an individual who participates in the Study, either as a recipient of the Investigational Product (defined below) or as a control.

Study Staff: the individuals involved in conducting the Study under the direction of the Investigator.

Investigational Product: the compound/medical device identified in the Protocol that is being tested in the Study.

Good Clinical Practices or **GCPs**: International Council of Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Harmonised Tripartite Guideline for

Good Clinical Practice as amended from time to time and the principles set out in the Declaration of Helsinki as revised from time to time.

Sponsor: the sponsor of the Study.

Medical Records: the Study Subjects' primary medical records kept by the Institution on behalf of the Investigator, including, without limitation, treatment entries, x-rays, biopsy reports, ultrasound photographs and other diagnostic images.

NMC Act: National Medical Commission (Professional Conduct, Etiquette and Ethics) Act 2019, and any rules or regulations made thereunder as may be amended from time to time or any replacement regulations.

Study Data: all records and reports, other than Medical Records, collected or created pursuant to or prepared in connection with the Study including, without limitation, reports (e.g., CRFs, data summaries, interim reports and the final report) required to be delivered to Sponsor pursuant to the Protocol and all records regarding inventories and dispositions of all Investigational Product.

Government Official: any officer or employee of a government or of any ministry, department, agency, or instrumentality of a government; any person acting in an official capacity on behalf of a government or of any ministry, department, agency, or instrumentality of a government; any officer or employee of a company or of a business owned in whole or part by a government; any officer or employee of a public international organization such as the World Bank or the United Nations; any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or any candidate for political office; any doctor, pharmacist, or other healthcare professional who works for or in any hospital, pharmacy or other healthcare facility owned or operated by a government agency, ministry or department.

Item(s) of Value: should be interpreted broadly and may include, but is not limited to, money or payments or equivalents, such as gift certificates; gifts or free goods; meals, entertainment, or hospitality; travel or payment of expenses; provision of services; purchase of property or services at inflated prices; assumption or forgiveness of indebtedness; intangible benefits, such as enhanced social or business standing (e.g., making donations to government official's favored charity); and/or benefits to third persons related to government officials (e.g., close family members).

RECITALS:

WHEREAS, IQVIA is providing clinical research organisation services to Sponsor under a separate contract between IQVIA and Sponsor. IQVIA's services include monitoring of the Study and contracting with clinical research sites;

WHEREAS, the Institution and Investigator (hereinafter jointly the "**Site**") are willing to conduct the Study and IQVIA requests the Site to undertake such Study.

NOW THEREFORE, the following is agreed:

1. CONDUCT OF THE STUDY

1.1. Compliance with Laws, Regulations, and Good Clinical Practices

Site agrees that Site and Study Staff shall perform the Study at Institution in strict accordance with this Agreement, the Protocol, any and all applicable local, national and international laws regulations and guidelines, including in particular, but without limitation, GCPs, MCI

Regulations or NMC Act as applicable, the New Drugs Drugs & Clinical Trial Rules of 2019 and state and local tax and finance regulations. Site and Study Staff acknowledge that IQVIA and Sponsor, and their respective affiliates, need to adhere to the provisions of (i) the Bribery Act 2010 of the United Kingdom (Bribery Act); (ii) the Foreign Corrupt Practices Act 1977 of the United States of America (FCPA) and (iii) any other applicable anti-corruption legislation.

1.2. Informed Consent Form

Site agrees to use an informed consent form that has been approved by Sponsor and is in accordance with applicable regulations and the requirements of the Institutional Review Board ("**IRB**") or Independent Ethics Committee ("**IEC**") that is responsible for reviewing the Study. Site shall obtain the prior written informed consent of each Study Subject.

1.3. Medical Records and Study Data

1.3.1. Collection, Storage and Destruction: Site shall ensure the prompt, complete, and accurate collection, recording and classification of the Medical Records and Study Data.

Site shall:

(i) maintain and store Medical Records and Study Data in a secure manner with physical and electronic access restrictions, as applicable and environmental controls appropriate to the applicable data type and in accordance with applicable laws, regulations and industry standards; and

(ii) protect the Medical Records and Study Data from unauthorized use, access, duplication, and disclosure. If directed by Sponsor or IQVIA, Site will submit Study Data using the electronic system provided by Sponsor or IQVIA or their designated representative and in accordance with Sponsor's instructions for electronic data entry. Site shall prevent unauthorized access to the Study Data by maintaining physical security of the electronic system and ensuring that Study Staff maintain the confidentiality of their passwords. Investigator agrees to collect all Study Data in Medical Records prior to entering it into the CRF. Site shall ensure the prompt submission of CRFs; and

(iii) take measures to prevent accidental or premature destruction or damage of these documents, for as long as required by applicable laws and regulations. Neither Institution nor Investigator shall destroy or permit the destruction of any Medical Records or Study Data without prior written notification to the Sponsor, and Institution shall continue to store Medical Records and Study Data, at the Sponsor's expense, for any period that the Sponsor may request in writing after retention is no longer required by any applicable law or regulation.

If the Investigator leaves the Institution, then responsibility for maintaining Medical Records and Study Data shall be determined in accordance with applicable regulations but Institution will not in any case be relieved of its obligations under this Agreement for maintaining the Medical Records and Study Data.

1.3.2. Ownership Institution shall retain ownership of Medical Records. The Institution and the Investigator hereby assign to Sponsor all of their rights, title and interest, including intellectual property rights, to all Confidential Information (as defined below) and any other Study Data.

1.3.3. Access, Use, Monitoring and Inspection Site shall provide original or copies (as the case may be) of all Study Data to IQVIA and Sponsor for Sponsor's use. Site shall afford Sponsor and IQVIA and their representatives and designees reasonable direct/remote access to Site's facilities and to Medical Records and Study Data so as to permit Sponsor and IQVIA and their representatives and designees to monitor the Study.

Site shall afford regulatory authorities reasonable access to Site's facilities and to Medical Records and Study Data, and the right to copy Medical Records and Study Data.

The Site agrees to cooperate with the representatives of IQVIA and Sponsor, and the Site agrees to ensure that the employees, agents and representatives of the Site do not harass, or otherwise create a hostile working environment for such representatives.

The Site shall immediately notify IQVIA of, and provide IQVIA copies of, any inquiries, correspondence or communications to or from any governmental or regulatory authority relating to the Study, including, but not limited to, requests for inspection of the Site's facilities, and the Site shall permit IQVIA and Sponsor to attend any such inspections. The Site will make reasonable efforts to separate, and not disclose, all Confidential Information that is not required to be disclosed during such inspections.

1.3.4. License Sponsor hereby grants to Institution a perpetual, non-exclusive, nontransferable, paid-up license, without right to sublicense, to use Study Data (i) subject to the obligations set forth in section 3 "**Confidentiality**", for internal, non-commercial research and for educational purposes, and (ii) for preparation of publications in accordance with Section 5 "**Publication Rights**".

1.3.5. Survival. This section 1.3 "**Medical Records and Study Data**" shall survive termination or expiration of this Agreement.

1.4. Duties of Investigator

Investigator is responsible for the conduct of the Study at Institution and for supervising any individual or party to whom the Investigator delegates Study-related duties and functions. In particular, but without limitation, it is the Investigator's duty to review and understand the information in the Investigator's Brochure or device labeling instructions, to ensure that all informed consent requirements are met, to ensure that all required reviews and approvals by applicable regulatory authorities and IRBs or IECs are obtained, and to review all CRFs to ensure their accuracy and completeness.

If the Investigator and Institution retain the services of any individual or party to perform Study-related duties and functions, the Institution and Investigator shall ensure this individual or party is qualified to perform those Study-related duties and functions and shall implement procedures to ensure the integrity of the Study-related duties and functions performed and any data generated.

Investigator agrees to provide a written declaration revealing Investigator's possible economic or other interests, if any, in connection with the conduct of the Study or the Investigational Product.
Investigator agrees to provide a written declaration revealing Investigator's disclosure obligations, if any, with the Institution in connection with the conduct of the Study and the Investigational Product.

Site agrees to provide prompt advance notice to Sponsor and IQVIA if Investigator will be leaving the Institution or is otherwise no longer able to perform the Study. The appointment of a new Investigator must have the prior approval of Sponsor and IQVIA.

1.5. Adverse Events

The Site shall report adverse events and serious adverse events as directed in the Protocol and by applicable laws and regulations. The Site shall cooperate with Sponsor in its efforts to follow-up on any adverse events. The Site shall comply with its IRB/IEC reporting obligations.

Sponsor will promptly report to the Site, the Site's IRB/IEC, and IQVIA, any finding that could affect the safety of participants or their willingness to continue participation in the Study, influence the conduct of the Study, or alter the Site's IRB/IEC approval to continue the Study.

1.6. Use and Return of Investigational Product and Equipment

Sponsor or a duly authorized agent of Sponsor, shall supply Institution or Investigator with sufficient amount of Investigational Product as described in the Protocol.

The Site shall use the Investigational Product and any comparator products provided in connection with the Study, solely for the purpose of properly completing the Study and shall maintain the Investigational Product as specified by Sponsor and according to applicable laws and regulations, including storage in a locked, secured area at all times.

Upon completion or termination of the Study, the Site shall return or destroy, at Sponsor's option, the Investigational Product, comparator products, and materials and all Confidential Information (as defined below) at Sponsor's sole expense.

Institution and Investigator shall comply with all laws and regulations governing the disposition or destruction of Investigational Product and any instructions from IQVIA that are not inconsistent with such laws and regulations.

The Site shall return any equipment or materials provided by Sponsor for use in the Study in Sponsor and Site have a written agreement for Site to acquire the equipment. Equipment provided to Site for the Study, if any, is listed on Attachment A hereto. If there are Site facility improvements provided by IQVIA or Sponsor in relation to the Study, then Site shall enter a separate written agreement with IQVIA or Sponsor with respect to such facility improvements.

1.7. Enrollment of Study Subjects

Site shall not be permitted to screen potential Study Subjects, randomize Study Subjects, receive Investigational Product or receive any payment until the Effective Date of this Agreement is reached.

1.8. Key Enrollment Date

The Site understands and agrees that if Site has not enrolled at least one (1) Study Subject by the Key Enrollment Date then IQVIA may terminate this Agreement in accordance with Section 15 "**Term & Termination**" Sponsor/IQVIA has the right to limit enrollment at any time.

1.9. Attendance at Start Up Meeting

If Sponsor or IQVIA requests Site's attendance at a Study startup meeting or other meeting necessary to provide information regarding the Study or Investigational Product, Site will be reimbursed for reasonable and necessary travel and lodging expenses (including meals) incurred to attend such meetings. Reimbursement will be as set forth in Attachment A.

2. PAYMENT

In consideration for the proper performance of the Study by Site in compliance with the terms and conditions of this Agreement, payments shall be made in accordance with the provisions set forth in Attachment A, with the last payment being made after the Site completes all its obligations hereunder, and IQVIA has received all properly completed CRFs and, if IQVIA requests, all other Confidential Information (as defined below). IQVIA will receive Site invoices and process payments unless otherwise agreed. Any queries regarding Site invoices or payments should be directed at the contact details outlined in Attachment A.

3. CONFIDENTIALITY

3.1 Definition

"**Confidential Information**" means the confidential and proprietary information of Sponsor and includes (i) all information disclosed by or on behalf of Sponsor to Institution, Investigator or other Institution personnel, including without limitation, the Investigational Product, technical information relating to the Investigational Product, all Pre-Existing Intellectual Property (as defined in Section 4) of Sponsor, and the Protocol; and (ii) Study enrollment information, information pertaining to the status of the Study, communications to and from regulatory authorities, information relating to the regulatory status of the Investigational Product, and Study Data and Inventions (as defined in Section 4).

Confidential Information shall not include information that:

(i) can be shown by documentation to have been public knowledge prior to or after disclosure by Sponsor, other than through wrongful acts or omissions attributable to Investigator, Institution or any of its personnel;

(ii) can be shown by documentation to have been in the possession of Investigator, Institution or any of its personnel prior to disclosure by Sponsor, from sources other than Sponsor that did not have an obligation of confidentiality to Sponsor;

(iii) can be shown by documentation to have been independently developed by Investigator, Institution or any of its personnel; or

(iv) is permitted to be disclosed by written authorization from Sponsor.

3.2 Obligations

Site and Site's personnel, including Study Staff shall not:

(i) use Confidential Information for any purpose other than the performance of the Study or

(ii) disclose Confidential Information to any third party, except as permitted by this Section 3 or by Section 5 "**Publication Rights**", or as required by law or by a regulatory authority or as authorized in writing by the disclosing party.

To protect Confidential Information, Site agrees to:

(i) limit dissemination of Confidential Information to only those Study Staff having a need to know for purposes of performing the Study;

(ii) advise all Study Staff who receive Confidential Information of the confidential nature of such information; and

(iii) use reasonable measures to protect Confidential Information from disclosure.

Nothing herein shall limit the right of Site to disclose Study Data as permitted by Section 5 "**Publication Rights**."

3.3 Compelled Disclosure

In the event that Institution or Investigator receives notice from a third party seeking to compel disclosure of any Confidential Information, the notice recipient shall provide Sponsor with prompt notice so that Sponsor may seek a protective order or other appropriate remedy. In the event that such protective order or other remedy is not obtained, the notice recipient shall furnish only that portion of the Confidential Information which is legally required to be disclosed and shall request confidential treatment for the Confidential Information.

3.4 Return or Destruction

Upon termination of this Agreement or upon any earlier written request by Sponsor at any time, Site shall return to Sponsor, or destroy, at Sponsor's option, all Confidential Information other than Study Data.

3.5 Survival

This Section 3 "**Confidentiality**" shall survive termination or expiration of this Agreement for ten (10) years.

4. INTELLECTUAL PROPERTY

4.1 Pre-existing Intellectual Property

Ownership of inventions, discoveries, works of authorship and other developments existing as of the Effective Date and all patents, copyrights, trade secret rights and other intellectual property rights therein (collectively, "**Pre-existing Intellectual Property**"), is not affected by this Agreement, and no Party or Sponsor shall have any claims to or rights in any Pre-existing Intellectual Property of another, except as may be otherwise expressly provided in any other written agreement between them.

4.2 Inventions

For purposes hereof, the term "**Inventions**" means all inventions, discoveries and developments conceived, first reduced to practice or otherwise discovered or developed by a Party or Sponsor or any of such entity's personnel in performance of the Study. Sponsor shall own all Inventions, that are conceived, first reduced to practice or otherwise discovered or developed by the Institution, the Investigator or any of their personnel in performance of the Study.

4.3 Assignment of Inventions

Site shall, and shall cause its personnel to, disclose all Inventions promptly and fully to Sponsor in writing, and Site, on behalf of itself and its personnel, hereby assigns to Sponsor all of its rights, title and interest in and to Inventions, including all patents, copyrights and other intellectual property rights therein and all rights of action and claims for damages and benefits arising due to past and present infringement of said rights. Site shall cooperate and assist Sponsor by executing, and causing its personnel to execute, all documents reasonably necessary for Sponsor to secure and maintain Sponsor's ownership rights in Inventions.

4.4 License

Sponsor hereby grants to Institution a perpetual, non-exclusive, non-transferable, paid-up license, without right to sublicense, to use Inventions, subject to the obligations set forth in Section 3 "**Confidentiality**," for internal, non-commercial research and for educational purposes.

4.5 Patent Prosecution

Site shall cooperate, at Sponsor's request and expense, with Sponsor's preparation, filing, prosecution, and maintenance of all patent applications and patents for Inventions.

4.6 Survival

This Section 4 "**Intellectual Property**" shall survive termination or expiration of this Agreement.

5. PUBLICATION RIGHTS

5.1 Publication and Disclosure

Institution and Investigator shall have the right to publish or present the results of Institution's and Investigator's activities conducted under this Agreement, including Study Data, only in accordance with the requirements of this Section. Institution and Investigator agree to submit any proposed publication or presentation to Sponsor for review at least thirty (30) days prior

to submitting any such proposed publication to a publisher or proceeding with such proposed presentation. Within thirty (30) days of its receipt, Sponsor shall advise Institution and/or Investigator, as the case may be, in writing of any information contained therein which is Confidential Information (other than Study Data) or which may impair the availability of patent protection for Inventions. Sponsor shall have the right to require Institution and/or Investigator, as applicable, to remove specifically identified Confidential Information (other than Study Data) and/or to delay the proposed publication or presentation for an additional sixty (60) days to enable Sponsor to seek patent protection for Inventions.

5.2 Multi-Center Publications

If the Study is a multi-center study, Institution and Investigator agree that they shall not, without the Sponsor's prior written consent, independently publish, present or otherwise disclose any results of or information pertaining to Institution's and Investigator's activities conducted under this Agreement until a multi-center publication is published; provided, however, that if a multi-center publication is not published within eighteen (18) months after completion of the Study and lock of the database at all research sites or any earlier termination or abandonment of the Study, Institution and Investigator shall have the right to publish and present the results of Institution's and Investigator's activities conducted under this Agreement, including Study Data, solely in accordance with the provisions of Section 5.3 "**Confidentiality of Unpublished Data.**"

5.3 Confidentiality of Unpublished Data

Institution and Investigator acknowledges and agrees that Study Data that is not published, presented or otherwise disclosed in accordance with Section 5.1 or Section 5.2 ("**Unpublished Data**") remains within the definition of Confidential Information, and Institution and Investigator shall not, and shall require their personnel not to, disclose Unpublished Data to any third party or disclose any Study Data to any third party in greater detail than the same may be disclosed in any publications, presentations or disclosures made in accordance with Section 5.1 or Section 5.2.

5.4 Media Contacts

Institution and Investigator shall not, and shall ensure that its personnel do not engage in interviews or other contacts with the media, including but not limited to newspapers, radio, television and the Internet, related to the Study, the Investigational Product, Inventions, or Study Data without the prior written consent of Sponsor. This provision does not prohibit publication or presentation of Study Data in accordance with this Section.

5.5 Use of Name, Registry and Reporting

No Party hereto shall use any other Party's name, or Sponsor's name, in connection with any advertising, publication or promotion without prior written permission, except that the Sponsor and IQVIA may use the Site's name in Study publications and communications, including clinical trial websites and Study newsletters. Sponsor will register the Study with a public clinical trials registry in accordance with applicable laws and regulations and will report the results of the Study publicly when and to the extent required by applicable laws and regulations.

5.6 Survival

This Section 5 "**Publication Rights**" shall survive termination or expiration of this Agreement.

6. PERSONAL DATA

The Site and IQVIA agree to comply with any applicable data privacy or data protection legislation in the processing of personal data, as it is defined under such applicable data privacy or data protection legislation.

7. STUDY SUBJECT INJURY

The Site shall promptly notify IQVIA and Sponsor in writing of any claim of illness or injury or death actually or allegedly due to an adverse reaction to the Investigational Product and cooperate with Sponsor in the handling of the adverse event.

Sponsor shall reimburse Institution for the direct, reasonable and necessary medical expenses incurred by Institution for the treatment of any adverse event experienced by, illness of or bodily injury to a Study Subject that is caused by treatment of the Study Subject in accordance with the Protocol, except to the extent that such adverse event, illness or personal injury is caused by:

(a) failure by Institution, Investigator or any of their respective personnel to comply with this Agreement, the Protocol, any written instructions of Sponsor concerning the Study, or any applicable law, regulation or guidance, including GCPs, issued by any regulatory authority, or

(b) negligence or willful misconduct by Institution, Investigator or any of their respective personnel, or

(c) failure of the Study Subject to follow the reasonable instructions of the Investigator relating to the requirements of the Study.

This Section 7 "**Study Subject Injury**" shall survive termination or expiration of this Agreement.

8. IQVIA DISCLAIMER

IQVIA expressly disclaims any liability in connection with the Investigational Product, including any liability for any claim arising out of a condition caused by or allegedly caused by any Study procedures associated with such product except to the extent that such liability is caused by the negligence, willful misconduct or breach of this Agreement by IQVIA.

This Section 8 "**IQVIA Disclaimer**" shall survive termination or expiration of this Agreement.

9. CONSEQUENTIAL DAMAGES

Neither IQVIA nor Sponsor shall be responsible to the Site for any lost profits, lost opportunities, or other consequential damages, nor shall Site be responsible to IQVIA or Sponsor for any lost profits, lost opportunities, or other consequential damages.

This Section 9 "**Consequential Damages**" shall survive termination or expiration of this Agreement.

10. DEBARMENT

The Site represents and warrants that neither Institution nor Investigator, nor any of Institution's or Investigator's employees, agents or other persons performing the Study at Institution, have been debarred, disqualified or banned from conducting clinical trials or are under investigation by any regulatory authority for debarment or any similar regulatory action in any country, and the Site shall notify IQVIA immediately if any such investigation, disqualification, debarment, or ban occurs.

This Section 10 **"Debarment"** shall survive termination or expiration of this Agreement.

11. FINANCIAL DISCLOSURE AND CONFLICT OF INTEREST

Upon Sponsor's or IQVIA's request, Site agrees that, for each listed or identified investigator or sub-investigator who is directly involved in the treatment or evaluation of Study Subjects, it shall promptly return to IQVIA a financial and conflict of interest disclosure form that has been completed and signed by such investigator or sub-investigator, which shall disclose any applicable interests held by those investigators or sub-investigators or their spouses or dependent children.

IQVIA may withhold payments if it does not receive a completed form from each such investigator and sub-investigator.

Site shall ensure that all such forms are promptly updated as needed to maintain their accuracy and completeness during the Study and for one (1) year after Study completion.
Site agrees that the completed forms may be subject to review by governmental or regulatory agencies, Sponsor, IQVIA, and their agents, and the Site consents to such review.

The Site further consents to the transfer of its financial disclosure data to the Sponsor's country of origin and to the U.S., even though data protection may not exist or be as developed in those countries as in the Site's own country.

This Section 11 "**Financial Disclosure and Conflict of Interest**" shall survive termination or expiration of this Agreement.

12. ANTI-KICKBACK AND ANTI-FRAUD

Institution and Investigator agree that their judgment with respect to the advice and care of each Study Subject will not be affected by the compensation they receive from this Agreement, that such compensation does not exceed the fair market value of the services they are providing, and that no payments are being provided to them for the purpose of inducing them to purchase or prescribe any drugs, devices or products.

If the Sponsor or IQVIA provides any free products or items for use in the Study, Institution and Investigator agree that they will not bill any Study Subject, insurer or governmental agency, or any other third party, for such free products or items.

Institution and Investigator agree that they will not bill any Study Subject, insurer, or governmental agency for any visits, services or expenses incurred during the Study for which they have received compensation from IQVIA or Sponsor, or which are not part of the ordinary care they would normally provide for the Study Subject, and that neither Institution nor Investigator will pay another physician to refer subjects to the Study.

13. ANTI-BRIBERY

Institution and Investigator agree that the fees to be paid pursuant to this Agreement represent fair compensation for the services to be provided by Site. Institution and Investigator represent and warrant that payments or Items of Value received pursuant to this Agreement or in relation to the Study will not influence any decision that Institution, Investigator or any of their respective owners, directors, employees, agents, consultants, or any payee under this Agreement may make, as a Government Official or otherwise, in order to assist Sponsor or IQVIA to secure an improper advantage or obtain or retain business.

Institution and Investigator further represent and warrant that neither they nor any of their respective owners, directors, employees, agents, or consultants, nor any payee under this Agreement, will, in order to assist Sponsor or IQVIA to secure an improper advantage or obtain or retain business, directly or indirectly pay, offer or promise to pay, or give any Items of Value to any person or entity for purposes of (i) influencing any act or decision; (ii) inducing such person or entity to do or omit to do any act in violation of their lawful duty; (iii) securing any improper advantage; or (iv) inducing such person or entity to use influence with the government or instrumentality thereof to affect or influence any act or decision of the government or instrumentality.

In addition to other rights or remedies under this Agreement or at law, IQVIA may terminate this Agreement if Site breaches any of the representations or warranties contained in this Section or if IQVIA or Sponsor learns that improper payments are being or have been made to or by Institution or Investigator or any individual or entity acting on its or their behalf.

14. INDEPENDENT CONTRACTORS

The Investigator and Institution and Study Staff are acting as independent contractors of IQVIA and Sponsor and shall not be considered the employees or agents of IQVIA or Sponsor.

Neither IQVIA nor Sponsor shall be responsible for any employee benefits, pensions, workers' compensation, withholding, or employment-related taxes as to the Investigator or Institution or their staff.

15. TERM & TERMINATION

15.1 Term

This Agreement will become effective on the date of approval of the Study by Drugs Controller General India or the date on which it is last signed by the parties, whichever date is later, (the "**Effective Date**") and shall continue until completion or until terminated in accordance with this Section 15 "**Term & Termination**". IQVIA shall attach a copy of the approval from the Drugs Controller General India approving the Study to this Agreement as Attachment B, and the Parties agree that such approval shall be incorporated by reference herein. If such approval has not been received as of the date the Parties sign this Agreement, IQVIA shall keep the original signed Agreements until receipt of such approval, and upon receipt of such approval, IQVIA shall attach a copy of the approval to each original Agreement as Attachment B and forward an original Agreement to each other Party thereafter, while retaining one original Agreement in its files. If such approval was received prior to the signatures of the Parties, IQVIA shall attach a copy of the approval hereto as Attachment B, and upon signature of all Parties, each Party shall receive an original of the Agreement, which shall include such approval as Attachment B.

15.2 Termination

IQVIA may terminate this Agreement for any reason effective immediately upon written notice. The Site may terminate upon written notice if circumstances beyond the Site's reasonable control prevent completion of the Study, or if it reasonably determines that it is unsafe to continue the Study. Upon receipt of notice of termination, the Site shall immediately cease any subject recruitment, follow the specified termination procedures, ensure that any required subject follow-up procedures are completed, and make all reasonable efforts to minimize further costs, and IQVIA shall make a final payment for visits or milestones properly performed pursuant to this Agreement in the amounts specified in Attachment A; provided, however, that ten percent (10%) of this final payment will be withheld until final acceptance by Sponsor of all CRF pages and all data clarifications issued and satisfaction of all other applicable conditions set forth herein. If a

material breach of this Agreement appears to have occurred and termination may be required, then, except to the extent that Study Subject safety may be jeopardized, IQVIA may suspend performance of all or part of this Agreement, including, but not limited to, subject enrollment.

16. NOTICE

Any notices required or permitted to be given hereunder shall be given in writing and shall be delivered:

(a) in person;
(b) by certified mail, postage prepaid, return receipt requested;
(c) by e-mail of .pdf/scan or other non-editable format notice with confirmed transmission report; or
(d) by a commercial overnight courier that guarantees next day delivery and provides a receipt,

and such notices shall be addressed as follows:

To Sponsor:	Biological E. Limited 18/1&3, Azamabad, Hyderabad – 500020, Telangana, India
To IQVIA	IQVIA RDS (India) Private Limited Omega Embassy Tech Square Marathahalli- Sarjapur Outer Ring Road, Kadubeesanahalli Bangalore KA 560103, India and IQVIA Inc. Global Legal Department 100 IMS Drive Parsippany, NJ 07054 USA Attention: General Counsel Email: officeofgeneralcounsel@iqvia.com
To Institution	Name: Dr. Rajesh Venkataraman Address: Head, Clinical Trials Adichuncahanagiri University Adichunchanagiri Hospital & Research Centre, B G Nagara, Nagamangala Taluk, Mandya District, Karnataka – 571 448 Tel: +9199800 38331
To Investigator	Name: Dr. Ravi B. Nagarajaiah Address: Adichunchanagiri Hospital & Research Centre, B G Nagara, Nagamangala Taluk, Mandya District, Karnataka – 571 448 Tel: +9194483 23893

17. FORCE MAJEURE

The performance by either Party of any obligation on its part to be performed hereunder shall be excused by floods, fires or any other Act of God, accidents, wars, riots, embargoes, delay of carriers, inability to obtain materials, failure of power or natural sources of supply, acts, injunctions, or restraints of government or other force majeure preventing such performance, whether similar or dissimilar to the foregoing, beyond the reasonable control of the Party bound by such obligation, provided, however, that the Party affected shall exert its reasonable efforts to eliminate or cure or overcome any of such causes and to resume performance of its obligations with all possible speed.

18. MISCELLANEOUS

18.1 Entire Agreement

This Agreement, including its attachment(s), constitutes the sole and complete agreement between the Parties and replaces all other written and oral agreements relating to the Study.

18.2 No Waiver/Enforceability

Failure to enforce any term of this Agreement shall not constitute a waiver of such term.

If any part of this Agreement is found to be unenforceable, the rest of this Agreement will remain in effect.

18.3 Assignment of the Agreement

This Agreement shall be binding upon the Parties and their successors and assigns.

The Site shall not assign or transfer any rights or obligations under this Agreement without the written consent of IQVIA and Sponsor.

Upon Sponsor's request, IQVIA may assign this Agreement to Sponsor or to a third party, and IQVIA shall not be responsible for any obligations or liabilities under this Agreement that arise after the date of the assignment, and the Site hereby consents to such an assignment. Site will be given prompt notice of such assignment by the assignee.

18.4 Third Party Beneficiary

The Parties agree that Sponsor shall have the right to enforce any of the provisions of this Agreement as a third-party beneficiary.

Each Party to this Agreement acknowledges that except for the Sponsor, there are no third-party beneficiaries with any rights to enforce any of the provisions of this Agreement.

18.5 Applicable Law

This Agreement shall be interpreted under the laws of the state or province and country in which Site conducts the Study.

18.6 Survival

The terms of this Agreement that contain obligations or rights that extend beyond the completion of the Study shall survive termination or completion of this Agreement, even if not expressly stated herein.

Signaure Page Follows

ACKNOWLEDGED AND AGREED BY IQVIA RDS (INDIA) PRIVATE LIMITED

Name: Bhairavi Bhinde

Title: Head of Operations

Signature: _____

Date: _____

BHAIRAVI JAYESH BHINDE

Digitally signed by BHAIRAVI JAYESH BHINDE
Date: 2021.06.17 20:28:30 +05'30'

ACKNOWLEDGED AND AGREED BY THE INVESTIGATOR:

Name: Dr. Ravi B Nagarajaiah

Signature: _____

Date: 17/6/21

Dr. RAVI. B. NAGARAJAIAH
Professor
Dept. of Medicine
AIMS, Hospital Research Center
B.G. Nagara, KMC Reg. No. 47342

ACKNOWLEDGED AND AGREED BY [Adichunchanagiri Hospital & Research Centre]:

By: Dr. Rajesh Venkataraman

Title (must be authorized to sign on Institution's behalf): Head - Clinical Trials

Signature: _____

Date: 17/6/2021

Dr. RAJESH VENKATARAMAN
Head, Clinical Trials
Adichunchanagiri Hospital & Research Centre
Adichunchanagiri University
B. G. Nagara - 571 448

ATTACHMENT A
BUDGET & PAYMENT SCHEDULE

A. **PAYEE DETAILS**

The Parties agree that the payee designated below is the proper payee for this Agreement, and that payments under this Agreement will be made only to the following payee ("**Payee**"):

Payee Name	SACCP CLINICAL RESEARCH
Payee Address	Adichunchanagiri Hospital & Research Centre, Adichuncahanagiri University B G Nagara, Nagamangala Taluk, Mandya District, Karnataka – 571 448»
Bank Name	CANARA BANK
Bank Street Address	ADI-CHUNCHANAGIRI INSTT. OF MEDICAL SCIEN Branch, BELLUR, KARNATAKA-571 448
Bank ID	8610
Bank Account #	8610101031980
Branch ID#	08610
IFSC code	CNRB0008610
Permanent Account Number (PAN) of Payee	AAAJA2708B
Payee Remittance Email Address	drrajesh.ahrc@gmail.com
SWIFT Code	CNRB0008610
GST Number	29AAAJA2708B1ZU

In case Company needs to contact the Payee, please provide the following information:

Site Contact Name : Dr.Rajesh Venkataraman
Contact Phone # : +91-99800 38331
Contact Email address : drrajesh.ahrc@gmail.com

In case of changes in the Payee's bank details, Site is obliged to inform IQVIA in writing by sending an email to respective IQVIA study team member.

Site shall contact its IQVIA study team member to provide signed documentation of changes to payee's bank details. Parties agree that in case of changes in bank details which do not involve a change of payee no further amendments are required.

The Parties acknowledge that the designated Payee is authorized to receive all of the payments for the services performed under this Agreement.

If the Investigator is not the Payee, then the Payee's obligation to reimburse the Investigator, if any, is determined by a separate agreement between Investigator and Payee, which may involve different payment amounts and different payment intervals than the payments made by the IQVIA to the Payee.

Investigator acknowledges that if Investigator is not the Payee, IQVIA will not pay Investigator even if the Payee fails to reimburse Investigator.

B. MINIMUM ENROLLMENT GOAL

Site acknowledges that Site's enrollment goal for Phase II part of the Study is **150** Study Subjects and for Phase III part of the Study is 100 Study Subject and that Site will use its best efforts to reach the enrolment goal within a reasonable timeframe after commencement of the Study at Site. If Site fails to adhere to this principle, IQVIA may reconsider Site's suitability to continue participation in the Study.

C. PAYMENT TERM

IQVIA will pay the Payee *'every 3 months'*, on a completed visit per subject basis in accordance with the attached budget. By signing this Agreement, Investigator and Institute agree on completing data entry in electronic data capture system (EDC) within 48 hours from completing Study visit.

Site represents that the services it provides under this Agreement are taxable services under the tax laws in India, and that it is required to charge applicable taxes for the services rendered to the IQVIA at the prevailing rate. Site represents that it is entitled to require such payment of the applicable taxes under the laws of India. Site undertakes to provide the IQVIA with an invoice, to be sent to the IQVIA at the address mentioned in Section N of this Attachment A, in respect of such taxable services and such invoice shall be in accordance with the terms of the applicable tax laws in India as may be amended from time to time or any successor legislation.

It should be noted that all payments made to the payee are subject to Tax Deducted at Source (TDS) in accordance with India tax laws, as amended from time to time. IQVIA will deduct the tax at the time of making payments unless a valid Certificate of low deduction or NIL deduction is obtained from tax authority is made available to IQVIA.

All fees set forth in the Agreement are exclusive of any taxes and duties (other than employment-related taxes, corporate income taxes) ("**Taxes**"). Site shall pay any and all Taxes that are imposed by legislation in connection with the provision of services.

Any expense or cost incurred by Site in performing this Agreement that is not specifically designated as reimbursable by IQVIA or Sponsor under the Agreement (including this Budget and Payment Schedule) is the sole responsibility of the Site.

All amounts specified in this Agreement are in Indian Rupees (INR) and are exclusive of GST. IQVIA will pay to the Payee any amount of GST that the Payee is required to pay in addition to the amounts set out in this Attachment A and in accordance with GST legislation.

Major, disqualifying Protocol violations are not payable under this Agreement

D. BUDGET TABLE

VISIT	VISIT AMOUNT (INR)	INSTITUTINAL OVERHEAD @ 25% (INR)	VISIT AMOUNT INCLUDING INSTITUTIONAL OVERHEAD (INR)
Screening*	4000	1000	5000
Enrollment (Dose#1)	5000	1250	6250

Enrollment (Dose#2)	5000	1250	6250
Follow-up Visit 4	3000	750	3750
Follow-up Visit 5	3000	750	3750
Follow-up Visit 6	3000	750	3750
Follow-up Visit 7 / End of Study	3000	750	3750
TOTAL PER SUBJECT	**26000**	**6500**	**32500**

** AMOUNT INCLUSIVE OF RTPCR TEST PERFORMED AT SITE'S LOCAL LAB*

Note:

1. Patient travel reimbursement will be paid separately (INR 500) per clinic visits as per ICF

E. SCREENING FAILURE

Reimbursement for screen failures will be at the amount

- of Three Thousand **Indian Rupees (INR 3000/-)** per subject (Inclusive of IOH)

not to exceed 20% screen failure(s) paid per total subject(s) randomized at the Site at the end of Study or a ratio of 1:4 (1 screen failure paid per 4 Study Subjects randomized for Phase II) and 1:5 (1 screen failure paid for per 5 Study Subjects randomized for Phase III).

To be eligible for reimbursement of a screening visit, supporting data entry must be completed and submitted to IQVIA along with any additional information, which may be requested by IQVIA to appropriately document the subject screening procedures.

F. DISCONTINUED OR EARLY TERMINATION SUBJECTS

Reimbursement for discontinued or early termination subjects will be prorated based on the number of confirmed completed visits.

G. UNSCHEDULED VISITS

Payment for unscheduled visits will be reimbursed in the amount of **One Thousand Indian Rupees (INR 1000)** [which includes overhead]. To be eligible for reimbursement for unscheduled visits, supporting data entry must be completed and submitted to the IQVIA, along with any additional information which may be requested by IQVIA, to appropriately document the unscheduled visit.

H. EC/IRB/IEC FEES

EC/IRB/IEC costs will be paid upon receipt of an invoice issued by the EC/IRB/IEC and are not included in the attached Budget. Payment will be made directly to the EC/IRB/IEC as per IQVIA's standard turn-around time. Any subsequent re-submissions or renewals, upon approval by IQVIA and Sponsor, will be paid upon receipt of appropriate documentation.

K. PATIENT TRANSPORTATION

The Site shall be reimbursed for patient transportation allowance in the amount of Five Hundred Indian Rupees (INR500) per visit in accordance with the ICF. Payment will be made upon receipt of invoice with patient number and visit date.

L. EQUIPMENT

Site shall be provided with the following equipment:

- Dry heat bath

All materials and equipment provided ("**Equipment**") by the Sponsor or IQVIA/vendors contracted by the Sponsor shall remain the sole property of the Sponsor/IQVIA/vendor, as the case may be.

Therefore, it is hereby agreed that such Equipment shall:
a) be subject to removal at any time upon the Sponsor's or, IQVIA's demand provided that such removal does not prevent the Site from conducting the Study and carrying out their obligations under this Agreement;
b) be used only for the purposes of the Study;
c) be used in accordance with any manuals or instructions while in possession of the Site;
d) shall remain in the same condition, ordinary wear and tear excepted. As long as the Equipment are in the possession of the Site, it is liable for maintenance or any risk of loss in connection with the Equipment during the conduct of the Study;
e) be clearly identified as the sole property of the Sponsor/IQVIA/vendor, as applicable, by clearly stating "BELONGS TO "Name of legal owner" in order to notify any third parties, including creditors, that the legal owner retains title thereto; and
f) upon completion or termination of the Study, IQVIA or Sponsor, together with Site assistance, shall arrange the return of all equipment provided for the Study within one (1) month of request to return, or if requested by the Sponsor or IQVIA in writing, arrange for the disposal of the Equipment as soon as reasonably practicable.

M. PAYMENT DISPUTES

Site will have thirty (30) days from the receipt of final payment to dispute any payment discrepancies during the course of the Study.

N. INVOICES

Invoices pertaining to this Study for the following items must be issued to IQVIA for reimbursement at the following address:

IQVIA RDS (India) Private Limited
Omega Embassy Tech Square Marathahalli -
Sarjapur Outer Ring Road, Kadubeesanahalli Bangalore-
KA- 560103, India
Attention: Payment Team

Please note that invoices will not be processed unless they reference the Sponsor name, Protocol number and Investigator name and site number. After receipt and verification, reimbursement for invoices will be included with the next regularly scheduled payment.

Invoices and any accompanying documentation must not include any personally identifying information of any Subject, including but not limited to Subject first or last name, initials, date of birth, address, telephone, passport number, email address, or credit card information. If invoices or any accompanying documentation do contain this information IQVIA will notify Payee. Payee will need to resubmit a redacted invoice and accompanying documentation that does not include any personally identifying information of any Subject.

NO OTHER ADDITIONAL FUNDING REQUESTS WILL BE CONSIDERED

All payments for this Study in accordance with the attached Budget will be paid by IQVIA electronically.

Clinical Trial Details (PDF Generation Date :- Mon, 07 Aug 2023 04:11:38 GMT)

CTRI Number	CTRI/2021/06/034014 [Registered on: 04/06/2021] - **Trial Registered Prospectively**
Last Modified On	06/01/2022
Post Graduate Thesis	No
Type of Trial	Interventional
Type of Study	Vaccine Biological Preventive
Study Design	Single Arm Study
Public Title of Study	Biological E's CORBEVAX vaccine clinical study for protection against Covid-19 disease.
Scientific Title of Study	A Prospective, multicentre, Phase II Seamlessly Followed by Phase III Clinical Study to Evaluate the Immunogenicity and Safety of Biological E's CORBEVAX Vaccine for Protection Against COVID-19 Disease When Administered to COVID-19-Negative Adult Subjects.

Secondary IDs if Any

Secondary ID	Identifier
BECT/COVID-19-PHASE-III/069 Ver: 2.1 dated:13.05.21	Protocol Number

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Dr Subhash Thuluva
Designation	Vice President - Clinical Development
Affiliation	Biological E.Limited
Address	Clinical Development Dept, 2nd floor, Road No.35, Jubilee Hills Hyderabad TELANGANA 500033 India
Phone	04071216248
Fax	04027675309
Email	subhash.thuluva@biologicale.com

Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
Name	Dr Subhash Thuluva
Designation	Vice President - Clinical Development
Affiliation	Biological E.Limited
Address	Clinical Development Dept, 2nd floor, Road No.35, Jubilee Hills TELANGANA 500033 India
Phone	04071216248
Fax	04027675309
Email	subhash.thuluva@biologicale.com

Details Contact Person (Public Query)

Details Contact Person (Public Query)	
Name	Dr TSA Kishore
Designation	Associate Vice President - Clinical Development
Affiliation	Biological E.Limited
Address	Clinical Development Dept, 2nd floor, Road No.35, Jubilee Hills Hyderabad TELANGANA 500033 India

Phone	04071216247
Fax	04027675309
Email	kishore.turaga@biologicale.com

Source of Monetary or Material Support

Source of Monetary or Material Support
> Biological E.Limited, 18/1&3, Azamabad, Hyderabad - 500020, Telangana, India.

Primary Sponsor

Primary Sponsor Details	
Name	Biological ELimited
Address	18/1&3, Azamabad, Hyderabad - 500020, Telangana, India.
Type of Sponsor	Pharmaceutical industry-Indian

Details of Secondary Sponsor

Name	Address
None	None

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Dr Ravi B Nagarajaiah	Adichunchanagiri Hospital & Research Centre	Dept of General Medicine,1st floor,B G Nagara Nagamangala Taluk, Mandya-571448 Mandya KARNATAKA	9448323893 ravibn972@yahoo.com
DrPNaveen Chander Reddy	AIG Hospital	4th floor, Plot No. 2/3/4/5, Survey No. 136/1, Mindspace Road, Gachibowli-500032, Hyderabad TELANGANA	9848045814 drnaveen.reddy@aighospitals.com
Dr Chandramani Singh	All India Institute of Medical Sciences	Room No. 17 Department of Community & Family Medicine, Aurangabad Road Phulwari Sharif, Patna 801507. Aurangabad BIHAR	09931733280 cmaiims57@gmail.com
Dr Swapnav Borthakur	Down Town Hospital	2nd floor of 3rd building, G. S. Road, Bormotoria, Dispur, Guwahati-781006 Dibrugarh ASSAM	9864038704 swapnav.bortharkar@gmail.com
Dr Anil Kumar Pandey	ESIC Medical College and Hospital	Room No. 440, 4th Floor, NH-3 behind BK Hospital New Industrial Town-121001 Faridabad HARYANA	7042918222 drpandeyak@yahoo.co.in
Dr Shiva Narang	Guru Teg Bahadur Hospital & UCMS	Department of Medicine, Dilshad Garden, Delhi-110095, North East DELHI	9899838807 shivanarang@gmail.com
Dr E Venkata Rao	Institute of Medical	Department of	9668443382

	Sciences & SUM Hospital	community Medicine, 3rd Floor,K-8, Kalinga Nagar, Ghatikia,Bhubaneswar-751003 Baleshwar ORISSA	e.venkata.rao@gmail.com
Dr Madhav Prabhu	KLES Dr. Prabhakar Kore Hospital and MRC	Department of Medicine, Nehru Nagar,Belgavi-590010 Belgaum KARNATAKA	9738462380 wiseman2380@yahoo.com
Dr Manish Kumar Jain	Maharaja Agrasen Superspeciality Hospital	Department of Pulmonology, Central Spine, Agrasen Aspatal Marg, Sector-7, Vidyanagar-302039 Jaipur RAJASTHAN	9414414834 doctormanishjain2@gmail.com
Dr Pajanivel Ranganadin	Mahatma Gandhi Medical College& Research Institute	1st floor, I block, Pondicherry-Cuddalore Road, ECRMain Road, Pillayarkuppam-607402 , Pondicherry PONDICHERRY	9443493122 pajanivelr@mgmcri.ac.in
Dr Maulesh Tailor	Pagarav Hospital & ICU	Basement, Plot No. 512/1, Nr. G-6 Circle, Opp. SBI Bank, Sector-23, Gandhinagar-382023 Gandhinagar GUJARAT	9979867922 drmauleshtailor@yahoo.com
Dr Jitendra Singh Kushwaha	Prakhar Hospital Pvt. Ltd	Department of Medicine, 8/219, Arya Nagar Road, Khalasi Line, Arya Nagar, Kanpur-208002 Kanpur Nagar UTTAR PRADESH	844852240 dr.jskushwahacr@gmail.com
Dr Sanjay Kala	Sarojini Naidu Medical College	Ground floor, Transfusion medicine department, Moti Katra, Mantola, Agra-282003 Agra UTTAR PRADESH	9839210012 surgerygsvmmc@gmail.com
Dr A Venkateshwar Rao	St.Theresas Hospital	Room No. 5, Department of Medicine, Sanathnagar-500018 Hyderabad TELANGANA	9440040662 drvenkateshwarraoavula@gmail.com
Dr Sandeep Jain	Tagore Hospital and Research Centre	Ground floor,Tagore Lane, Sector-7, Shipra Path, Madhyam Marg, Mansarovar-302020 Jaipur RAJASTHAN	9414069583 drsandeeprjain@yahoo.co.in

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics

			Committee?
Ethical Committee, Mahatma Gandhi Medical College and Research Institute	Approved	02/08/2021	No
Ethics Committee downtown hospital	Approved	16/08/2021	No
Ethics Committee GSVM Medical College	Approved	08/09/2021	No
Ethics Committee, St. Theresa's Hospital	Approved	07/06/2021	No
Guru Teg Bahadur Hospital Ethics Committee	Approved	03/06/2021	No
IEC ESIC Medical College and Hospital,	Approved	08/06/2021	No
IEC Prakhar Hospital Pvt Ltd	Approved	04/06/2021	No
IEC, All India Institute of Medical Sciences, Patna	Approved	09/06/2021	No
IEC, Maharaja Agrasen Hospital	Approved	06/06/2021	No
Institutional Ethics Committee of AH and RC Adichunchanagiri Hospital and Research Center	Approved	24/06/2021	No
Institutional Ethics Committee, IMS & SUM Hospital	Approved	07/07/2021	No
Institutional Ethics committee, KLES Dr. Prabhakar Kore Hospital	Approved	17/06/2021	No
Institutional Ethics Committee- AIG Hospital	Approved	15/06/2021	No
Pagarav Ethics committee	Approved	17/07/2021	No
Tagore Hospital Ethics Committee	Approved	03/07/2021	No

Regulatory Clearance Status from DCGI

Status	Date
Approved/Obtained	20/05/2021

Health Condition / Problems Studied

Health Type	Condition
Healthy Human Volunteers	Active immunization for the prevention of COVID-19 disease

Intervention / Comparator Agent

Type	Name	Details
Intervention	Biological E's SARS-CoV-2 (COVID-19)Vaccine-CORBEVAX	Dose: 0.5ml, Route of administration: Intramuscular injection, Frequency: Two doses at Day 0 and Day 28.
Comparator Agent	None	None

Inclusion Criteria

Inclusion Criteria

Age From	18.00 Year(s)
Age To	80.00 Year(s)
Gender	Both
Details	Inclusion Criteria ONLY for Phase II: 1.Male or female (non-pregnant) subject between ? 18 to 55 years of age. 2.Subject seronegative to anti-SARS-CoV-2 antibody prior to enrolment. Inclusion Criteria ONLY for Phase III: 1.Male or female subject between ? 18 to 80 years of age. Inclusion Criteria for Phase II and Phase III: 1.Subject or their legally acceptable representative (LAR) is willing to provide a written informed consent for voluntary participation in the study. 2. Subject, in the opinion of the investigator, has ability to communicate and willingness to comply with the requirements of the protocol. 3.Subject is virologically seronegative to SARS-CoV-2 infection as confirmed by RT-PCR prior to enrolment. 4.Subject is seronegative to HIV 1 & 2, HBV and HCV infection prior to enrolment. 5.Subject is considered of stable health as judged by the investigator, determined by medical history and physical examination. 6.Female subject of child bearing potential must have a negative urine pregnancy test (UPT), and willingness to avoid becoming pregnant through use of an effective method of contraception or abstinence from the time of study enrolment until six weeks after the last dose of vaccination in the study. 7.Male subject, who is sexually active, must agree to use double-barrier contraception (e.g. condom with spermicide) with his female partner during the study period. Male subject should also agree to avoid semen donation or providing semen for in-vitro fertilization during the study duration. 8.Subject agrees not to participate in another clinical trial at any time during the total study period. 9.Subject agrees to refrain from blood donation during the course of the study. 10.Subject agrees to remain in the town where the study centre is located, for the entire duration of the study.

Exclusion Criteria

Exclusion Criteria	
Details	1.History of vaccination with any investigational or approved vaccine against COVID-19 disease. 2.Subject living in the same household as that of any active COVID-19 positive individual at the time of enrolment. 3.History of receipt of any licensed vaccine within 1 month prior to screening, likely to impact on interpretation of the trial data (e.g., influenza vaccines); 4.Subjects with any clinically significant abnormal haematology and biochemical laboratory parameters tested at screening as judged by the investigator. 5.Subjects with Body temperature of ?100.4°F (>38.0°C) or symptoms of an acute illness at the time of screening or prior to vaccination. 6.Pregnant women, nursing women or women of childbearing potential who are not actively avoiding pregnancy during the study. 7.Subjects with known current or chronic history of any of the following conditions, likely to affect participation in the study: i.severe psychiatric conditions; ii.any bleeding disorder (e.g. factor deficiency, coagulopathy or platelet disorder); iii.allergic disease or reactions likely to be exacerbated by any component of the study vaccine (BE CORBEVAX vaccine); iv.neurological illness, and any other serious chronic illness requiring hospital specialist supervision. 8.Subjects requiring chronic administration (defined as more than 14

	days in total) of immunosuppressant (e.g. corticosteroids, cytotoxic drugs or antimetabolites, etc.) or other immune-modifying drugs (e.g. interferons) during the period starting six months prior to the first vaccine dose including use of any blood products. i.For corticosteroids, this will mean prednisone ?0.5 mg/kg/day, or equivalent. ii.Inhaled and topical steroids are allowed. iii.Receipt of prohibited concomitant medication that may jeopardize the safety of the participant or interpretation of the data. 9.Any confirmed or suspected immunosuppressive or immunodeficient condition, based on medical history and physical examination (no laboratory testing required). 10.Any medical condition that in the judgment of the investigator would make study participation unsafe. 11.Planned use of any investigational or non-registered product other than the study vaccine during the trial period or 3 months prior to enrolment. 12.Current or planned participation in prophylactic drug trials for the duration of the study. 13.Individuals who are part of the study team or close family members of individuals conducting the study.

Method of Generating Random Sequence	Not Applicable
Method of Concealment	Not Applicable
Blinding/Masking	Open Label

Primary Outcome

Outcome	Timepoints
1.Proportion of subjects with solicited adverse reactions/symptoms 2.Proportion of subjects with unsolicited adverse events (AEs) 3.SAEs & MAAE in all subjects. 1.Anti-RBD IgG antibodies in terms of ratio of IgG1 to IgG4 anti-RBD titres. 2.Neutralizing antibody titre 3.Immunogenicity in terms of GMC/T 4.Proportion of subjects seroconverted in terms of ?2-fold & ?4-fold rise 5.Cell mediated immunity assessment in terms of cytokine expression from stimulated PBMCs (INF-?, IL-4)	1.during first 60 minutes of post vaccination and subsequent 7 days. 2.28-day follow-up period after each dose. 3.At 6 and 12months post 2nd dose. 1.at day 42 vs baseline. 2.at baseline and again at day 42. 3.at baseline and again at day 42. 4.in baseline seronegative subjects and ?2-fold rise in baseline seropositive subjects along with their GMFR at day 42 5.at baseline and at day 42

Secondary Outcome

Outcome	Timepoints
At Phase-II: Anti-RBD IgG concentrations (GMC, Fold Rise, GMFR)	At baseline, day 28, 42 and 56 and at 6 and 12 months post second dose.
Anti-RBD IgG subclass assessment in terms of ratio of IgG1 to IgG4 titres	At day 42 & day 56.
Neutralizing antibody titre	At baseline, day 28, 42, 56 and at 6 and 12 months post second dose.
Cell mediated immunity assessment in terms of cytokine expression from stimulated PBMCs (INF-?, IL-4)	At baseline and at day 42
At Phase-III: Proportion of subjects with solicited adverse reactions/symptoms	During first 60 minutes of post vaccination observation period and for subsequent 7 consecutive days

Proportion of subjects with unsolicited adverse events (AEs)	During the 28-day follow up period after each dose
SAEs and MAAES	During the entire study period
Safety follow-up visit	At 6 and12 months post 2nd dose

Target Sample Size	**Total Sample Size=**1268 **Sample Size from India=**1268 **Final Enrollment numbers achieved (Total)=**Applicable only for Completed/Terminated trials **Final Enrollment numbers achieved (India)=**Applicable only for Completed/Terminated trials
Phase of Trial	Phase 2/ Phase 3
Date of First Enrollment (India)	07/06/2021
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**2 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Closed to Recruitment of Participants
Publication Details	None
Brief Summary	This is a prospective, open-label, single arm, phase II seamlessly followed by Phase III clinical study design to evaluate the immunogenicity and safety of CORBEVAX vaccine for Protection Against COVID-19 Disease When administered to COVID-19-Negative Adult Subjects between18-80 years of age. A total of 1268 male and non-pregnant female adult, from moderate to high-risk population with and without comorbidities will be enrolled across both phases of the study. Subjects must be RT-PCR negative to SARS-CoV-2 antigen. A total of 100 subjects, aged 18 to 55 years, will be enrolled in Phase II for safety assessment and a total of 1168 subjects, aged 18 to 80 years, will be enrolled in Phase III to receive BioE's SARS-CoV-2 vaccine (CORBEVAX). The study will be conducted in compliance with GSR 227(E), ICH and Indian good clinical practice guidelines in force at the time of study conduct.