



## ICMR - National Institute of Epidemiology

R – 127, TNHB, 2<sup>nd</sup> Main Road

Ayapakkam, Chennai - 77

044 – 26136201 | [director.nie@icmr.gov.in](mailto:director.nie@icmr.gov.in)

NIE/PS/LTE/2022/01

Date: 21.01.2022

### **Tender/Quotation for providing Clinical Trials Liability Insurance**

ICMR-NIE is coordinating the trial, titled “Safety and immunogenicity of the third dose of COVISHIELD/COVAXIN vaccine using homologous and heterologous regimen in immunocompromised patients: single-blind, randomized non-inferiority trial”, with the following hospitals in India.

- Jawaharlal Institute of Postgraduate Medical Education and Research, Puducherry
- Cancer Institute (WIA) Adyar, Chennai
- Madras Medical college and Rajiv Gandhi Government General Hospital, Chennai
- Government Hospital of Thoracic Medicine, Chennai
- Tata Memorial Hospital, Mumbai
- King Edward Memorial Hospital Seth Gordhandas Sunderdas Medical College, Mumbai
- TNMEDICAL College and Nair Hospital, Mumbai

This multi-centric randomized clinical trial is designed with the primary objective of comparing immunogenicity between homologous and heterologous precautionary dose of COVID-19 vaccine among fully vaccinated, immunocompromised adults. The following five groups of immunocompromised individuals will be included in the trial.

1. Haematolymphoid malignancies on chemotherapy or within six months of chemotherapy or within two years of monoclonal antibodies
2. Patients currently on haemodialysis
3. Patients who underwent solid organ transplant and receiving or had received immunosuppressive therapy in the previous 6 months
4. Patients with HIV currently on ART (for at least 6 months) and with CD4 count more than 200
5. Patients with autoimmune diseases and on immunosuppressive therapies

The trial plans to recruit 1400 immunocompromised adults (280 in each immunocompromised group) visiting the above-mentioned hospitals for their follow-up. Fully vaccinated immunocompromised individuals will be randomized to receive homologous (same vaccine as that of primary series) or heterologous (different vaccine than that of primary series) COVID-19 vaccine. Blood samples from the participants will be collected at different time intervals (0, 28 days, 6 months) to assess the humoral and cellular immune responses. The duration of the study will be 8 months.

Bids are invited from eligible insurance companies who are interested in providing clinical trials liability policy or liability insurance, indicating the conditions and extent of coverage, date of commencement and expiry of coverage, and conditions thereof, including the premium and other costs, as per rules, for the aforementioned

studies.

The terms for the policy are –

1. Maximum of 35 Lakh Rupees per occurrence
2. Aggregate insurance of 5 Crore Rupees.

The rules of compensation can be downloaded from the following link:

[https://cdsco.gov.in/opencms/export/sites/CDSCO\\_WEB/Pdf-documents/NewDrugs\\_CTRules\\_2019.pdf](https://cdsco.gov.in/opencms/export/sites/CDSCO_WEB/Pdf-documents/NewDrugs_CTRules_2019.pdf)

The **clarifications**, if any, have to be done before submission of the tender/quotation, i.e. before **27<sup>th</sup> January, 2022 03.00 PM**.

Technical queries: Director, ICMR - NIE, Chennai +91-44-26136201 e-mail: [director.nie@icmr.gov.in](mailto:director.nie@icmr.gov.in)

Administrative queries: Administrative Officer, ICMR – NIE, Chennai +91-44-26136258 e-mail: [stores@nie.gov.in](mailto:stores@nie.gov.in)

**Confidentiality Agreement:**

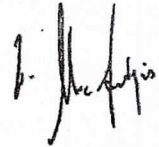
The PDF documents of Protocol and Participant Information Sheet shall be shared on signing Confidentiality agreement (Annexure I) with ICMR – NIE. The confidentiality agreement signed on Rs.20/- stamp paper shall be sent to [director.nie@icmr.gov.in](mailto:director.nie@icmr.gov.in) and send the original agreement through Post/Courier to ICMR – NIE.

**Bid submission:**

- Please submit your tender/quotation at the following address with complete documentation, by **07.02.2022 03.00 PM**. The closed cover should be superscribed with “Quotation for providing Clinical Trials Liability Insurance”.

**The Director,  
ICMR – National Institute of Epidemiology,  
R – 127, Second Main Road,  
TNHB, Ayapakkam, Chennai – 77**

- Bids received through e-mail/telegram/fax will not be accepted
- No additional cost will be paid which is not mentioned in the bid



**ADMINISTRATIVE OFFICER**

**Confidentiality Agreement Format**

**(To be printed on 20 rupees stamp paper and sent to ICMR - NIE)**

**To,**  
The Director,  
ICMR – National Institute of Epidemiology,  
R – 127, Second Main Road,  
TNHB, Ayapakkam, Chennai – 77

**Subject:** Signing Confidentiality disclosure agreement in reference to the Tender/Quotation for providing Clinical Trials Liability Insurance

**Reference:** NIE/PS/LTE/2022/01 dated 21.01.2022

**Study Title:** “Safety and immunogenicity of the third dose of COVISHIELD/COVAXIN vaccine using homologous and heterologous regimen in immunocompromised patients: single-blind, randomized non-inferiority trial”

**CONFIDENTIALITY (NON-DISCLOSURE) AGREEMENT**

<Firm Name>, a company incorporated under the Companies Act, 1956 and having its registered office at <<address>> declares the following:

My employees, organization and I will hold the information disclosed in all documents shared related to the subject mentioned above and data (oral, written, graphic, demonstrative, electronic or otherwise) generated during the said study as confidential. It would not be reproduced, published, or disclosed without any written authorization from The Director, ICMR – NIE, Chennai - 77.

**Signature:** \_\_\_\_\_

**Date:** \_\_ \_\_/\_\_ \_\_/\_\_ \_\_ \_\_ \_\_  
(dd / mmm / yyyy)

**Name & Designation:** \_\_\_\_\_

**Company Seal:**