Proposal on COVID-19 Vaccination Drive

Submitted to the Office of the Principal Scientific Advisor, Govt. of India

Name of the institute: CSIR-NEIST (Council of Scientific and Industrial Research- North East Institute of Science and Technology), Jorhat, Assam

Incubator: Not applicable

Faculty:

Contact details: Director, CSIR-NEIST, Jorhat

Objective:

1. Determination of immunogenicity against COVID-19 in vaccinated individuals
2. Longitudinal serosurveillance of vaccinated individuals to check the sustainability of anti SAR-CoV-2 IgG in recurrent infections

Type of Intervention: Post vaccination study

Details of intervention: Proposal is attached as per format

Do you have State Government connection, or will you require support from CSR: CSIR-NEIST have strong tie-up with the State Governments of North East India, particularly Assam, Manipur, Meghalaya, Nagaland, and Arunachal Pradesh. Recently, CSIR-NEIST has entered into MoUs with the State Governments for collaborative research for the development and benefit of the region through science and technology intervention.

States that you can provide technology to: COVID-19 immunoassay laboratory facility of CSIR-NEIST, Jorhat proposes to provide immunogenicity testing service to the states of Assam, Manipur, Meghalaya, Nagaland, Arunachal Pradesh, Sikkim, Mizoram and Tripura to support post vaccination studies and perform immunogenicity assays and longitudinal serosurveillance of the individuals vaccinated with COVID-19 vaccines.

Please answer following questions depending on the intervention you choose and ifapplicable to you:

- Can you do the community engagement yourselves or will need help by CSR: Need help of CSR
- If you have a market ready technology available, how do you plan to deploy and number of unites available: Not applicable
- Do you wish to partner with an NGO? If yes, name the NGO and provide details on how u will partner? (item wise costing should include cost to NGO for their scope of work):

**** For this type intervention, please send a separate 1-2 pager proposal that will include abstract of the planned/proposed work, methodology, tentative budget, and estimated timeline.**

Proposal Title

Strengthening of high throughput immunoassay laboratory facility to support assessment of COVID-19 vaccination in North Eastern region

(Proposed Budget: 396.20 lakhs)

submitted by

CSIR North East Institute of Science and Technology
Jorhat 785006, Assam

submitted to the

Office of the Principal Scientific Advisor

Govt. of India

1. **Name of The Organization:**CSIR-NEIST (Council of Scientific and Industrial Research- North East Institute of Science and Technology), Jorhat, Assam
2. **Type of the Organization:** Public Research Institutes
3. **Title of Proposal:** Strengthening of high throughput immunoassay laboratory facility to support assessment of COVID-19 vaccination in North Eastern region
4. **Proposal Duration:** 12 months
5. **Relevant Category:**Clinical Immunogenicity Laboratory
6. **Objectives:**
    i. Determination of immunogenicity against COVID-19 in vaccinated individuals
    ii. Longitudinal serosurveillance of vaccinated individuals to check the sustainability of anti SAR-CoV-2 IgG in recurrent infections
7. **Abstract of the planned/proposed work:**

CSIR NEIST established a well-equipped BSL-2 COVID-19 Testing Lab, fortified with highly qualified and trained personnel and *in vitro* diagnostic certified equipments. The testing facility is equipped with various state-of-the-art equipment and facilities including high throughput automatic liquid handling systems and Class II Biosafety Cabinets. The BSL-2 laboratory was designed and established following the strict guidelines of the DBT and ICMR. The laboratory facility, which spans in about 9200 sq. ft., has the capacity to carry out RT-PCR-based COVID-19 testing of 3000-5000 samples per day. The establishment of the COVID-19 testing laboratory has paved way for CSIR-NEIST to be a part of a pan-CSIR initiative called "CSIR-Phenome India", which is designed to undertake long-term longitudinal observational cohort study of health outcomes in Indian population (Naushin et al., 2021). As a partner institute under this study, CSIR-NEIST is a designated laboratory for performing COVID-19 serological study with particular focus on the North East Indian population. This serology testing project aimed to develop a standardized protocol for obtaining lifestyle, dietary, and clinical information towards establishing a prospective Indian cohort and carrying out serological profiling of patients infected with SARS-CoV-2 to determine the anti-SARS-CoV-2 antibody titres at various time intervals and ascertain the burden of the disease. With the aim to establish and validate immunoassay for estimation of COVID-19 vaccine response and test the immunogenicity in COVID-19 vaccinated individuals, it is proposed to strengthen the service facilities of the existing COVID-19 immunoassay laboratory facility of CSIR-NEIST, Jorhat to support and accelerate the country's vaccination programme and development of COVID-19 vaccines in the pipeline. The facility will establish and standardize high-throughput automated assays for estimating immunogenicity of various COVID-19 vaccinated candidates. The facility will provide the service to perform the immunogenicity assays of the individuals vaccinated with COVID-19 vaccines. This study will also help in understanding the sustainability of antibodies developed in every individual after vaccination. Through the proposed facility, CSIR-NEIST will partner with the institutions of North East India involved in COVID-19 vaccination through the State Government to obtain clinical samples, demographic and lifestyle data, clinical history and anthropometric parameters of the vaccinated individuals. Access to COVID-19 clinical samples that may be required for establishment and validation of the immunoassays will be made through the biorepositories established in CSIR-IGIB and CSIR-CCMB as the partner institute. One of the immediate benefits of the proposed facility will be the creation of knowledge of whether the patients have developed significant and lasting antibodies post COVID-19 vaccination. The establishment of such a facility with longitudinal biological sampling, serological data generation, and vaccine safety data will align with the framework of UN-SDG and the National Health Mission and will facilitate the development of vaccine and provide aid to clinical decision making as well as national healthcare policy decisions. CSIR will benefit significantly by this endeavor as it will hold invaluable

prospective biological samples, clinical, and demographic data to promote interdisciplinary research in healthcare space. In addition, the discussion of clinically significant results with the participants of the study and encouragement to seek appropriate medical attention will result in a healthy and productive scientific workforce.

8. Methodology:

Objective	**Methodology/experimental design detailed work plan**	**Alternate strategies**
Determination of immunogenicity against COVID-19 in vaccinated individuals	• Blood sample collection from vaccinated individuals in clot activator vials • Separation of serum • Checking antibody levels (anti S IgG and anti N IgG) in serum using CLIA-based immunoassays in high-throughput automated system Cobase411 (Roche Diagnostics)	• Blood sample collection from vaccinated individuals in clot activator vials • Separation of PBMC and serum • Checking mRNA expression and serum levels of proinflammatory cytokines by using RT-qPCR and ELISA, respectively.
Longitudinal serosurveillance of vaccinated individuals to check the sustainability of anti SARS CoV 2 IgG in recurrent infections	• Blood sample collection from vaccinated individuals in clot activator vials in an interval of 7 days • Separation of serum • Checking antibody levels (anti S IgG and anti N IgG) in serum using CLIA-based immunoassays in high-throughput automated system Cobase411 (Roche Diagnostics)	• Blood sample collection from vaccinated individuals in clot activator vials in an interval of 7 days • Separation of PBMC and serum • Checking mRNA expression and serum levels of proinflammatory cytokines by using RT-qPCR and ELISA, respectively.

9. Estimated timelines and milestones:

Activities to be undertaken to achieve a particular objective	**Month of start of activity**	**Month of end of activity**	**Indicators of progress**
Procurement of consumables	0^{th} month after fund release	2^{nd} month	Start of working bench
Sample collection, conducting the immunoassays and data generation	0.5^{th} month	12^{th} month	Report generation
Data analysis	1^{st} month	12^{th} month	Report generation

10. Tentative budget (in Rs.):

Budget Head	**1st quarter (0-3 month)**	**2nd quarter (4-6 month)**	**3rd quarter (7-9 month)**	**4th quarter (10-12 month)**	**Total**
Supplies & Consumables ***Justification:*** *Includes all materials required for conducting the assays in addition to those required for providing services.*	1,50,00,000	1,50,00,000	50,00,000	10,00,000	3,60,00,000
Consultant ***Justification:*** *Consultant Clinician for supervising clinical data and reporting 500tests/day (Honorium @ Rs 60,000 consolidated per month)*	1,80,000	1,80,000	1,80,000	1,80,000	7,20,000
Personnel (*Lab Technician @Rs12,000/month x 5 numbers*) ***Justification:*** *Lab technician number per person 100tests/day*	1,80,000	1,80,000	1,80,000	1,80,000	7,20,000
Infrastructure ***Justification:*** *Maintenance of infrastructure of the facilities pertaining to varied services*	20,00,000	-	-	-	20,00,000
Institutional Overhead	20,000	20,000	20,000	20,000	80,000
Travel ***Justification:*** *For travels related to the execution of the project.*	50,000	-	50,000	-	1,00,000
Total	**1,74,30,000**	**1,53,80,000**	**54,30,000**	**13,80,000**	**3,96,20,000**