



icmr
INDIAN COUNCIL OF
MEDICAL RESEARCH

NIRBI
NATIONAL INSTITUTE FOR
RESEARCH IN BACTERIAL INFECTIONS

आई. सी. एम. आर. - राष्ट्रीय जीवाणु संक्रमण अनुसंधान संस्थान
ICMR - NATIONAL INSTITUTE FOR RESEARCH IN BACTERIAL INFECTIONS
Formerly, ICMR-National Institute of Cholera and Enteric Diseases (ICMR-NICED)
स्वास्थ्य अनुसंधान विभाग, स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार
Department of Health Research, Ministry of Health & Family Welfare, Govt. of India

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WHO COLLABORATING CENTRE FOR RESEARCH AND TRAINING ON DIARRHOEAL DISEASES

Date – 08/08/2024

Ref. No. – NIRBI/S&P/Upscaling Project/3rd Party Validation/1/24-25

TENDER ENQUIRY

Quotations are hereby invited on behalf of the Director, ICMR-NIRBI, Kolkata-700010 for **Objective-1 of Third Party Validation Service for Vaccine Development** for ICMR-Ad Hoc Project entitled "Upscaling and third-party validation of newly developed bacterial ghost-based vaccine formulation against typhoid and paratyphoid fever" (Short Title : Upscaling Project) in ICMR-NIRBI.

General Term and Condition of the Tender –

1. The tender will be governed by the rules and regulations laid by ICMR and Government of India.
2. The Director, ICMR-NIRBI, is the competent authority to take any decision regarding this tender. Any decision taken by the Competent Authority is final and binding on every party.
3. The Director, ICMR-NIRBI reserves the right to accept or reject any quotations without providing subsequent justification to any party.
4. The supplied product/rendered service must be certified as 'Satisfactory' by the end user before payment request is raised by the bidder.
5. The supplied product/rendered service must meet specification and quality mentioned in the bid document.
6. The supplied product/rendered service must be delivered within stipulated timeline as per specification.
7. Contact ICMR-NIRBI via email: storeniced1@gmail.com or visit in-person at ICMR-NIRBI, P-33, C.I.T. Road, Scheme-XM, Beliaghata, Kolkata-700010 on any working day (Mon-Fri, except Govt. Holiday) from 10.30 AM to 05.30 PM for further query.



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पी-33, सी.आई.टी. रोड, स्किम - XM, बेलियाघाटा, कोलकाता - 700 010, पश्चिम बंगाल, भारत

P-33, C.I.T. Road, Scheme - XM, Beliaghata, Kolkata - 700 010, West Bengal, India



+91-33-2363 3373 (निदेशक/Director), +91-33-2370 1176, 5533 (प्रशासन/Administration)



www.niced.org.in

SCOPE OF WORK

Sl. No.	Objective	Detailed Workflow
1	Preparation of Non-GMP materials (Ghost based immunogen) for stability and toxicological studies	<p>Step 1: <u>Preparation of Non-GMP materials (Ghost based immunogen)</u></p> <p>Chemicals and reagents needed for preparation of bacterial ghost, evaluation of formation of bacterial ghost, estimation and quantification of bacterial ghost</p> <p>Step 2: <u>Stability Study</u></p> <p>Proteomic analysis, proteomic profiling of the immunogen at different conditions, analysis of stability related parameters</p> <p>Step 3: <u>Toxicological Study</u></p> <p>In-vitro analysis (kit based) and in-vivo analysis of toxicological parameters</p>
** Refer to Point no. 2 of T&Cs for Time Limit For Each Stage of the Scope of Work		

BID ESTIMATED VALUE

Sl. No.	Objective	Detailed Workflow	Estimated Cost
1	Preparation of Non-GMP materials (Ghost based immunogen) for stability and toxicological studies	Step 1: Preparation of Non-GMP materials (Ghost based immunogen)	Rs. 500000.00
		Step 2: Stability Study	Rs. 500000.00
		Step 3: Toxicological Study	Rs. 500000.00
		Total	Rs. 1500000.00

SUBMISSION OF BIDS

1. Bids to be submitted on or before 23.08.2024 in the Tender Box installed on 1st Floor, NICED-I Building, ICMR-NIRBI, P-33, C.I.T. Road, Scheme-XM, Beliaghata, Kolkata – 700010 in person or by registered post.
2. If the Vendor is not under exempted category for submission of EMD as per Govt. rules, EMD at the rate of 3% of quoted price must be submitted along with the required bid documents. EMD will be released after completion and finalization of Tender process.
 - a. The EMD will be in the Name of The Director, ICMR-NIRBI, Kolkata-700010 in form of Demand Draft/FD.
3. Bid Security Deposit must be submitted by the selected vendor at the rate of 3% of quoted price for Duration of Contract + 1 Month.
 - a. The Bid Security Deposit will be in name of The Director, ICMR-NIRBI, Kolkata-700010 in the form of Demand Draft/FD.

TERM AND CONDITION

1. A single company can take responsibility of entire Scope of Work. Sub-contract or formation of consortium with other companies is allowed. Undertaking from all collaborators in this regard must be submitted by the bidder, failing which the bid application will be rejected.
2. Time Bound Outcome is required. It is expected to complete parts of the Scope of Work as mentioned in the following table –

Sl. No.	Objective	Timeline for Job Completion
1	Preparation of Non-GMP materials (Ghost based immunogen) for stability and toxicological studies	0 month to 6 months

3. Bidder and/or collaborators must submit the following Certifications in their application –
 - a. R&D (DCGI or DSIR – Government of India) accreditation for outsourcing company
 - b. CCSEA certification
 - c. License for conducting Clinical Trial in India
4. The bidder and/or collaborator must have required Experience Criteria as stated below –
 - a. Minimum 5 years' experience on GMP manufacturing in the field of Vaccine Research
 - b. Minimum 5 years' experience on preclinical Animal Study
 - c. Minimum 5 years' experience on Conducting Clinical Trial in India

The bidder must provide certificate, document and licenses in this regard to be qualified on the basis required experience criteria.

5. Payment Terms and Price Breakup –

- a. The bidder must accept the term and condition of payment as per ICMR guideline.
- b. Payment will be released in parts as per outlined in Scope of Work after completion of the work.
- c. No extra payment will be released by ICMR outside the Scope of Work in any condition.
- d. Bidder must submit price breakup in the format given in Annexure-I of the bid document.
- e. Tax/Cess/Surcharge are subject to provision laid by Government of India. All quoted prices must be inclusive of Tax/Cess/Surcharge.

6. The bidder must provide details of their Infrastructural Strength including the information sought the following list -

- a. Manufacturing Facilities
- b. Personnel and Expertise
- c. Documentation and Records
- d. Risk Mitigation
- e. Compliance with Regulatory Standards
- f. Validation Protocols Communication and Support Matrix

7. Additional Documents to be provide by bidder:

- a. GST registration
- b. Declaration of Non-Liquidation Status of Company
- c. Bidder Annual Turnover

8. The bidder must not be undergoing any Criminal Investigation by Govt. of India or any State Govt. agencies. The bidder must not be under trial for misconduct/breach of contract/malpractice in Medical Research Field. Undertaking in this regard is to submitted along with bid documents.

9. If addition/modification of any part of existing bid document is required, the same will be published as Corrigendum of the Bid on official website of ICMR-NIRBI, i.e., <https://www.niced.org.in/> . The vendors are requested to check relevant sites regularly for updates.

Annexure-I

Price Breakup for First Objective of Third-Party Validation Service

Objective	Scope Of Work	Price (before tax)	Tax	Total
Preparation of Non-GMP materials (Ghost based immunogen) for stability and toxicological studies	Step 1: Preparation of Non-GMP materials			
	Step 2: Stability Study			
	Step 3: Toxicological Study			
	Total			

We hereby declare that no additional charge will be admissible apart from the amount that has been provided in the abovementioned price breakup. Only in the instance of modification in existing tax structure, amount paid towards tax will be adjusted as per revised rates.

Sign and Stamp of the Bidder

Date-

Place-

** please mention the applicable rate of taxes in the 'Tax' column



Sr. Admin. Officer



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_____ End of Bid Document _____