

BRIC-Translational Health Science and Technology Institute

(An institute of the Biotechnology Research and Innovation Council,
Department of Biotechnology, Ministry of Science and Technology, Govt. of India)

Request for Expression of Interest (REOI)

FOR

**Development of a novel monoclonal antibody: Process development and GMP manufacturing
of drug substance and drug product for Investigational New Drug**

‘REOI’ document can be downloaded from following websites:

www.thsti.res.in

www.eprocure.gov.in/epublish/app

(REOI No: THSTI/S&P/REOI/02/25-26)

Dated: 20/08/2025

REQUEST FOR EXPRESSION OF INTEREST

Subject: Expression of Interest for Development of a novel monoclonal antibody: Process development and GMP manufacturing of drug substance and drug product for Investigational New Drug.

BRIC-Translational Health Science and Technology Institute (BRIC-THSTI) Faridabad (herein after referred as 'the Institute' or 'THSTI') is an institute of the Biotechnology Research and Innovation Council (BRIC), Department of Biotechnology, Ministry of Science and Technology, Government of India.

The Executive Director of BRIC-THSTI invites Expression of Interest (EOI) from interested agencies/firms that meet the eligibility criteria as outlined in the REOI document.

Schedule for the Request for Expression of Interest:

Date of Publication	:	20/08/2025 at 1500 Hrs.
Date and Time for Pre-EOI Meeting	:	27/08/2025 at 1100 Hrs.
Last date for receipt of queries from the bidders (if any)	:	27/08/2025 at 1800 Hrs.
Last date to notify the amendments in the EOI	:	01/09/2025 at 1800 Hrs.
Start date and time of submission of EOI	:	02/09/2025 at 1100 Hrs.
Last Date and Time for submission of EOI	:	10/09/2025 at 1100 Hrs.
Date and Time of Opening of EOI	:	10/09/2025 at 15:30 Hrs.
Estimated Value of works	:	1000 Lakhs
Earnest Money Deposit (EMD)	:	₹ 20,00,000/-
EOI Validity	:	120 days from the date of opening.

Note:

- In case, the last date of receipt of EOIs and/or the day of opening of EOIs is declared as a Public Holiday or there is non- functioning of the institute due to any unavoidable reason, the next working day will be treated as the last date of receipt of EOIs and/or the day of opening of EOIs. The time will remain the same. No separate intimation will be given in this connection.

- ii. Kindly note that only offline submission of EOI will be considered against this REOI. Requests for extension of date and time for submission will not be entertained. The Executive Director, THSTI reserves the right to accept/ reject any or all EOI either in part or in full without assigning any reasons thereof.
- iii. The EMD mentioned above should be deposited with THSTI at the time of submitting the EoI in the form of DD/TDR in favour of THSTI payable at Faridabad or by online mode through payment gateway link available at <https://thsti.res.in/en/Tender> . For bidders who are found to be ineligible on scrutiny, the EMD amount will be returned within 30 days after publication of the result of EOI assessment process.
- iv. In case of any clarification with regard to submission of EOIs, please contact to Sh. Manoj Kumar, Section Officer (S&P) (Tel: 0129-2876300/437) manoj.kumar@thsti.res.in and purchase@thsti.res.in
- v. Interested bidders should submit their EOI in the prescribed format to the following address in hard copy:

To,
Sh. V. S. Rao,
Administrative Officer (S&P),
BRIC-Translational Health Science and Technology Institute (THSTI)
Dept. of Biotechnology, Govt. of India,
NCR Biotech Science Cluster,
3rd Milestone, Faridabad–Gurugram Expressway,
Faridabad- 121001 (Haryana)

Sd/-
AO (S&P)
THSTI, Faridabad

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1. Background:

BRIC-THSTI has developed a novel human monoclonal antibody (mAb) with the potential to function as a therapeutic drug against pathogenic organisms of interest. The mAb has been developed to Research Cell Bank (RCB) stage and is now ready for progression into GMP-compliant manufacturing for Investigational New Drug (IND), preclinical safety assessment, and early-phase human trials. Presently, BRIC-THSTI is interested in process development and GMP-compliant manufacturing for IND filing.

2. Scope of Work:

- i. Generate and characterize Master Cell Bank (~200 vials) using the provided RCB in a GMP-compliant facility.
- ii. Establish consistent, scalable and regulatory compliant mAb manufacturing process for Drug Substance and Drug Product suitable for IND filing in India and globally.
- iii. Develop and qualify analytical methods for batch release and characterization.
- iv. Manufacture and supply drug substance for preclinical studies (at ~20L scale).
- v. Manufacture and supply drug substance (at ~100L scale) and drug product (~1000 vials) under GMP for Phase-I clinical trial.
- vi. Analytical and stability studies, and product characterization.
- vii. Viral clearance study.

Note: Some variation in scales or quantities is possible, based on requirements of preclinical and clinical studies, or available scales at the bidder's facility. Further details will be provided in the RFP document.

3. Expected Outcomes: The expected outcomes from the current phase of the mAb development are:

- i. Well characterized Master Cell Bank.
- ii. Robust, scalable, and regulatory-compliant mAb manufacturing process.
- iii. Drug substance and drug product for preclinical and phase-I clinical trial.
- iv. CMC data required for IND filing in India and globally in different jurisdictions.

4. Project Duration:

- i. The entire work should be completed within twelve months of releasing the work order.
- ii. The entire documentation and testing reports should be submitted within the project duration.
- iii. Training to the identified group of users in BRIC-THSTI also to be provided within the project duration.

5. Role of BRIC-THSTI & Bidder

- i. **Role of BRIC-THSTI:** -BRIC-THSTI shall provide the RCB expressing the mAb of interest. BRIC-THSTI will also provide critical reagents required for binding assay as part of batch release.

ii. **Role of Bidder:**

- A. Bidder shall be responsible for all deliverables under scope.
- B. The following activities as mentioned in para 2 above must be undertaken at the bidder's facility;
 - B.1 Generate Master Cell Bank (~200 vials) using the provided RCB in a GMP-compliant facility.
 - B.2 Establish consistent, scalable and regulatory compliant mAb manufacturing process for Drug Substance and Drug Product suitable for IND filing in India and globally.
 - B.3 Develop and qualify analytical methods for batch release and characterization.
 - B.4 Manufacture, and supply drug substance for preclinical studies (at ~20L scale).
 - B.5 Manufacture drug substance (at ~100L scale) under GMP for Phase-I clinical trial
 - B.6 Analytical and stability studies, and product characterization.
- C. The following activities as mentioned in para 2 above may be subcontracted to a suitable third party with approval of THSTI;
 - C.1 Characterize Master Cell Bank.
 - C.2 Manufacture and supply drug product (~1000 vials) under GMP for Phase-I clinical trial).
 - C.3 Analytical product characterization (specialized tests only)
 - C.4 Viral clearance study.
- D. Bidder shall be responsible for obtaining relevant regulatory approvals for carrying out the work falling in their scope.

6. Eligibility Criteria:

The following will be the Pre-Qualification Criteria (PQC).

S. No	Pre-Qualification Criteria	Supporting copy of documents required
1.	The bidder shall be a legal entity, registered as a company under respective acts in India.	Registration of firm /organization/Company Incorporation Certificate from Registrar of Companies (ROC) /Partnership deed etc. whichever is applicable.
2.	The bidder must be registered in India with taxation and other administrative authorities.	GST Registration and PAN Card.
3.	The bidder should have provided process development and GMP manufacturing services to at least two (2) industry partners in India/overseas and have infrastructure capability and adequate resources to execute the scope of work.	Appropriate proof (summary of max 2 pages of text) indicating experience, number of similar projects handled, infrastructure and capabilities, and any regulatory approvals for the facilities to be used. The detailed capabilities, case studies etc. not to be provided at this stage but will be requested at the time of final proposal submission during RFP stage.

4.	The bidder should not have incurred overall loss in the past three (3) years. (applicable on commercial firms/organizations only)	Certificate from the Chartered Accountant of the Organization/ Audited Balance sheets for last three financial years or Income Tax return.
5.	The bidder should have good track-record and currently not be black-listed/ barred by any Central / State Government/ Public Sector Undertaking, Govt. of India, (applicable on commercial firms/organizations only)	Undertaking on the Letterhead of the bidder duly signed & Stamped by Authorized Signatory.
6.	The bidder should not be involved in any major litigation that may have an impact of affecting or compromising the conditions required under this EoI.	Undertaking on bidder's Letterhead, duly signed and stamped by the Authorized Signatory.

7. Terms and Conditions:

- i. The bidder is required to submit a copy of this REOI document, with all pages signed by the authorized person, to confirm that bidder has read and understood the conditions of this REOI document and that the proposal is submitted in full understanding and agreement of the requirements of BRIC-THSTI.
- ii. The complete EOI shall be without alteration or erasures, except those to accord with instructions issued by the BRIC-THSTI or as necessary to correct errors made by the bidder, in which case, such corrections shall be initialled by the person or persons signing the EOI.
- iii. Wherever a specific form is prescribed in the REOI document, the bidder shall use the form to provide relevant information. If the form does not provide space for any required information, space at the end of the form or additional sheets shall be used to convey the said information. For all other cases, the bidder shall design a suitable format to hold the required information.
- iv. BRIC-THSTI reserves the right to call for any clarifications confined in the broad scope, wherever such a clarifications become necessary for proper judgment in evaluation.
- v. The details related to payment terms, IPR and extra items will be outlined in the forthcoming RFP document.

8. Default or failure: In the event of the occurrence of any of the following, including but not limited to the circumstances listed below, the same shall constitute a good and sufficient reason for initiating action for default and/or failure:

- i. If the bidder is incapable of carrying out the work.
- ii. If the bidder misconducts in any manner.

- iii. If there is any change in the constitution of the bidder (if a firm) or in the circumstances or organization of the bidder, which is detrimental to the interests of BRIC-THSTI.
- iv. Dissolution of the bidder (If a firm or commencement of liquidation) or winding up (whether voluntary or compulsory) of the bidder (if a company or appointment of a receiver or Manager of any of the bidder 's assets and / or insolvency or the bidder (if a sole proprietorship) or of any partner of the bidder (if a firm).
- v. Distress, execution, or other legal process being levied on or upon any of the bidders goods and /or assets.
- vi. Death of bidder (if an individual).
- vii. If the bidder or any person employed or engaged by him shall make or offer for any purpose connected with the contract any gift, gratuity, royalty, commission, gratification or other inducement (whether money or in any other form) to any employee or agent of BRIC-THSTI.

9. Termination: BRIC-THSTI may terminate the contract at any time by written notice, without affecting its right to claim damages for delay, poor work, bad workmanship, or any other breach of the contract.

10. Arbitration: Any claim, dispute or difference arising out of or in connection with this REOI and the subsequent RFP and which cannot be settled by mutual consultations, shall be referred to sole Arbitration or an Arbitrator to be appointed by mutual consultations. The award of the Arbitrator shall be final and binding between the parties as per the terms and conditions of the Agreement to be executed on award of contract. The Arbitration proceeding shall be governed by the Arbitration and Conciliation Act,1996 and the seat of arbitration shall be Haryana.

11. Jurisdiction of Dispute: All dispute(s) under this REOI shall be subject to the jurisdiction of Punjab and Haryana High Court.

12. Terms not expressly provided for: In case this REOI document does not contain provisions or terms for dealing with a situation that may arise during the execution of the works, the relevant provisions contained in the General Financial Rule 2017 or other relevant rules of the Govt. of India shall be followed and the same will be binding on the bidder.

13. Assessment Process:

- i. All EOI documents must be submitted and received by BRIC-THSTI on or before the due date specified in the REOI.
- ii. The EOIs will be evaluated strictly as per the pre-qualification criteria outlined in the REOI document.
- iii. BRIC-THSTI reserves the right to conduct a physical inspection of the bidders' facilities to assess infrastructure, technical capabilities, and compliance with stated claims. THSTI may also conduct a physical inspection of the proposed third parties for any of the subcontracted activities mentioned in Para 5 above. .
- iv. All applicants will be formally notified of the outcome of the assessment process.

Note: During the RFP stage the proposers will be required to submit their proposal through GeM portal providing complete technical details on capabilities, work plan, and financial quote. The interested organizations/facilities are, therefore, advised to take note of this requirement and initiate the necessary steps to ensure timely registration on the GeM portal, if not already registered. The bidders must complete their registration process, update their profiles, and comply with all eligibility requirements stipulated by GeM in order to be able to view, download, and submit their proposal against the forthcoming RFP.

14. Authorized Signatory: The ‘Applicant’ mentioned in the REOI document shall mean the one who has signed the EOI document forms. The applicant should be the Head of the laboratory/institution/organization or a duly Authorized Representative, for which a Certificate of Authority shall be submitted. All certificates and documents (including any clarifications sought and any subsequent correspondence) submitted thereby, as far as possible, shall be furnished and signed by the Authorized Representative.

15. Documents to accompany EOI: The following documents are to be submitted with the EOI, in the format of which is provided as enclosed to this REOI:

S. No.	Name of the Document	Attachment No.
I.	Cover letter of EOI Submission	1
II.	General Information sheet of the bidder.	2
III.	Authorization Letter.	3
IV.	Undertaking with regard to laboratory facility.	4
V.	Financial information and solvency certificate.	5
VI.	Technical capabilities.	6
VII.	Undertaking with regard to blacklisting.	7
VIII.	Undertaking with regard to non-litigation.	8
IX.	EoI document with each page duly stamped and signed by the Authorized signatory.	9
X.	Copy of MSME certificate (if applicable).	10
XI.	Copy of cancelled cheque.	11
XII.	Any other information which bidder may like to provide.	12

16. Rejection of EOI:

The EOI is liable to be rejected if:

- i. The proposal is not submitted as per the requirements indicated in the EOI.
- ii. Including the financial bid/quotation along with EOI.
- iii. Not in the prescribed format.
- iv. Not properly stamped and signed as per requirements.
- v. Received after the expiry of due date and time.
- vi. Joint ventures/consortia are not allowed to submit EOI.
- vii. All relevant supporting documents are not furnished with the PQC.
- viii. The proposal shall be substantially responsive without any material deviation.
- ix. Applications not fulfilling the terms of the document will be summarily rejected.
- x. Any other non-compliance.

17. Format of Technical bid including Organizational capability:

ATTACHMENT #1

COVER LETTER OF EOI SUBMISSION

[Location, Date]

To: [Name and address of Employer]

Dear Sir(s):

We, the undersigned, offer to provide the work /job for [Insert title of Assignment/job] in accordance with your REOI dated [Insert Date]..

We hereby declare that all the information and statements made in this EOI are true and accept that any misinterpretation contained in it may lead to our disqualification.

Our EOI is binding upon us and subject to the modifications resulting from Technical discussions.

We understand you are not bound to accept any Proposal you receive.

Name of Firm
Authorized Signature [In full and initials]
Name and Title of Signatory
Address

ATTACHMENT #2

General Information sheet of the Bidder/Company

1.	Name of bidder	
2.	Address	
3.	Telephone Number	
4.	Fax Number	
5.	Email	
6.	Web Site	
7.	Legal status i. Government/ Public Sector Undertaking. ii. Propriety firm. iii. Partnership firm (if yes, give partnership deed). iv. Limited company or limited corporation. v. Member of a group of companies (if yes, give name and address, and description of other companies) . vi. Subsidiary of a large corporation (if yes give the name and address of the parent organization) If the company is subsidiary, state what involvement if any, will the parent company have in the project.	
8.	Is the firm a registered company? If yes, submit Documentary proof date of establishment.	
9.	Correspondence Address: Name Address E-mail Phone Fax	
10.	Submit valid GST registration certificate.	
11.	Income Tax PAN Card.	
12.	Is the firm registered under Labour Laws Contract Act? If yes, submit valid registration certificate.	
13.	Number of years of experience in the relevant field? Submit documentary evidence.	
14.	Number of Offices / Project Locations.	
15.	List the major clients with whom your organization has been/ is currently associated.	

16.	Have bidder/ its sister concern ever been blacklisted by any govt. or quasi govt. /PSU in India during the last five years. Necessary declaration to be submitted along with the technical bid.	
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Seal and Signature of Bidder

ATTACHMENT #3

**Authorization Letter
(To be submitted on Facility's Letterhead)**

To,
Executive Director
Translational Health Science and Technology Institute
NCR Biotech Science Cluster, 3rd Milestone,
Faridabad-Gurgaon Expressway, Faridabad

Subject: Letter for Authorized Signatory
Ref: EoI No. THSTI/EoI/..... /202X dated.....

Sir,
This has reference to your above-mentioned Expression of Interest (EoI) for Development of a novel monoclonal antibody: Process development and GMP manufacturing of drug substance and drug product for Investigational New Drug.

Mr./Ms./Mrs./Dr is hereby authorized to submit the EoI documents and participate in the processing on behalf of M/s..... (Laboratory/Facility Name), whose signature is below.

(Specimen Signature of Representative)
Date:
Place:

Yours faithfully,

(Signature of the Authorized signatory)
Name:
Designation:
Seal:
Place:

ATTACHMENT #4

Undertaking with regard to laboratory facility (To be submitted on facility's Letterhead)

To,
Executive Director
Translational Health Science and Technology Institute
NCR Biotech Science Cluster, 3rd Milestone,
Faridabad-Gurgaon Expressway, Faridabad

Subject: Undertaking regarding laboratory infrastructure.
Ref: THSTI/EoI/.....dated.....

Sir,

It is hereby confirmed and declared that under the scope of work for 'Development of a novel monoclonal antibody: Process development and GMP manufacturing of drug substance and drug product for Investigational New Drug', M/s (Laboratory/Facility Name) does have

- i. Adequate laboratory infrastructure and
- ii. Adequate no. of experienced staff/skilled manpower for completion of the scope of work.

However, scope of work under the modules stated below would be outsourced to the agencies mentioned.

Module X: _____ (outsourced to XXXXX.)

Module Y: _____ (outsourced to YYYYY.)

Yours faithfully,

(Signature of the Authorized signatory)

Name:

Designation:

Seal:

Place:

ATTACHMENT # 5

FINANCIAL INFORMATION AND SOLVENCY CERTIFICATE

S. No	Name of the bidder	Turnover (Rs. Crores)			Net worth (Rs. Crores)
		2021-22	2022-23	2023-24	2023-24

Note:

- 1 Submit the audited financial statement/ audited annual report of the last three financial years.
- 2 The bidders should submit the solvency certificate indicating an amount equal to or not less than 40% of the advertised value of this REOI. Copy of Fresh Solvency Certificate issued by any scheduled Bank is required to be submitted. The date of solvency certificate issued by bank should not be prior to 03 months from the date of submission of bid.

ATTACHMENT # 6

FORMAT FOR TECHNICAL CAPABILITY

Please provide a summary of technical capabilities max 2 pages of text indicating experience, number of similar projects handled, projects done for international clients for submission in India/overseas, infrastructure and capabilities, and any regulatory approvals for the facilities to be used. Detailed capabilities, case studies etc. not to be provided at this stage, but will be requested at the time of final proposal submission.

If certain modules are to be subcontracted to third parties, please provide summary descriptions of the capabilities and credentials of the third parties. This information may be provided with 1-2 paragraphs (max 1 page) of information per subcontracted party.

ATTACHMENT # 7

**Undertaking with regard to Blacklisting
Declaration Letter
(to be printed in Letterhead)**

To, Executive Director
Translational Health Science and Technology Institute
NCR Biotech Science Cluster, 3rd Milestone,
Faridabad-Gurgaon Expressway, Faridabad

Dear Sir,

We hereby confirm and declare that we, M/s is not blacklisted/..... De-registered/ debarred by any Government department/ Public Sector Undertaking/ Private Sector/ or any other agency for which we have Executed/ Undertaken the works/ Services during the last 5 years.

For -----

Authorized Signatory
Date:

ATTACHMENT # 8

Undertaking with regard to Non-Litigation Declaration Letter (to be printed in Letterhead)

Sir/Madam,

This is to notify you that our Company/LLP/Partnership/Society/Proprietorship < Please delete whichever is not applicable> intends to submit a proposal in response to , we also declare that our Company/LLP/Partnership/Society/Proprietorship has during the last three years, neither failed to perform on any agreement, nor has been evidenced by imposition of a penalty by an arbitral or judicial authority or a judicial pronouncement or arbitration award, nor been expelled from any project or agreement nor have had any agreement terminated for breach by us.

Sincerely,

(Signature of the Authorized Person)

Name:
Designation:

ATTACHMENT # 9

EoI Document with each page duly stamped and signed by the authorized signatory.

ATTACHMENT # 10

Copy of MSME Certificate (if applicable)

ATTACHMENT # 11

Copy of cancelled cheque.

ATTACHMENT # 12

Any other information which bidder may like to provide.

End of the Document

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