

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

**Joint Operation of a Healthy-Volunteer Phase I Clinical Trial Unit at Medical
Research Centre (MRC)**

(REOI No: THSTI/S&P/REOI/06/26-27)

Dated: 01st October, 2026

'REOI' document can be downloaded from the following websites:

www.thsti.res.in

www.eprocure.gov.in/epublish/app

REQUEST FOR EXPRESSION OF INTEREST

for

Joint Operation of a Healthy-Volunteer Phase I Clinical Trial Unit at Medical Research Centre (MRC)

BRIC-Translational Health Science and Technology Institute (BRIC-THSTI), Faridabad (hereinafter referred to 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	01/10/2026 at 4:00 PM
Date and Time for Inspection of Facility	05/10/2026 to 09/10/2026 from 11:00 AM to 4:00 PM
Date and Time of Pre-EOI Meeting	13/10/2026 at 11:00 AM
Last date for receipt of queries from the bidders (if any)	16/10/2026 at 5:00 PM
Last date to notify the amendments in the EOI	19/10/2026 at 6:00 PM
Last Date and Time for submission of EOI	04/11/2026 at 11:00 AM
Date and Time of Opening of EOI	04/11/2026 at 11:30 AM
Estimated Value of Investment	Rs. 4.50 Crores
Earnest Money Deposit (EMD)	Rs. 9.00 Lakh
EOI Validity	120 days from the date of opening.

Note:

- i. **Submission of any financial bid, price quotation, commercial offer, or indicative pricing along with the EoI document shall render the EoI liable for rejection. Bidders are strictly advised not to include any financial information in their EoI submissions. The required financial bids shall be invited only at the Request for Proposal (RFP) stage.**
- ii. In case the last date of receipt of EOIs and/or the day of opening of EOIs is declared 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.

- iii. 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 EOIs, either in part or in full, without assigning any reasons thereof.
- iv. 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 the 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 the EOI assessment process.
- v. 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
- vi. Interested bidders should submit their EOI in the prescribed format, **in hard copy**, to the following address:

**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 of Collaboration

BRIC-THSTI has established, at its Medical Research Centre (MRC), the core physical infrastructure and key equipment required for a Phase I clinical research facility. BRIC-THSTI now wishes to operationalise this facility into a CDSCO/ICMR-compliant, inspection-ready Healthy Volunteer Phase I Clinical Unit with full early-phase clinical trial capability. This requires BRIC-THSTI to establish quality systems, approved procedures, validated processes, regulatory-ready documentation, trained personnel, and governance frameworks that it does not presently possess in-house.

BRIC-THSTI is therefore inviting Expression of Interest from a partner with proven early-phase clinical trial operations, quality, and regulatory expertise, to accelerate this readiness and to help establish best-in-class standards aligned with CDSCO/ICMR requirements, ICH-GCP, and data integrity principles. The end state envisaged is a fully operational, inspection-ready Phase I Clinical Research Unit capable of running healthy-volunteer and early-phase studies under a harmonised BRIC-THSTI–collaborator operating framework, and of serving as a platform for programmes from both organisations as well as other academic and industry partners.

A Joint Steering Committee (JSC), comprising representatives of both BRIC-THSTI and the selected collaborator, shall be established to provide strategic oversight of the partnership, facilitate the transfer of information between the Parties, and ensure the successful completion of the milestones set out at Section 2 below, within the agreed time period.

2. Scope of Work and Timeline

Activities from 1 – 9 are to be completed within twelve (12) months of signing the governance documents. The months shown are indicative.

S.No	Activity	Month	Lead
1.	Governance: sign governance documents, form the JSC, appoint the Project Lead and approve the RACI matrix	0–1	Joint
2.	Regulatory Readiness assessment: facility and floor plan, statutory/regulatory/EHS requirements, QMS, SOPs, equipment and systems	1–3	Joint
3.	Quality Management System: quality manual, policies, master SOPs, document control, training, deviation/CAPA and change control	2–5	Joint
4.	Facility readiness: zoning, workflow, signage, access control, CCTV, temperature mapping and emergency systems	2–6	Joint

	Qualification: calibration, URS/DQ/IQ/OQ/PQ of equipment, and computerised system validation (CSV)/21 CFR Part 11 assessment	3–8	Joint
6.	Training and mock operations: GCP and SOP training, mock drills, mock pharmacy and sample handling	6–9	Joint
7.	Regulatory dossier: compile and submit to CDSCO	6–9	BRIC-THSTI; collaborator advises
8.	Inspection readiness: internal audit, mock inspection by a third-party audit and CAPA closure	6–10	Joint; Cost for audit borne by THSTI
9.	Pilot study: feasibility, protocol-specific plans, site initiation and go/no-go decision	10–12	Joint; collaborator recommends go-live
10.	Onboard clients requiring First-in-Human (FIH) studies and perform clinical trials at the facility.	13-36	Joint

3. Roles and Responsibilities

Area	BRIC-THSTI	Collaborator
Facility	Owns and provides the clinical, pharmacy, laboratory and support spaces; controls access, security and maintenance.	Advises on workflow and facility readiness.
Costs	Bears capital expenditure, Bears Operation costs - Facility qualification, maintenance, utilities, regulatory fees Cost for conducting the clinical trials will be borne by the sponsor of the concerned study.	Bears the cost of its seconded personnel and of the support it provides. Analytical studies will be outsourced.

Personnel	Provides staff to be trained and to take over operations.	Seconds, at its own cost, qualified staff for: • Operations Manager • QA Manager • Pharmacist • Engineering and Maintenance Engineer • Project Coordinator • Manager - CSV • Nurse
Quality system	Approves the quality manual, SOPs and controlled documents through the JSC, and holds quality oversight.	Co-authors the QMS, SOPs, deviation/CAPA processes, RACI matrix and escalation pathways.
Qualification and data integrity	Owens data governance, privacy compliance and records retention.	Leads the qualification strategy (URS/DQ/IQ/OQ/PQ), CSV/Part 11 and data-integrity requirements; reviews qualification documents.
Regulatory	Applies for, obtains and holds all licences and permissions, including from CDSCO; compiles and submits the dossier.	Provides regulatory strategy, dossier review, gap assessment, mock inspection and the go-live recommendation.
Clinical operations	Owens pharmacy, volunteer registry and recruitment, medical oversight, emergency preparedness, participant safety and laboratory operations.	Supports these functions through its seconded staff, working under BRIC-THSTI SOPs.
Training	Nominates staff for training.	Develops the curriculum and competency requirements, and delivers training.
Governance	Nominates JSC members.	Nominates JSC members.
Intellectual property	Each Party retains its pre-existing IP. Ownership of jointly generated IP will be decided case by case, in good faith, in the Definitive Agreement.	

4. Commercial Model

BRIC-THSTI shall compensate the Collaborator under a revenue-sharing model. The activities that may be undertaken, together with their respective funding arrangements and modes of payment, are set out below:

Nature of Activity	Funding Details and Mode of Payment
Trial initiated by the Institution for its own purposes	Funded by BRIC-THSTI
Trial initiated by the Institution for a third-party client	Payment received from the third-party client, routed through BRIC-THSTI
Trial initiated by the Collaborator for its own purposes	Funded by the Collaborator
Trial initiated by the Collaborator for a third-party client	Payment received from the third-party client, routed through BRIC-THSTI
Trial undertaken jointly by the Institution and the Collaborator	Jointly funded, routed through BRIC-THSTI

In all of the above cases, invoicing shall be raised in the name of BRIC-THSTI, as ownership of the facility vests with the Institution. The cost equivalent of the activity shall be advanced or paid, as the case may be, to the Collaborator within fifteen (15) days.

User charges shall be apportioned broadly in proportion to the respective investments, as determined and submitted during the RFP process, and may be revised annually on a mutually agreed basis. Differential pricing may be adopted for government, academic, and industrial sponsors.

5. Assessment Process

- i. EOIs shall be evaluated strictly in accordance with the pre-qualification criteria stipulated in the REOI document.
- ii. Bidders satisfying the pre-qualification criteria shall be shortlisted for the subsequent RFP stage and duly notified accordingly.
- iii. The RFP shall be finalized based on the QCBS (Quality and Cost Based Selection) system, wherein the techno-commercial evaluation shall be conducted through a marking system based on the following metrics:

S.No	Parameter of evaluation and scoring basis
A. First-in-Human (FIH) experience of the collaborator	
A1	Number of qualifying FIH trials completed in the last ten years
A2	Scope and complexity of qualifying FIH trials (i) integrated SAD/MAD design with sentinel dosing and data-driven dose escalation decided by a Safety Review Committee; (ii) FIH of a biological product, monoclonal antibody or vaccine; (iii) FIH of a novel modality (e.g., antibody-drug conjugate, oligonucleotide, peptide, cell or gene therapy) or of an IMP with identified high-risk factors; (iv) integrated/adaptive FIH protocol (e.g., SAD, MAD and food-effect parts in a single protocol); (v) on-site IMP preparation/dose compounding and blinding by the unit pharmacy; (vi) FIH trial conducted in India under CDSCO Form CT-06 permission.
B. Phase I unit establishment and regulatory track record	

B1	Phase I units/CRUs established, operationalised or supported to inspection readiness by the collaborator, for itself or for a partner, in the last ten (10) years
B2	Regulatory inspections of the collaborator's Phase I/FIH operations (CDSCO, US FDA, EMA/EU national authority, MHRA, TGA, WHO or equivalent) closed without critical findings in the last seven (7) years. Inspections limited to BA/BE scope shall not be counted:
C. Revenue sharing model	
C2	Profit sharing model (provide as ratio) 1. Trial initiated by the Institution for its own purposes 2. Trial initiated by the Institution for a third-party client 3. Trial initiated by the Collaborator for its own purposes 4. Trial initiated by the Collaborator for a third-party client 5. Trial undertaken jointly by the Institution and the Collaborator
D. Phase I quality systems and safety infrastructure at the collaborator's site	
D1	Phase I-specific SOPs in current use (list of SOP titles and effective dates only): dose escalation and Safety Review Committee; sentinel dosing; medical emergency and resuscitation; FIH IMP handling; prevention of over-volunteering (volunteer database/wash-out checks); 24-hour medical cover and stopping rules.
D2	Validated computerised systems in use for Phase I operations (eSource/EDC, CTMS, volunteer database, LIMS) with CSV/Part 11 evidence

6. Pre-Qualification Criteria

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

S. No	Pre-Qualification Criteria	Supporting copy of documents required
1.	The collaborator 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 collaborator must be registered in India with taxation and other administrative authorities.	GST Registration and PAN Card.

	The collaborator shall have conducted/or been a part of, within the seven (7) years preceding the last date of submission of EOI, at least two (2) first-in-human (FIH) clinical trials of a new chemical entity or new biological entity (including vaccines) in healthy volunteers, in India and/or overseas, in the role of Clinical Research Unit (CRU) operator and/or of the principal clinical-operations/quality provider to such a unit. Each such trial shall have been conducted under a regulatory permission for a clinical trial (CDSCO permission in Form CT-06 under Rule 22 of the New Drugs and Clinical Trials Rules, 2019; US FDA IND; EU/UK CTA; Australian CTN; or equivalent). Note: Bioavailability/bioequivalence (BA/BE) studies, including studies permitted in Form CT-07 or conducted at a BA/BE study centre registered in Form CT-09 under the said Rules, and pharmacokinetic studies of already-approved molecules or formulations, shall not be counted towards this criterion.	A study-wise declaration for each qualifying FIH trial, supported by: (a) trial registry number (CTRI/ClinicalTrials.gov/EU CT/ISRCTN/ANZCTR), where registered; (b) regulatory permission reference and date; and (c) work order, sponsor certificate or redacted contract confirming the collaborator's role. Sponsor and molecule identities may be redacted provided the registry or permission reference remains verifiable. Summary not to exceed two (2) pages of text; detailed case studies will be requested at the RFP stage. (Attachment #6).
4.	The collaborator should not have incurred overall loss in the past three (3) years (applicable to commercial firms/organizations only).	Certificate from the Chartered Accountant of the Organization/Audited Balance Sheets for the last three financial years or Income Tax returns.
5.	The collaborator should have a good track record and not have been black-listed/de-registered/debarred by any Central/State Government/Public Sector Undertaking, Govt. of India (applicable to commercial firms/organizations only) during the last five (5) years.	Undertaking on the Letterhead of the collaborator, duly signed and stamped by the Authorized Signatory (Attachment #7).

	The collaborator shall not have, in the three (3) years preceding the last date of submission of EOI, any unresolved US FDA Warning Letter or 'Official Action Indicated' classification, CDSCO suspension/cancellation order, or equivalent regulatory action from any national regulatory authority, pertaining to its Phase I/clinical operations.	Undertaking on the collaborator's letterhead, signed and stamped by the Authorized Signatory, listing all regulatory inspections of its Phase I/clinical units in the last five (5) years with their outcome and closure status.
7.	The collaborator 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 the collaborator'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 the 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 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 to the broad scope, wherever such clarifications become necessary for proper judgment in evaluation.

8. Site Visit and Pre-REOI meeting

Bidders are encouraged to submit their EOI after visiting the facility and satisfying themselves as to the site conditions, infrastructure, and other matters considered relevant by them.

By submitting an EOI, the bidder shall be deemed to have made a complete and careful examination of the Bidding Documents, received all relevant information requested from BRIC-THSTI, satisfied itself as to all matters necessary for submitting an informed EOI, and accepted that any inadequacy, lack of completeness, or incorrectness of information provided in the Bidding Documents shall not be a basis for any claim for compensation, damages, or extension of time from BRIC-THSTI, or a ground for termination of the Definitive Agreement by the bidder.

9. Amendment of EOI

Bidders may submit suggestions for changes/modifications to the EOI document. Such suggestions shall be considered at the sole discretion of THSTI and are not binding for incorporation. Amendments to the EOI document, if any, shall be consolidated and issued only once, on the last day specified for amendments, and the amended document shall be published on the THSTI website.

10. Documents to Accompany EOI

The following documents are to be submitted with the EOI, in the formats enclosed with 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 personnel and technical capability	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 the bidder may like to provide.	12.
XIII.	Power of Attorney for signing of EOI.	13.

11. 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 shall, as far as possible, be furnished and signed by the Authorized Representative.

12. 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. **The financial bid/quotation is included along with the EOI.**
- iii. It is not in the prescribed format.
- iv. It is not properly stamped and signed as per requirements.
- v. It is received after the expiry of the 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 is not substantially responsive or contains any material deviation.
- ix. The application does not fulfil the terms of the document (such applications will be summarily rejected).
- x. There is any other non-compliance.

13. Conflict of Interest

A bidder shall not have a Conflict of Interest that affects the EOI process. Any bidder found to have a Conflict of Interest shall be disqualified. A bidder shall be liable for disqualification and forfeiture of its Earnest Money Deposit if any legal, financial, or technical adviser engaged by BRIC-THSTI in relation to this collaboration is engaged by the bidder, its members, or any associate thereof, in any manner, for matters related to or incidental to this collaboration, during the EOI process or subsequent to the issue of the Letter of Award or execution of the Definitive Agreement.

14. Change in Ownership

By submitting an EOI, the bidder acknowledges that it was pre-qualified and shortlisted on the basis of the technical and financial capacity represented in its EOI. In the event of a change in ownership or control of the bidder, the bidder shall be required to inform BRIC-THSTI forthwith, along with all relevant particulars. BRIC-THSTI may, in its sole discretion, disqualify the bidder or withdraw the Letter of Award, as the case may be, and shall be entitled to forfeit the Earnest Money Deposit or Performance Security, as applicable, without prejudice to any other right or remedy available to it.

15. 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 fails to fulfil the obligations under the Scope of Work (Section 2) and the Roles and Responsibilities (Section 3), notwithstanding repeated escalations to remedy such non-performance within the specified timelines.

- ii. 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.
- iii. 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 of the bidder (if a sole proprietorship) or of any partner of the bidder (if a firm).
- iv. Distress, execution, or other legal process being levied on or upon any of the bidder's goods and/or assets.
- v. 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.

16. Termination

BRIC-THSTI may terminate the Definitive Agreement by written notice in accordance with its terms, without prejudice to its right to claim damages for delay in achieving the milestones in Section 2, non-performance of the collaborator's responsibilities under Section 3, or any other breach of the Agreement.

17. 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 consultation, shall be referred to a sole Arbitrator to be appointed by mutual consultation. The award of the Arbitrator shall be final and binding between the parties as per the terms and conditions of the Definitive Agreement to be executed with the selected collaborator. The arbitration proceedings shall be governed by the Arbitration and Conciliation Act, 1996, and the seat of arbitration shall be Faridabad, Haryana.

18. Jurisdiction of Dispute

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

19. 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 EOI process or the implementation of the collaboration, the relevant provisions contained in the General Financial Rules, 2017, or other relevant rules of the Govt. of India shall be followed, and the same will be binding on the bidder.

20. Confidentiality

Information relating to the examination, clarification, evaluation, and recommendation concerning bidders shall not be disclosed to any person not officially concerned with the process.

BRIC-THSTI will treat all information submitted as part of an EOI in confidence and will require all those who have access to such material to treat it likewise. BRIC-THSTI may not divulge any such information unless directed to do so by a statutory entity with the power under law to require its disclosure, or as may be required by law or in connection with a legal process.

21. Disclaimer

All information contained in this REOI document is provided in good faith. Though adequate care has been taken in its preparation, interested agencies shall satisfy themselves that the document is complete in all respects, and the information contained herein is not intended to be exhaustive. Interested bidders are required to make their own enquiries and assessments wherever necessary.

This REOI is not an agreement and is neither an offer nor an invitation by BRIC-THSTI to any prospective bidder or other person. Its purpose is to provide interested parties with information that may assist them in preparing their EOI. BRIC-THSTI, its employees, and advisors make no representation or warranty and accept no liability to any bidder or applicant for any loss, damage, cost, or expense that may arise from or be incurred on account of anything contained in this REOI, including its accuracy, adequacy, completeness, or reliability, or arising in any way from participation in this EOI process.

BRIC-THSTI may, in its absolute discretion, update, amend, or supplement the information contained in this REOI without assigning any reason, and reserves the right to withhold or withdraw the process at any stage, with intimation to those who have submitted an EOI. The issue of this REOI does not bind BRIC-THSTI to select any bidder, and BRIC-THSTI reserves the right to reject all or any of the EOIs without assigning any reason whatsoever.

Information provided in this document or imparted to any respondent as part of the EOI process, is confidential to BRIC-THSTI and shall not be used by the respondent for any purpose other than preparation of its EOI, nor distributed to or shared with any other person or agency.

22. Cost of Bidding

Bidders shall be responsible for all costs associated with the preparation of their EOI and their participation in the EOI process. BRIC-THSTI shall not be responsible or liable for such costs in any manner, regardless of the conduct or outcome of the process.

23. Format of Technical Bid including Organizational Capability

The formats for the documents listed in Section 13 are provided in the Attachments below.

ATTACHMENT #1 – COVER LETTER OF EOI SUBMISSION

[Location, Date]

To: The Executive Director, BRIC-THSTI, NCR Biotech Science Cluster, Faridabad

Dear Sir/Madam,

We, the undersigned, offer to collaborate with BRIC-THSTI for the Joint Operation of a Healthy-Volunteer Phase I Clinical Trial Unit at Medical Research Centre (MRC) in accordance with your REOI dated.....

We hereby declare that all the information and statements made in this EOI are true and accept that any misrepresentation 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. Proprietary 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 a subsidiary, state what involvement, if any, the parent company will have in the project.	
8. Is the firm a registered company? If yes, submit documentary proof and 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 the Contract Labour (Regulation and Abolition) 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. Has the 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.	

Seal and Signature of Bidder

ATTACHMENT #3 – AUTHORIZATION LETTER

(To be submitted on company's Letterhead)

To,
The 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/Madam,

This has reference to your above-mentioned Expression of Interest (EOI) for Joint Operation of a Healthy-Volunteer Phase I Clinical Trial Unit at Medical Research Centre (MRC).

Mr./Ms./Mrs./Dr. is hereby authorized to submit the EOI documents and participate in the processing on behalf of M/s (Name of the company), 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 PERSONNEL AND
TECHNICAL CAPABILITY
(TO BE SUBMITTED ON COMPANY'S LETTERHEAD)**

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

Subject: Undertaking regarding personnel and technical capability.

Ref: THSTI/EOI/..... dated.....

Sir/Madam,

It is hereby confirmed and declared that under the scope of work for 'Joint Operation of a Healthy-Volunteer Phase I Clinical Trial Unit at Medical Research Centre (MRC)', M/s (Company Name) does have:

- i. Adequate access to early-phase clinical operations, quality assurance, regulatory affairs, CSV/21 CFR Part 11 expertise; and
- ii. An adequate number of qualified and experienced personnel for secondment to the roles listed under Section 3 (Personnel).

However, scope of work under the activities of the Scope of Work (Section 2, S.No.) 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

Name of the bidder	Turnover (Rs. Crores)			Net worth (Rs. Crores)
	2023-24	2024-25	2025-26	2025-26

Note:

1. Submit the audited financial statement/audited annual report of the last three financial years.
2. The bidders should submit a solvency certificate indicating an amount equal to or not less than 40% of the advertised value of the Estimated Value of Works. **A fresh Solvency Certificate issued by any scheduled bank must be submitted. The solvency certificate should not have been issued more than three (3) months prior to the date of submission of the bid.**

ATTACHMENT #6 – FORMAT FOR TECHNICAL CAPABILITY

Please provide a summary of technical capabilities, max 10 pages of text, indicating experience, number of similar clinical unit partnerships/projects handled, projects done for international clients, infrastructure and capabilities, and any regulatory approvals (e.g., CDSCO, ICMR, GCP) for the facilities to be used. Detailed capabilities, case studies, etc. are not to be provided at this stage, but will be requested at the time of final proposal submission. The qualifying FIH trials claimed under PQC 3 shall be listed in the below format

Details of qualifying First-in-Human trials

S.No	Registry no. and regulatory permission ref./date	Design and IMP type (e.g., SAD/MAD; NCE/NBE/vaccine)	Country and site	Role of collaborator (CRU operator/ops/QA)	Evidence enclosed (page no.)
1					
2					
3					

If certain activities of the Scope of Work (Section 2) 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 in 1–2 paragraphs (max 1 page) per subcontracted party.

ATTACHMENT #7 – UNDERTAKING WITH REGARD TO BLACKLISTING

Declaration Letter (to be printed on Letterhead)

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

Dear Sir/Madam,

We hereby confirm and declare that we, M/s , are not blacklisted/de-registered/debarred by any Government department/Public Sector Undertaking/Private Sector or any other agency for which we have executed/undertaken works/services during the last 5 years.

For

Authorized Signatory

Date:

ATTACHMENT #8 – UNDERTAKING WITH REGARD TO NON-LITIGATION

Declaration Letter (to be printed on 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 the REOI for Joint Operation of a Healthy-Volunteer Phase I Clinical Trial Unit at Medical Research Centre (MRC).

We also declare that our Company/LLP/Partnership/Society/Proprietorship has, during the last three years, neither failed to perform on any agreement, nor been subject to the 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 had any agreement terminated for breach by us.

Sincerely,

(Signature of the Authorized Person)

Name:

Designation:

ATTACHMENT #9 – EOI DOCUMENT DULY STAMPED AND SIGNED

EOI Document with each page duly stamped and signed by the Authorized Signatory.

ATTACHMENT #10 – COPY OF MSME CERTIFICATE

Copy of MSME Certificate (if applicable).

ATTACHMENT #11 – COPY OF CANCELLED CHEQUE

Copy of cancelled cheque.

ATTACHMENT #12 – ANY OTHER INFORMATION

Any other information which the bidder may like to provide.

ATTACHMENT #13 – POWER OF ATTORNEY FOR SIGNING OF EOI

(To be submitted on the Bidder's Letterhead, duly notarised)

Know all men by these presents, We, (name of the firm and address of the registered office) do hereby irrevocably constitute, nominate, appoint, and authorise Mr./Ms. (Name), presently employed with us and holding the position of , as our true and lawful attorney (the "Attorney") to do in our name and on our behalf all such acts, deeds, and things as are necessary or required in connection with or incidental to the submission of our EOI for the Joint Operation of a Healthy-Volunteer Phase I Clinical Trial Unit at Medical Research Centre (MRC) proposed by BRIC-THSTI, including but not limited to signing and submission of all applications, EOI documents, and other writings, participating in bidder conferences, representing us in all matters before BRIC-THSTI, and generally dealing with BRIC-THSTI in all matters connected with or arising out of our EOI and/or upon award thereof to us.

AND we hereby agree to ratify and confirm all acts, deeds, and things done or caused to be done by our said Attorney pursuant to and in exercise of the powers conferred by this Power of Attorney.

IN WITNESS WHEREOF WE, , THE ABOVE-NAMED PRINCIPAL, HAVE EXECUTED THIS POWER OF ATTORNEY ON THIS DAY OF, 20.....

For
(Signature, name, designation, and address)
Witnesses:

- 1.
- 2.

Accepted
(Signature, name, designation, and address of the Attorney)
Notarised

End of the Document

.....