ट्रांसलेशनल स्वास्थ्य विज्ञान एवं प्रौद्योगिकी संस्थान

TRANSLATIONAL HEALTH SCIENCE AND TECHNOLOGY INSTITUTE

(An autonomous Institute of the Dept. of Biotechnology, Ministry of Science & Technology, Govt. of India)

NCR-Biotech Science cluster, 3rd mile stone, Faridabad-Gurugram Expressway, Faridabad

Phone No. : 0129-2876300 Fax No: 0129-2876 402 Website: www.thsti.res.in

Request for Proposal (RFP)

For

Creating an Electronic Data capture platform for Inter-Institutional Program for Maternal, Neonatal and Infant Sciences-A translational approach to studying Preterm birth at THSTI, NCR Biotech Science Cluster, Faridabad

(RFP No.: THSTI/RFP/PBC/19-20)

25th Sep 2019

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Abbreviations

SOW	Scope of Work
IWRS	Interactive Web Response System
LMS	Lab Management system
CTMS	Clinical Trial Management System
eTMF	Electronic Trial Master File
EDC	Electronic Data Capture
CRF	Case Record Form
CFR	Code of Federal Regulations
THSTI	Translational Health Science and Technology Institute
TDS	Tax Deducted at Source

SECTION-1: NOTICE INVITING REQUEST FOR PROPOSAL (RFP)

Ref. No. THSTI/RFP/PBC/19-20 **Date:25th Sep, 2019**

Pursuant to your application in response to our Expression of Interest Request for Procurement of Clinical Data Management System (CDMS)/ EDC **(Electronic Data Capture) tool to capture the clinical study data in electronic format at THSTI,** and the qualification conducted thereafter**,** your firm has been shortlisted as a Bidder to participate in the final bidding process.

Sl No	Name of the instrument	Qty. Required	Enquiry Ref. No.	EMD to be given (INR)
01	Creating an Electronic Data capture platform for Inter-Institutional Program for Maternal, Neonatal and Infant Sciences	01	Ref. No. THSTI/RFP/PBC/19-20	64,000.00

On behalf of Executive Director, Translational Health Science and Technology Institute (THSTI) sealed Request for Proposal (RFP) is invited for **Creating an Electronic Data capture platform for Inter-Institutional Program for Maternal, Neonatal and Infant Sciences-A translational approach to studying Preterm birth** at THSTI, NCR Biotech Science Cluster, Faridabad at THSTI, NCR- Biotech Science Cluster, Faridabad.

The complete set of Request for Proposal (RFP) document may be downloaded from our website: www.thsti.res.in or Government of India's CPP portal or may be obtained from the Purchase Section, THSTI, Faridabad from 25th Sep to 16th Oct 2019 between 10:00 AM to 3:00 PM at free of cost.

If the technical specification requires any modification, suitable corrigendum/amendments to the Request for Proposal (RFP) will be issued and the same will form part of the Request for Proposal (RFP) document. All corrigendum/amendments etc., if any, will be notified only on the THSTI website and no separate advertisement will be released for the same. Prospective firms(s) are therefore advised to regularly visit the THSTI website for any such updates.

Note: The applicant(s) or firm(s) who were qualified as per the eligibility criteria mentioned in the published EOI document No. **EOI No.: THSTI/EOI/PBC/2018-19** are only invited as well as eligible to submit the Request for Proposal document.

Section Officer (S&P)
For and On behalf of Executive Director, THSTI

SECTION-2: INTRODUCTION

Translational Health Science and Technology Institute (THSTI) is an autonomous Institute of the Department of Biotechnology, Ministry of Science and Technology, Govt. of India. The institute is an integral part of the interdisciplinary NCR Biotech Science Cluster located at Faridabad, and is designed as a dynamic, interactive organization with the mission to conduct innovative translational research and to develop research collaborations across disciplines and professions to translate concepts into tangible products to improve human health.

This work under consideration pertains to the pre-term work project which is a hospital based prospective cohort study that will enroll women early in their pregnancy and follow them through their pregnancy until childbirth and till 6 months post-partum. The aim is to identify environmental, clinical and biological causal factors, gain mechanistic insight into disease progression and use modern science to identify measurement tools that can help in early risk stratification of pregnant women for Preterm Birth (PTB) in a large hospital-based cohort of 8000 pregnant women at the Gurgaon Civil Hospital (GCH), Gurgaon. A large bio-bank of longitudinally collected varied bio specimens of these pregnant women with well characterized information on environmental, clinical, social and epidemiological determinants at different time points in pregnancy is being established.

Pregnant women coming to the antenatal clinic of GCH are approached by the study nurses to ascertain their eligibility for participation in the study. Women who have a pregnancy of less than 20 weeks' gestation as determined by a 'dating' ultrasound and who are willing to come to Gurgaon Civil Hospital (GCH) for follow up antenatal visits are eligible if they were willing to participate in the study and give their written consent for it. Information related to maternal age and nutritional factors, socio-demographic details, psychosocial stress, past and present pregnancy details, medical history and other co-morbidities are obtained and recorded in structured and pre-tested case recording forms (CRF). The enrolled participants are followed up at pre-defined periods during the course of the pregnancy. Serial ultrasounds are done at <14 weeks, 11-14 weeks, 18-20 weeks, 30-32 weeks and 35-37 weeks to assess the gestational age, fetal growth, cervical length, placental position, size, echogenicity and vascular flow at GCH. Besides this serial bio specimens (namely blood, urine, saliva, etc.) are being collected across pregnancy, delivery and post-delivery and reposited in a bio bank. We have at present 6,00,000 samples in the biobank.

At present, we have enrolled 6000 plus participants in the study and currently the platform for data collection of study is paper based. Since we are managing a very large data set, the current manual process for QC and QA is causing major delays, which restrict the investigators to access clean data timely. Considering the increasing quantum of data, we are shifting the platform to Electronic data

capture (EDC). Hence, we would like to hire a professional organization for developing and designing a study specific platform for EDC and help us in smooth capturing of data electronically.

The background, objectives and Scope of Work (SOW) to be accomplished by the applicant(s) are provided in the subsequent sections of this document. The applicant(s) may take note of the following:

i. To be considered for Award of Work process, applicant should submit their RFPs in accordance with the requirements contained in this document.
ii. THSTI reserves the right to update, amend and supplement the information in this document including the scope of work before the last date and time up to the receipt of Proposal(s).
iii. This document is non-transferable.
iv. THSTI reserves the right, without assigning any reasons, to abort the whole process.

Section 3: Contract

This Contract, the following terms shall be interpreted as indicated**:**

(i) "The Order" means the Purchase Order placed by the Purchaser including all the attachments and appendices thereto and all documents incorporated by reference therein;

(ii) "The Contract Price" means the price payable to the Supplier under the Order for the full and proper performance of its contractual obligations;

(iii) "The Goods" means all the equipment, machinery, and/or other materials, which the Supplier is required to supply to the Purchaser under the Contract;

(iv) "Services" means services ancillary to the supply of the Goods, such as transportation and insurance, and any other incidental services, such as installation, commissioning, provision of technical assistance, training and other obligations of the Supplier covered under the Contract

(v) "GCC" mean the General Conditions of Contract contained in this section.

(vi) "SCC" means the Special Conditions of Contract.

(vii) "The Purchaser" as specified in Special Conditions of Contract.

(viii) "The Purchaser's country" is "India".

(ix) "The Supplier" means the individual or firm supplying the Goods and Services under this Contract.

(x) "Day" means calendar day.

(xi) RFP means Request for Proposal which is the current document.

1.1 Application

1.1.1 These General Conditions shall apply to the extent that they are not superseded by provisions in other parts of the Contract.

1.2 Use of Contract Documents and Information

The bidder shall not, without the Purchaser's prior written consent, disclose the Contract, or any provision thereof, or any specification, plan, drawing, pattern, sample or information furnished by or on behalf of the Purchaser in connection therewith, to any person other than a person employed by the Supplier in performance of the Contract. Disclosure to any such employed person shall be made in confidence and shall extend only so far, as may be necessary for purposes of such performance.

1.3 Submission of the bids

All bids complete in every respect must reach this office within the last date and time of receipt of bid. No extension shall be allowed for any reason what so ever. Late tenders, Tenders received without Bid security/Earnest Money, cost of bidding documents, if applicable etc. shall be rejected summarily.

1.4 Delivery and Documents

The software will be designed, tested and installed in THSTI server / Cloud Server as per specifications mentioned in the scope of work in the tender. The database will be installed on THSTI server / Cloud server and necessary client /user licenses will be made available to all the users as defined in the tender. The successful bidder will have to sign a service contract, the terms and conditions of which will be mutually accepted by both. The successful bidder will also have to submit the escalation matrix up to the head of the organization in case of technical difficulties to be resolved and any trouble shooting need during the entire term of the contract.

If required, there must be the provision of on premise hosting for one or more studies as per the THSTI’s requirement; however, the software installation is in cloud based with dedicated and secured space in Indian server.

1.5 Payment

The Payment will be made upon successful installation and the qualification checks performed for the software. TDS will be deducted as per Income Tax Rules 1962.

1.6 Prices

All the prices quoted will be in Indian Rupees

1.7 Subcontracts

1.7.1 The Supplier shall notify the Purchaser in writing of all subcontracts awarded under this Contract if not already specified in the bid. Such notification, in his original bid or later, shall not relieve the Supplier from any liability or obligation under the Contract

1.7.2 Sub-contract shall be only for bought-out items and sub-assemblies.

1.8 Performance Security

1.8.1 The successful Bidder shall furnish the performance security equivalent to 10% of the total cost of the contract in the form of Bank Guarantee from scheduled bank after installation/ commissioning of the equipment(s) valid for 12 (Twelve) months effective from date of delivery.

1.8.2 The payment will be released on receipt of performance security as per 1.8.1 above,

1.9 Delays in the Supplier's Performance

Since time is the essence of the contract, delivery of the Goods and performance of the Services shall be made by the Service Contractor in accordance with the milestones defined under section 1.5 and further detailed out in the RFP document.

1.10 Penalty

If the Supplier fails to deliver any or all of the Goods or to perform services within the period(s) specified in the Contract, the Purchaser shall, without prejudice to its other remedies under the Contract, deduct from the Contract Price, as penalty, a sum equivalent to 0.5% per week and the maximum deduction is 10% of the contract price.

1.11 Termination for Default

1.11.1 The Purchaser may, without prejudice to any other remedy for breach of contract, by written notice of default sent to the Supplier, terminate the Contract in whole or part:

(i) If the Supplier fails to deliver any or all of the Goods within the period(s) specified in the order, or within any extension thereof granted by the Purchaser.

(ii) If the Supplier fails to perform any other obligation(s) under the Contract.

(iii) If the Supplier, in the judgment of the Purchaser has engaged in corrupt or fraudulent practices in competing for or in executing the Contract.

(iv) The detailed clauses for the termination will be laid out in the service contract

1.11.2 For the purpose of this Clause:

(v) "Corrupt practice" means the offering, giving, receiving or soliciting of gratification to influence the action of a public official(s) in the procurement process or in contract execution.

(vi) "Fraudulent practice" means a misrepresentation of facts in order to influence a procurement process or the execution of a contract to the detriment of the purchaser, and includes collusive practice among Bidders (prior to or after bid submission) designed to establish bid prices at artificial non-competitive levels and to deprive the purchaser of the benefits of free and open competition;'"

1.12 Force Majeure

1.12.2 The Supplier shall not be liable for forfeiture of its performance security, liquidated damages or termination for default, if and to the extent that, it's delay in performance or other failure to perform its obligations under the Contract is the result of an event of Force Majeure.

1.12.3 For purposes of this Clause, "Force Majeure" means an event beyond the control of the Supplier and not involving the Supplier's fault or negligence and not foreseeable. Such events may include, but are not limited to, acts of the Purchaser either in its sovereign or contractual capacity, wars or revolutions, fires, floods, epidemics, quarantine restrictions, act of God and freight embargoes.

1.13 Resolution of Disputes

1.13.1 The Purchaser and the supplier shall make every effort to resolve amicably by direct informal negotiation any disagreement or dispute arising between them under or in connection with the Contract.

1.13.2 If, after thirty (30) days from the commencement of such informal negotiations, the Purchaser and the Supplier have been unable to resolve amicably a contractual dispute, either party may require that the dispute be referred for resolution to the formal mechanisms. These mechanisms may include, but are not limited to, conciliation mediated by a third party, adjudication in an agreed national or international forum, and national or international arbitration.

1.13.3 In case of Dispute or difference arising between the Purchaser and a domestic supplier relating to any matter arising out of or connected with this agreement, such disputes or

difference shall be settled in accordance with the Indian Arbitration & Conciliation Act, 1996, the rules there under and any statutory modifications or re-enactments thereof shall apply to the arbitration proceedings. The dispute shall be referred to the Director THSTI and if he is unable or unwilling to act, to the sole arbitration of some other person appointed by him willing to act as such Arbitrator. The award of the arbitrator so appointed shall be final, conclusive and binding on all parties to this order.

1.14 Applicable Law

The place of jurisdiction would be Faridabad, INDIA.

1.15 Notices

For the purpose of all notices, the following shall be the address of the Purchaser and Supplier.

Executive Director,
Translational Health Science &Technology Institute (THSTI),
3rd milestone, Gurgaon- Faridabad Expressway
Faridabad, Haryana -121001

C**ontractor** **(**To be filled in by the Contractor)

…….....

…….....

…….....

2 INSTRUCTIONS TO BIDDERS

2.7 PREPARATION OF BIDS

2.7.1 Documents Comprising the Bid

The bid is required to be submitted in **two parts**. One part is the Techno- Commercial Unpriced Bid and the other part is the Financial/Price Bid.

1.7.1.1 The Techno-Commercial Unpriced Bid prepared by the Bidder shall include the following without indicating the price in the Bid Form.

(i) EMD in the form of Demand draft drawn in the favor of "THSTI" and payable at Faridabad

(ii) Signed Bid Form.

(iii) Documents requested as per the special conditions of the contract

2.7.1.2 The Price/Financial Bid shall comprise the Techno Commercial Bid with price indicated in the bid form.

2.8 Bid Prices

2.8.1 The Bidder shall indicate the total bid price for complete integrated data management services as sought in the tender.

2.8.2 Prices quoted by the bidder shall remain fixed during the entire period of contract and shall not be subject to variation on any account. A bid submitted with an adjustable price the bid will be treated as non - responsive and rejected.

2.9 Bid Currencies

Prices shall be quoted in Indian Rupees Only.

2.10 Documents Establishing Bidder's Eligibility and Qualifications

2.10.1 Pursuant to THSTI, the bidder shall furnish, as part of the bid, documents establishing the bidders' eligibility to bid and qualification to perform the contract if the bid is accepted.

2.10.2 That the bidder meets the qualification criteria listed in Bid Document.

2.11 Period of Validity of Bids

Bids shall remain valid for 90 days from the date of opening the bid prescribed by the Purchaser. A bid valid for a shorter period may be rejected by the Purchaser as non-responsive.

2.12 Format and Signing of Bid

2.12.1 The Bidder shall submit the bids in two separate envelops. One envelope shall contain Techno commercial un-priced bid and the other shall contain the priced bid.

2.12.2 The original and all copies of the bid shall be typed or written in indelible ink and shall be signed by the Bidder or a person or persons duly authorized to bind the Bidder to the Contract. All pages of the bid, except for un-amended printed literature, shall be initialed by the person or persons signing the bid.

2.12.3 Any interlineations, erasures or overwriting shall be valid only if the persons or persons signing the bid endorse them.

2.12.4 The Bidder shall furnish information on commissions or gratuities, if any paid or to be paid to agents relating to this Bid, and to contract execution if the Bidder is awarded the contract as per the bid form.

2.12.5 The bid once accepted and awarded the contract the bidder will be obliged to execute the contract for the delivery and commissioning of the product at THSTI.

2.13 Submission of Bids

The complete bid document to be submitted as per the letter of Invitation.

2.14 Sealing and Marking of Bids

2.14.1 The bidder shall seal the Techno Commercial Unpriced Bid and the Price/Financial Bid in two separate envelops duly marked as “Techno Commercial Unpriced Bid” and “Price/Financial Bid” respectively. Both the envelopes shall then be sealed in one outer (main) envelope.

2.14.2 The inner and outer envelopes shall:

(iv) Be addressed to the Purchaser at the following address:

Executive Director
Translational Health Science &Technology Institute,
THSTI -3rd milestone, Gurgaon- Faridabad Expressway
Faridabad, Haryana -121001

(v) Bear the Item Name /Reference No./ Last Date For Submission Of Tender / Date of opening of Tender / Firm’s Name & Address and a statement "Do not open before Time hrs (IST) on Date."

2.14.3 If the outer envelope is not sealed and marked as required Clause 12.2, the Purchaser will assume no responsibility for the bid's misplacement or premature opening.

2.14.4 Fax or e-mail bids will be rejected.

2.15 Deadline for Submission of Bids

2.15.1 Bids must be received by the Purchaser at the address specified under Clause 2.8.2

2.15.2 Not later than the time and date specified in the Invitation for Bids. In the event of the specified date for the submission of Bids being declared a holiday for the Purchaser, the Bids will be received up to the appointed time on the next working day.

2.15.3 The Purchaser may, at its discretion, extend this deadline for submission of bids by amending the bid documents in accordance with Clause 5.1, in which case all rights and obligations of the Purchaser and Bidders subject to the previous deadline will thereafter be subject to the deadline as extended.

2.16 Late Bids

Any bid received by the Purchaser after the deadline for submission of bids as prescribed by the Purchaser, pursuant to Clause 16, will be rejected and/or returned to the Bidder.

2.17 Modification and Withdrawal of Bids

2.17.1 The Bidder may modify or withdraw its bid after the bid's submission; provided that written notice of the modification or withdrawal is received by the Purchaser prior to the deadline prescribed for submission of bids.

2.17.2 The Bidder's modification or withdrawal notice shall be prepared, sealed, marked and dispatched in accordance with the provisions of Clause 15. A withdrawal notice may also be sent by telex or cable or fax or e mail but followed by a signed confirmation copy, post marked not later than the deadline for submission of bids.

2.17.3 No bid may be modified subsequent to the deadline for submission of bids.

2.17.4 No bid may be withdrawn in the interval between the deadline for submission of bids and the expiration of the period of bid validity specified by the Bidder on the bid form. Withdrawal of a bid during this interval may result in the Bidder's forfeiture of its bid security.

2.18 OPENING AND EVALUATION OF BIDS

2.18.1 Opening of Bids by the Purchaser

The Purchaser will open all Techno Commercial Un-priced Bids, in the presence of Bidders' representatives who choose to attend, as per the schedule given in invitation to bids.

2.18.2 Clarification of Bids

To assist in the examination, evaluation and comparison of bids, the Purchaser may, at its discretion ask the bidder for any clarification(s) of its bid. The request for clarification and the response shall be in writing and no change in the price substance of the bid shall be sought, offered or permitted. However, no post Bid clarifications at the initiative of the Bidder shall be entertained.

2.19 Preliminary Examination

2.19.1 The Purchaser may waive any minor informality, non-conformity, or irregularity in a bid, which does not constitute a material deviation, provided such a waiver, does not prejudice or affect the relative ranking of any Bidder.

2.19.2 Prior to the detailed evaluation, the Purchaser will determine the substantial responsiveness of each bid to the Bid Document. For purposes of these Clauses, a substantially responsive bid is one, which conforms to all the terms and conditions of the Bid Document without material deviations.

2.19.3 On downloading from the web site, the language of standard clauses etc. mentioned in this 'Bid Document' should not be tampered with/ changed/modified in any manner whatsoever. If any such modification etc. is noticed the purchaser at any stage, the bid shall be rejected immediately and EMD shall stand forfeited.

2.20 Evaluation & Comparison of Bids

2.20.1 Conditional tenders/discounts etc. shall not be accepted. Rates quoted without attached conditions (viz. Discounts having linkages to quantity, payment terms etc.) will only be considered for evaluation purpose. Thus conditional discounted rates linked to quantities and prompt/advance payment etc., will be ignored for determining inter-se position. The Purchaser however reserves the right to use the discounted rate/rates considered workable and appropriate for counter offer to the successful tenderers.

2.21 Contacting the Purchaser

Any attempt by any Bidder to influence the Purchaser in its decisions on bid evaluation, bid comparison or contract award may result in rejection of the bid.

2.22 Purchaser's Right To Accept Any Bid and To Reject Any or All Bids

2.22.1 The Purchaser reserves the right to accept or reject any bid, and to annul the bidding process and reject all bids at any time prior to award of Contract, without thereby incurring any

liability to the affected Bidder or bidders or any obligation to inform the affected Bidder or bidders of the grounds for the Purchaser's action.

2.22.2 Evidence regarding credibility of stable performance and maintenance service capability must be provided. The purchaser reserves the right to make judgment on this score and reject bids that, in the purchaser's view, do not carry sufficient credibility for performance and/or service.

2.23 Notification of Award

2.23.1 Prior to expiry of the period of bid validity, the purchaser will notify the successful bidder in writing by Purchase Order.

2.23.2 Upon the successful Bidder's furnishing of performance security, the purchaser will promptly notify each unsuccessful Bidder and will discharge its bid security.

2.24 Order Acceptance

2.24.1 The successful bidder should submit acceptance of the Purchase Order immediately but not later than 21 days in any case from the date of issue of the Purchase Order failing which it shall be presumed that the vendor is not interested and his bid security is liable to be forfeited

2.24.2 Service Level Agreement and Service Contract will be signed with the successful bidder for effective implementation of the contract

2.24.3 The Successful bidder has to sign Confidentiality and Non-disclosure agreement with THSTI before any information is shared with the bidder in respect to the clinical trial.

2.25 Supplier Integrity

The Bidder is responsible for and obliged to conduct all contracted activities in accordance with the Contract using state of the art methods and economic principles and exercising all means available to achieve the performance specified in the contract.

3 BID FORM

To,
Executive Director,
Translational Health Science &Technology Institute,
THSTI
3rd milestone, Gurgaon- Faridabad Expressway
Faridabad, Haryana -121001

Sir,

Having examined the bidding document, the receipt of which is hereby duly acknowledged, we the undersigned offer to participate in the RFP for Procurement of EDC **(Electronic Data Capture) tool to capture the clinical study data in electronic format at THSTI** and in conformity with the said bidding documents for a sum or such other sums as may be ascertained from the bid.

We undertake if our bid is accepted, for Procurement of EDC **(Electronic Data Capture) tool to capture the clinical study data in electronic format at THSTI**, we agree to deliver the services in accordance with the delivery schedule specified.

We agree to abide by this bid for requisite period as fixed for bid opening as per the instructions to the bidders. Further it shall remain binding upon us and accepted at any time before the expiry of that period.

Until a formal contract is prepared and executed, this bid, together with your written acceptance thereof and your notification of award shall constitute a binding contract between us.
Commission and gratuities, if any, paid or to be paid by us to the agents relating to this bid, and to contract execution if we are awarded the contract, are listed below:

Name and address of agent	**Amount in Rupees**	**Purpose of Commission (if none, state "none")**

We understand that you are not bound to accept the lowest or any bid you may receive. Dated

this _____day of_____20_____

Signature_____In the capacity of_____

Duly authorized to sign the bid for and on behalf of_____

(For price bid format to be submitted in sealed second envelops duly marked as "Price/Financial Bid")

(Stamp and Sign of Bidder)

4. Form of Performance Bank Guarantee/Bank Guarantee

(TO BE SUBMITTED FROM ANY INDIAN NATIONALIZED BANKS ONLY)

BG No. Date:

From, The Name of the Bank	To, THSTI, Faridabad

In consideration of the **THSTI**, Faridabad having offered to accept the terms and conditions of the proposed agreement between The Institute……and…… (hereinafter called "the Contractor(s)"for the work……. (hereinafter called "the said agreement'') having agreed to production of an irrevocable Bank guarantee for Rs…… (Rupees…….only) as a security/guarantee form the contractor(s) for compliance of his obligations in accordance with the terms and conditions in the said agreement.

1. We (Indicate the name of the Bank) (hereinafter referred to as the ''Bank'') hereby undertake to pay to THSTI an amount not exceeding Rs…… (Rupees…… only) on demand.

2. We…(indicate the name of the Bank) ……. do hereby undertake to pay the amounts due and payable under this Guarantee without any demur, merely on a demand from the Institute stating that the amount claimed is required to meet the recoveries due or likely to be due from the said contractor(s). Any such demand made on the Bank shall be conclusive as regards the amount due and payable by the Bank under this Guarantee. However, our liability under this Guarantee shall be restricted to an amount not exceeding Rs…… (Rupees……only).

3. We, the said Bank, further undertake to pay to THSTI any money so demanded notwithstanding any disputes raised by the contractor(s) in any suit or proceeding pending before any Court or Tribunal relating thereto, our liability under this present being absolute and unequivocal. The payment so made by us under this bond shall be a valid discharge of our liability for payment thereunder, and the contractor(s) shall have no claim against us for making such payment.

4. We (indicate the name of the Bank) …… further agree that the Guarantee herein contained shall remain in full force and effect during the period that would be taken for the performance of the said agreement, and it shall continue to be enforceable till all the dues of the Institute under or by virtue of the said agreement have been fully paid, and its claims satisfied or

discharged, as per the terms and conditions of the said agreement have been fully and properly carried out by the said contractor(s), and accordingly discharges this guarantee.

5. We……(Name of the bank)… further agree with THSTI that THSTI shall have the fullest liberty without our consent, and without effecting in any manner our obligations hereunder, to vary any of the terms and conditions of the said agreement or to extend time of performance by the said contractor(s) from time to time any of the powers exercisable by THSTI against the said contractor(s), and to forbear or enforce any of the terms and conditions relating to the said agreement, and we shall not be relieved from our liability by reason of any such variation or extension being granted to the said not be relieved from our liability by reason of any such variation or extension being granted to the said contractor(s) or for any forbearance, act of omission on the part of the Institute or any indulgence by the Institute to the said contractor(s) or by any such matter or thing whatsoever which under the law relating to sureties would, but for this provision, have effect of so relieving us.

6. This Guarantee will not be discharged due to the change in the constitution of the Bank or the contractor(s).

7. We (Name of the bank)……. lastly under take not to revoke the Guarantee except with the previous consent of THSTI in writing. This bank Guarantee on the Bank or its successors or permitted assigns.

8. We……(Indicate the name of the Bank) …… lastly undertake not to revoke this Guarantee except with (indicate the name of the Bank) the previous consent of THSTI extended on demand by THSTI. Notwithstanding anything mentioned above, our liability against this Guarantee is restricted to Rs…….(Rupees……..only), and unless a claim/demand is made on the bank in writing on or before ……all your rights under the Guarantee will be forfeited and we shall be relieved and discharged from all liabilities thereunder.

Authorized Signatories of the Bank with name and Seal

Name of the Officer:
Designation:
Code if any:
Date:
Place

5. SPECIAL CONDITIONS OF THE CONTRACT

The purpose of this Request for Proposals (RFP) refers to Electronic Data Capture tool within the context of a multi centric study in India.

THSTI is looking for the procurement of the CDMS or EDC (Electronic Data Capture) tool which can support the following:

5.a. Upcoming project details are as follows:

- Number of users who should be able to access the application simultaneously: 55
- Number of unique pages: 180 (approx.)
- Expected number of edit checks required: 2500
- Duration of study: 5 years from the delivery of live EDC application

5.b. Functional Requirements

The proposed CDMS should cover applications in the areas of Electronic Data Capture (EDC).

The vendor may describe additional features of the proposed products that could be of interest to the organization under each heading or in separate documentation as appropriate.

The vendor should be able to import/ migrate data from existing MS – SQL server 2014 to new Clinical Data Management system which will be created by the bidder

5.c. CRF and Database Design

Data Entry screens must be capable of being programmed to resemble layout of paper CRF.
Ability to generate annotated CRF from the CDMS.
Ability to generate database structure documentation from the CDMS itself.
Web Collaboration tool for CRF design review.
Global CRF Standards library supporting three tiers (i.e., general standards, therapeutic area specific standards and trial specific data modules): - Global Library supporting two flags for data elements: mandatory flag and optional flag. - Global Library containing database structure, screen definition and edit check programs/rules
Flexible data entry screens can be designed by a novice user in Clinical Data Management.
Data entry screen sequence customizable to follow a logical decision tree.

i. Database Build

Support of different field level data entry conventions: - Mandatory “always” (e.g., Participant initials) - Mandatory but with the possibility to leave it empty by clicking the related NA (not available or missing) check box; - Ability to enter NA in all fields by introducing the related information as comments/ notes
Audit trail information at field level including: - User - Date/Time of modification - Old and new value of the amended field - Reason for amendment
Ability to store both text and codes (e.g., YES/NO or 1 /2).
Capability to generate data sets from a user-friendly interface.
User-friendly drag and drop, point and click based rules builder using a rules wizard.
Dynamic forms and visits.
Functionality to design output driven data sets in the context of the study build.
Repeating modules or variations of repeating modules can be applied to various unique CRFs for front end use, while data is related and stored on the backend in a single data set.
Data entry screens and views built in the test module looks the same in both the test module as it does in the production database.
Drag and drop, click and dragging entry screen objects preferable for programming/ customization.
The following data entry fields can be programmed: - open text/character fields (at least 500 characters) with wrap-around capability meric fields, - date fields, - time fields, - drop down lists, - check boxes, - radio buttons
Data entry fields can be formatted (e.g. left/right/top/bottom alignment, wrap-around is minimized; excessive scrolling to the right or down can be minimized, etc.).
Ability to configure date fields to allow partial dates without front-end data checks firing.
Code lists can be employed so that codes associated with text values are easily retrievable.
Ability to link Adverse Events and Medications for each participant.
Ability to configure email alerts based on defined criteria.
Ability to restrict who has access to protocol violation listings.
Ability to indicate responses as 'Not Done' or 'Not Applicable' or 'Unknown'. These values should be contained within the back end dataset and not within a separate table, so that edit checks may be run against them, etc…

Ability to enter data into a field if the data does not conform to all field requirements (e.g. a number is recorded in alphanumeric/ text field on the CRF).
A separate test environment for validation and testing of both database and edit checks that is outside the production environment, hosted either on a separate server or a validation area built into the product that functions in the same manner as the production environment. Once validation and testing have been performed, the database and/or edit checks (as well as updates) can be released into the production environment.
Database should be accessible online and offline both.

ii. Edit Check Programming

Query text for edit check output can be defined upon programming edit checks.
Ability to add edit checks after the database is in production.
User-friendly drag and drop, point and click based rules builder using a rules wizard.
Ability for query text to be configurable such that actual discrepant data values can be populated within query text automatically when check fires.
Query text length is at least 500 characters.
Groups of edit check programs may be run against study data.
Ability to program the checks within a single form and cross form/ cross data set checks
Edit check functionality can be applied to unscheduled visits / forms.
Batch validation can be initiated at any unscheduled time (e.g. manually).
Batch validation can be scheduled at pre-defined time points as needed to avoid system performance issues during peak usage times.
Edit checks can be configured to fire at point of initial data entry.
Visual prompts or dialogue boxes that pop up when non-conformant data is entered into a formatted data field.
Edit checks to be configured to fire at point of initial data entry or during batch validation or upon review.
Ability to compare multiple data fields within the same CRF.
Ability to compare multiple data fields across different CRFs.

iii. Database Amendments

Database amendments (CRFs and edit checks) and post production changes can be performed without disabling the database for an extended period of time.
Amended structures can be done at the module level, tested in a validation area, and then released into the production environment.
Design and testing in the validation area does not disrupt ongoing data processing in production.
Database can be versioned at the module/data set level (as opposed to the CRF or page level).
Database version is identifiable within the interface for applicable modules, forms or datasets.
Ability to apply newly versioned CRFs to specified subjects while allowing former version (s) to remain in effect for other specified subjects to whom the amendment does not apply.
Ability to add new checks after data entry has started and to run new checks on previous data.

iv. End-User Interface

-Two interface are required; tab based for data collection (Android platform) and web based interface for rest of the operational activities.
Automatic participant numbering: - By study number + center number + sequential participant number (with the possibility of including existing preset study/center numbers)
Screen to review the Audit Trail data.
System should be email enabled.
Audit Log facility for CRF modification traceability.
Ability for external data load.
Spell Checker.
Ability to store screen failures in the database.
Flexible record data entry screen definition: - Tabular form, - Full screen form
Page (screen) navigation: - Page by page (sequential next and previous page) - Direct access through a full index page
Index page showing the different CRF page statuses but not limited to: - Never entered, - Entered by site ready for SDV, if applicable, - Reviewed by DM, - Locked by the CRA for monitoring SDV review, if applicable, - Frozen by the CRA or DM, - Locked by the DM, - Navigation through pages defined by page status

v. Database Reports

Standard system and metrics reports available but not limited to: - CRF page or module inventory status reports - Missing page reports, - Outstanding query report, - Query Status Report - Query Trend Report, - Audit Trail Report (filter by participant number, data field, page number), - User Account Report
Ad hoc reports customizable: - By the DM, - Ease of report generation - By all users (includes user friendly search by example engine)
Support of the local format date/number/unit measure.
Print preview mode available.
Save/Run report and its query definition, access through user profiles.
Export report to PDF, Excel, XML, SAS, TXT & CSV
Graphic analysis facility (as a part of data review tool).
Ability to convert completed CRFs into PDF format.
Ability to restrict access to reports by roles and user profiles.
Ability to store user generated queries, tracking and versioning of queries.

Ability to generate the data entry reconciliation report (to find out the error rate performed by the users).
Dashboard and the reports must be available in graphical form for easy data translation, to provide quick and easy report analysis. - Dashboards: The Key Performance Indicators should be available in a dashboard format that can be easily transferred and downloaded. - Charts (Line Graphs, Bar Graphs, and Pie Charts) and access can be granted based on user's roles and responsibilities in the study.
Custom reports creation functionality must be available.

vi. Data Monitoring

Ability for the CRA to inform, electronically, the site personnel about the detail for each problem found at page/field level.
Allow the CRA user to deactivate/ re-generate queries manually for a CRF for which an explanation is not clear and query should still open.
Ability to change the query result status when the problem has been solved.
Ability to track Source Document Verification at the field, page or participant level.
Display of Adverse Events and Medications on one screen.

vii. Data Entry

CDMS should have the provision for both online and offline entry.
Icon or signal indicating the data entry status of particular screens/CRFs.
Feature for indicating that the response to a data field is Not Done or Not Applicable.
Ability to upload the documents.
Capability to print CRFs with the participant's data (for QC Audit use, medical listings etc.).
Ability for data update, data deletions & addition of notes and comments in the CRFs.
Ability to restrict, through database rights and roles, the ability to perform clinical data updates or data deletions.

viii. Discrepancy Management

Tracking of data query status with the possibility of manual deactivation of wrong generated query.
Ability to store/save query text and resolution text to reuse for manual queries.
Ability to run checks in online and batch mode.
Ability to check the edit checks in test mode before deployment to move into the production mode.
Ability for the DM to make self-evident changes.
Ability to print list of all self-evident changes.
Ability to flag protocol violations.
Discrepancy management module within the front end user interface for easy navigation and resolution of discrepancies that have fired in the system.
Discrepancy management module should allow discrepancy views to be sorted by investigational site, by subject, or by CRF.
Customization features can be easily and quickly learned by a layperson with a good aptitude for programming logic but without extensive programming knowledge.
Discrepancies can be converted into PDFs and word format to generate the DCFs (Data Clarification Form)/ QCF (Query & Correction Form)
Ability to generate manual queries on a field or at the form level via simple actions.
Only one discrepancy captured on a printed query page/DCF/QCF (One data query per printed form).

Ability to print query drafts prior to a query status of Open, Answered, Reviewed & Closed.
Data query format template can be customizable/configurable.
Quick link between discrepancy and data screen/CRF page in question.
Symbols/ indicators on the data entry screen indicating whether there is a discrepancy on the data field and status of the discrepancy (e.g. relevant data fields highlighted in red if there are active or sent discrepancies relating to that data point).
System back end tracks date of query generation, answered, completed and follow-up/ re-raise query.

ix. Database Lock/Unlock

Ability to close/freeze the access to the data for a given study and archive, either at the full study lock, interim analysis or for a subset of data.
Ability for locking and freezing tasks to be performed by DM personnel, assigned with appropriate database rights and roles.
Ability to freeze data at page, visit, participant and site level.
Ability to lock data at page, visit, participant and site level.
Ability to unfreeze data at page, visit, participant and site level.
Ability to unlock data at page, visit, participant and site level.
Record in audit trail of unlocked items.
Ability to generate database snapshots by date ranges.
Ability to generate database snapshots by variables.
Ability to generate database snapshot by status flag (locked participants, etc.).
Ability to generate database snapshots by participant.
Ability to perform soft lock.

x. Event Tracking and Trial Status

Audit Trail compliant with 21CFR part 11.
Electronic signature process is 21CFR part 11 compliant.
Ability to review and have one signature per activity/ per visit/ per site, but need the flexibility to change if required.
Ability to see that the site is locked after all participants' data has been reviewed and approved.
Functionality supports centralized tracking mechanism.

xi. External Data Load

Ability to load external data and display on screens with an ability to restrict this display if required.
Ability to have screens to enter additional data (e.g., comment on data at a field level for flagging clinical and non-clinical significance) and restrict the display if required.
Ability for edit checks to be run against batch-loaded data.
Ability to load data from different sources such as lab data.
Centralized coding (i.e., Normal Lab Values/Ranges) to manage upload of external data.
Tools for gaining efficiency in applying local reference range to particular sets of data.
Ability to Export and Import data as per standards.
Ability for a site to choose lab ranges from multiple local labs.

xii. Integration with other modules

Ability to integrate with other available clinical research tools such as IVRS (Interactive Voice Response System), IWRS (Interactive Web Response System), Lab Management system, Biorepository, CTMS (Clinical Trial Management System), eTMF (Electronic Trial Master File) etc.

Ability of system to interface with SAS & other statistical software
CDMS should have the ability to allow users to import, retrieve and view documents and data from workflows and reports through web access and other applications as well.

xiii. Rights and Roles / Database Administration

Database administration can easily be managed and performed by the authorized personnel.
Database Access: This includes the authority to assign full, limited, read-only, or no access as necessary.
The following roles exist for EDC trials (if applicable), but not limited to: - Project Manager, - Data Manager, - Database Administrator, - Biostatistician, - Database Developer, - CRA/Study Monitor, - Site Coordinator/Nurses, - Investigator
Flexible workflow modification.
Ability to generate a report listing all users who have accessed and modified data (audit trail print out).
Ability to define roles and responsibilities for tasks.
Ability to provide field level access rights assignment.
Available tasks to be assigned contain equivalents to the following: - creation and view of roles and users, - delete and activate roles, - suspend or delete users, - generate and edit data queries, - view data queries, - print queries, - answer/close queries
- create reports view, - update or delete reports, - view and print subject data, - create and set-up sites, - change or delete sites, - enroll subjects, - edit subject information, - create unscheduled visits, - enter data into data entry screens and add notes, - change data without a query, - delete data of subject, visits, or modules, - lock and unlock subject data, - track CRFs, - indicate monitoring status of e-CRFs (EDC only)

xiv. Technical Support and Training

Technical Support - Remote, telephonic and email support. - 24*7 helpdesk management and dial in support for handling minor bug fix/error - The technical support escalation procedure and timelines must be defined.
The bug reporting, documentation and resolution procedure including the minimum response time must be explained.
Train the trainer program must be available for CRA, Site and DM functionality.
On-site training and support must be provided under existing contracts. This contract should include onsite training at the time of delivery of EDC application and after any operational update which requires face to face interaction.
Training and Implementation: user training; product delivery and implementation including customizations, if needed, and user testing of all application components in parallel or as applicable
Online training & e-learning must be available with the product.
The selected vendor will also provide at least 5 days of system administration training which will include, but not be limited to: • System administration • User management • System management • Database management • Creation of reports The vendor will also provide THSTI with documentation in electronic form with instructions on how to use the system and system administration.
Vendor must ensure that the system upgrades/ new version are available to THSTI.
Specify the cost of onsite training, besides the mandatory training mentioned above.

xv. Documentation

The application developer documentation must be provided.
User manual documentation must be provided.
Validation (IQ, OQ and PQ) documentation must be provided.

xvi. Security, Confidentiality and Audit Trail

System must be capable to protect the integrity, authenticity, and confidentiality of the study data. Vendor must ensure that the Internet-based access to the system with additional challenges are clearly documented to ensure security and confidentiality of study data. The following processes and/or system functionality in relationship to system security, confidentiality and auditing must be provided: <u>System Functionality for:</u> - Audit Trail - Electronic Signature The methodology used by the system for security and electronic signatures must be provided: - User identification when accessing a study database (e.g., login username and password, password management). - Site users for e-signing participant visit data or a set of data modified by user. <u>Procedures for:</u> - Backup and restore - Disaster Recovery/Business Continuity (including data hosting capabilities, redundancy, and facility security)

System Status:

- List all currently known limitations of your product

xvii. System Architecture

THSTI is open to a system hosted either in-house or off-site. The architecture should be designed to protect the critical data and services running on the production servers so as not to interfere with any applications which may be utilizing the data.

xviii. Hardware Requirements

The vendor will provide the CDMS with hardware system specifications, including operating system and database server software. These specifications must be adequate to meet the THSTI's needs for at least 5 years for both On-premise and cloud based hosting with India based server therefore, consideration must be made for growth.

xix. Hosting

Vendor should be able to provide the hosting on the following:

- **Cloud based hosting** should be provided in secured and dedicated space in India based server and if required THSTI can ask for the on-premises hosting. Vendor must ensure that hosting server is easily accessible through all the sites without effecting the speed when multiple users are accessing the database at a particular time.

  On premises hosting with test and production environment for the databases. Automatic daily backups must be installed within the system. All the systems and server requirements and configuration must be clearly mentioned in the documents.

Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) must be performed and documented by the vendor and all documents must be provided to THSTI.

Vendor must ensure to provide the support during Performance Qualification (PQ) and test database setup to be performed by the THSTI.

xx. Backup and Disaster Recovery Strategy

The vendor will also provide THSTI its preferred backup strategy for the system. If the proposed system is a "hosted" system, then the selected vendor must provide THSTI with the backup and disaster recovery strategies. If its cloud based then mirror backup must be available with disaster recovery strategy and must have a provision to setup the backup at THSTI server also.

6. PRICE BID / FINANCIAL BID

The pricing is to be provided as follows

6.1 ON PREMISE RATES

S.NO	Particulars	Amount
	Installation of CDMS on THSTI Server. This cost will be inclusive of installation, Operational and Performance qualifications respectively (**Price exclusive of taxes)**	
	Annual support and Maintenance cost for Five years (Price exclusive of taxes)	
	Cost for Data Migration	
	Additional training cost (if required), besides the mandatory training (Price exclusive of taxes)	
	Additional total annual cost for extending the entire services beyond 5th year	
	Additional costing for dedicated server hosting	
Goods and Service tax		
Total all-inclusive cost for 5 years		

In Words Rupees _____only

Note: -

1. If there is a discrepancy between the unit price and total price THE UNIT PRICE shall prevail.

Place :
Date:

Name:

Business Address _____

Signature of Tenderer _____

Seal of Tenderer _____

6.2 CLOUD HOSTED RATES

Sr No	Particulars	Amount
1	Charges inclusive of application installation, Licensing, hosting and support cost of hosting on external cloud based server. The rate will be applicable from the date of study going live for 5 years (**Price exclusive of taxes)**	
2	Cost of Data Migration	
3	Annual support and Maintenance cost for Five years (Price exclusive of taxes)	
4	Additional total annual cost for extending the entire services beyond 5th year	
5	Additional training cost (if required), besides the mandatory training (Price exclusive of taxes)	
Goods and Service tax		
Total all-inclusive cost for 5 years		

In Words Rupees _____**only**

Note: -

2. If there is a discrepancy between the unit price and total price THE UNIT PRICE shall prevail.

Place :
Date:

Name:

Business Address _____

Signature of Tenderer _____

Seal of Tenderer _____