



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

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

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Expression of Interest (EOI) 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**

(EOI No.: THSTI/EOI/PBC/2019-20)

03rd April, 2019

NOTICE INVITING EOI

Ref. No. THSTI/EOI/PBC/2019-20

Date: 03rd April, 2019

On behalf Executive Director, THSTI sealed Expression of Interest (EOI) is invited from eligible and interested firms 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.

Title of the work/service(s)	Cost of EOI Document
Creating an Electronic Data capture platform for Inter-Institutional Program for Maternal, Neonatal and Infant Sciences-A translational approach to studying Preterm birth	Rs. 2000

The complete set of Expression of Interest document may be downloaded from our website: www.thsti.res.in and CPP Portal www.eprocure.gov.in. or may also be collected from the Purchase Section, THSTI, Faridabad on submission of written request and on payment of Rs 2000/- by crossed Demand Draft (Non-refundable); may be drawn on a scheduled commercial Bank in India, in favour of "THSTI, Faridabad", in case of downloading EOI document from the institute website, the firm must submit cost of EOI document Rs.2000/- with its EOI, otherwise EOI will be rejected straightway.

To solicit prospective bidders' feedback, on specifications/terms of the EOI, a pre-EOI meeting with all the prospective bidders is scheduled to be held on 11/04/19 at 2:00 PM. The venue of the meeting will be THSTI, Faridabad. Interested firms are invited to attend the same with a written statement of their queries.

All future corrigendum/amendments etc., if any, will be notified only on the THSTI website and no separate advertisement will be released for the same. Prospective bidders are therefore advised to regularly visit the THSTI website for any such updates.

**Section Officer,
THSTI**

DATA SHEET / TIME LINES

Document No	THSTI/EOI/PBC/19-20
Name of the Work	Creating an Electronic Data capture platform for Inter-Institutional Program for Maternal, Neonatal and Infant Sciences-A translational approach to studying Preterm birth
Brief Scope of Work	An electronic data capture (EDC) system is required for the collection of clinical data in electronic format
Estimated Cost of the Project	30 Lakhs
Period of Contract	90 Days from the acceptance of purchase order
Non-refundable cost of processing	Rs. 2000/-
Start date of sale of EOI Document	04/04/19
Pre-EOI meeting	11/04/19 at 2:00 PM
Revision of EOI (If Required)	12/04/19
Last date & time of submission of EOI applications hard copy	04/05/19 by 6:00 PM
Date & Time of Opening of EOI applications	06/05/19 by 3:00 PM

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.

THSTI has set up niche centres for research in areas relevant to planned translational work. They are: Vaccine and Infectious Disease Research Centre (VIDRC), Pediatric Biology Centre (PBC), Centre for Bio-design & Diagnostics (CBD), Drug Discovery Research Centre (DDRC), Centre for Human Microbial Ecology (CHME) and Policy Centre for Biomedical Research (PCBR). Clinical Development Services Agency (CDSA) and National Bio-design Alliance (NBA) are THSTI's extramural centres.

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 repositied 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.

1. Electronic Data Capture : An electronic data capture (EDC) system is a computerized system designed for the collection of clinical data in electronic format for use mainly in clinical research studies. The clinical data will be collected by the THSTI staff at two of our sites at Gurgaon & Delhi.

2. Brief Scope of Work & specifications

EDC systems should provide:

1. Graphic user interface as an independent/standalone application (data-entry, query management and reporting) compatible with android/windows systems
2. Offline and online data entry /save feature
3. Integrate with all the sub domains of the study i.e. site, quality and data management teams, configurable role-based access control of data
4. Edit checks both online and offline
5. Platform for automated and manual discrepancy/query management (generation and resolution)
6. Provision of audit trails for data entries /corrections
7. Capability to import/ migrate data from existing MS – SQL to Clinical Data Management system
8. Ability to generate standard and customized reports.
9. Data storage in reputed secure cloud-based servers (Amazon Web Services/ Microsoft Azure/Google Cloud) with dedicated server space, assured uptime of 99.9%, appropriate bandwidth, appropriate storage with control panel credentials present exclusively with THSTI
10. All the sensitive data must be transferred and stored in the server in encrypted format.
11. Exporting of data in multiple (excel, csv, sas, pdf & dta) format
12. Scalable solution that can adapt to with changes in the study protocols (Change user/Site/CRF's Page)
13. 21CFR part 11 compliant
14. Training and retraining (annual and after every upgrade) for THSTI staff to run the EDC
15. Any bug fixes whatsoever it may arise within the course of study shall be provided by the bidder without any upgrade or additional cost.
16. Helpdesk operations- The bidder should provide 24*7 helpdesk management and dial in support for handling minor bug fix/error.
17. The system must support extensive logging at all levels and associated tools for audits and quick alerting in case of unforeseen malicious access.
18. An SMS or email alert facility for any critical breakdown or activity should be available as per the configuration.

It may be noted that this invitation should not be construed as a Tender/ Request for Proposal (RFP) in any form and would not be binding on the institute in any manner whatsoever.

3. Sealed offer prepared in accordance with the procedure enumerated in this document should be submitted to the Executive Director, THSTI, NCR Biotech Science Cluster, 3rd Milestone, Faridabad-Gurgaon Expressway, Faridabad by **05/05/2019 latest by 2:00 PM. The EOI should be valid for 180 days from the date of opening.** The organization / agency who is submitting the offer is required to do so after visiting the institute and examining the whole system. Before submitting his/her offer, the consultant should be apprised about the detailed requirements, expectations, nature of studies conducted by THSTI and the nature of work he/she is expected to do.

4. The application should be accompanied with the following information failing with the EOI will be summarily rejected: -

- A.** A capability statement (Not more than two pages).
- B.** A write up on the understanding of the assignment with respect to the aforementioned brief scope of work.
- C.** Company/ Organization profile giving details of current activities and management structure.
- D.** Evidence of incorporation.
- E.** Annual report including balance sheet and profit and loss account statement for the past three years.

5. Expectations from the professional organization/ agency: -

Apart from the scope of work described in earlier section, the agency is expected to understand the specific needs of THSTI in this endeavour and come up with a complete plan. The representatives from the organization / agency should interact with the concerned officials/Investigators from THSTI to understand the requirement.

6. Pre-qualification of the Organization :-

The agency / organization submitting the offer will be shortlisted, who are capable of rendering high degree of professional services in the field. These short listed agencies may be invited later to submit their proposals. Additionally, the agencies/organizations must fulfil the following criteria :-

- A.** Should be a reputed and established company/ organization having minimum experience of serving at least 2 similar clients and should have at least 3 years of developing and designing the study specific Electronic Data Capture Platform (provide reference).
- B.** Should demonstrate the EDC platform either through Skype or in person prior to their proposal.
- C.** The organization should have capacity to deliver within 3 months from the allotment of work order & should be able to support and maintain the platform (for runtime errors, server downlink errors and any other system errors) for 3 years from the date of delivery.
- D.** Undertaking for never been black listed by Centre/State Government/any PSU/private sector.
- E.** Registration with Income Tax and Service Tax authorities
- F.** Preference will be given to the agencies/consultants who are currently executing similar type of work.

7. Methodology:-

The methodology for finalization of work proposal will be in two stages, comprising the offer for the said proposal in the first stage, and inviting the techno-commercial offer /Request for proposal (RFP) from the qualified agency / organization in the second stage. The evaluation procedure for the finalization of proposal would follow on the quality- cum cost-based system. The scoring would be done on the basis of below parameters:

S.no	Description of Parameter	Maximum marks	Scores obtained
1	Number of similar clients, served in past. 10 marks for each client, based on the submission of	30	

	satisfactory report from the client.		
2	Technical proposal as per the clause 4 (a),4(b),4 (c)	40	
3	Live demonstration of the application in front of committee designated by THSTI competent authority	30	

The agencies scoring more than 70 marks would be considered for further RFP process. The marks will be given by the committee at its own discretion. In this regards the decision of the Executive Director shall be binding to the bidder.

The cost associated with the preparation, visits and submission of the proposal shall be borne by the bidder.

8. Terms of Reference:-

Terms of reference for the proposal outlining the techno-commercial offer / RFP are as follows:-

- A.** Only shortlisted Organizations will be issued techno-commercial documents, wherein technical and financial offers are to be submitted separately.
- B.** Executive Director, THSTI reserves the right to cancel/withdraw the process if necessity so arises, or to seek further information/details.
- C.** Organization / Agency found to have indulged in any corrupt or fraudulent practices will be out rightly rejected.

8. Whether the firm/ organization has any widely accepted certifications. If yes, furnish certified copies:

9. Turnover for the last three years:

10. List of projects in the last five years in which firm/ organization/consultant has delivered services similar to that in proposed advertisement:

Name of the Project	Year	Country	Value	Recipient's Name	Short description of the Project

11. Whether the following documents have been enclosed with the application: -

1	A capability statement	Yes/ No
2	A write up on the understanding of the assignment after site inspection.	Yes/ No
3	Company/ Organization profile giving details of current activities and management structure	Yes/ No
4	Evidence of incorporation	Yes/ No
5	Annual report including balance sheet and profit and loss account statement for the past three Years /Income tax related documents.	Yes/ No

(Signature of the Bidder)

Name

Place:-

Date:-