ट्रांसलेशनल स्वास्थ्य विज्ञान
एवं प्रौद्योगिकी संस्थान
TRANSLATIONAL HEALTH SCIENCE
AND TECHNOLOGY INSTITUTE

(An Autonomous Institute of the Department of Biotechnology, Govt. of India)
NCR Biotech Science Cluster, 3rd Milestone, Faridabad – Gurugram Expressway, P.O. Box No. 04, Faridabad - 121001

Recruitment notice no.: THS-C/RN/05/2023 **Dated: 03rd May 2023**

1. 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 products to improve human health.

2. THSTI has built several inter-institutional collaborations and connectivity with industry supported by well-trained teams of research and laboratory staff. This foundation has helped pursuit of thematic research programmes which can be broadly categorized as, (a) Infectious diseases and Immunology (b) Maternal and Child Health, (c) Non-communicable disease (d) Multidisciplinary clinical and translational research. These will be strengthened by four core facilities viz. Small Animal Facility, Data Management Centre, Biorepository and Bioassay Laboratory that will serve not only the research programmes of THSTI, but also the National Capital Region Biotech Science Cluster and other academic and industrial partners.

3. This recruitment is to fill up the vacancies for project positions at Clinical Development Services Agency (CDSA) center. CDSA is a niche center of THSTI established to facilitate development of affordable healthcare products for public health diseases. It is the only public Centre in the country created with a mandate to support and nurture cost-effective, high quality, not-for-profit technology-based preclinical and clinical product development as well as support clinical research conducted by public agencies. It works towards development of an eco-system for training and learning and work with public sector institutions, and small and medium enterprises (SME) to translate innovative technologies into medical products for public good.

   The main objectives of CDSA are:

   a) As an academic Clinical Research Unit, to undertake & provide end -to- end clinical study support for investigators and SMEs in study planning, set up, conduct: project management, monitoring, data management, safety reporting, analysis and report writing
   b) Build research capacity and capability through high quality training in the area of clinical development/trials and regulation
   c) Support and strengthen clinical research environment in the country
   d) Regulatory science and policy support: provide tools and approaches to support researchers, regulators, health policy makers & industry

Applications are invited from eligible candidates to fill up the following positions:

1.	**Name of the post & Project**	**Consultant Medical Monitor (01 position)**
	Name of the Study	(A Phase III, Multicenter, Randomized, Double-blind, Three-arm Placebocontrolled Trial to Evaluate the Efficacy and Safety of two vaccines in Preventing Tuberculosis (TB) in Healthy Household Contacts of Newly Diagnosed Sputum Positive Pulmonary TB Patients funded by ICMR in Six States of India)
	Emoluments	Rs 80,000/-
	Age	45 years
	Duration	Up to 31 December 2023
	Minimum Educational Qualification and Experience	**Essential qualification and work experience:** • MD/MS or Postgraduate diploma from a recognized university with 2years of R&D experience OR. OR • MBBS/BDS or Allied medical degree from a recognized University with 5years of R&D experience. **Desirable qualification and work experience:** Candidate with relevant experience in medical affairs and/ or medical monitoring of research projects will be preferred Past experience of working on Vaccine projects and/or regulatory studies will be an advantage.
	Job profile	**<u>Responsibilities</u>** • The roles & responsibilities of Medical Monitor (MM) are as follows but not limited to: • The MM, in consultation with safety oversight committees, will provide safety review during the execution of the clinical trial as per the pre-defined and approved safety management plan. This oversight includes reviewing safety information and providing applicable recommendations. • Interpretation of single and/ or grouped adverse events, serious adverse events, drug effect and attribution of causality, and disease condition • Educating, training, and mentoring research teams in safety monitoring and reporting • Conduct on-site medical monitoring visit and communicate the observations through detailed visit report • Assist sponsor in preparation of expedited and periodic reports • Review of clinical narrative reports describing the event and support in finalization. • Participate in the development of CRF, statistical analysis plan (SAP), DMC charter and other documents as required by the study. • Participate in study management team meetings, DMC and technical review

		meetings, as required. • Interact with investigative sites, address protocol/medical questions in consultation with sponsor medical monitor • Perform review of data generated by data listings or statistical analyses. • Review medical coding of safety data • Review individual data with SAEs and potentially clinically important laboratory tests or vital sign abnormalities. • Participate in all reviews and procedures required for database lock. • Provide the Study Team with medical expertise during key activities • Contribute to, draft and/or edit Clinical Study Reports (CSR) • Assist in the development of scientific meeting abstracts and presentations as well as manuscripts Any other assignment with Clinical Portfolio Management team, basedon project deliverables or exigencies. **Skills** • Ability to gain trust and confidence with stakeholders. • Operational skills including focus and commitment to quality management and problem-solving • Influencing skills including negotiation and teamwork • Effective communication skills, the provision of timely and accurate information to stakeholders • Understanding of GCP, regulations, and guidelines • Knowledge of adverse medical event investigation, analysis, and reporting procedures and standards • Fair and ethical. Creates a culture that fosters high standards of ethics. Basic business computer skills (MS Word, Excel, e-mail)
2.	**Name of the post & No.**	**Consultant- Senior Program Manager, (01 Position)**
	Name of the Program	NBM Program
	Emoluments	Rs. 1,25,000/-
	Age Limit	55 Years
	Duration	One year
	Location	CDSA, THSTI, NCR, Biotech Science Cluster, Faridabad
	Minimum Educational Qualification and Experience	**Essential qualification and work experience:** Medical professional qualification (MBBS OR BDS or equivalent qualification)from a recognized university with at least 8 years of work experience in clinical project management and/or drug development. **OR**

		Post graduate degree in a Science or health related discipline with at least 10 years of work experience in clinical project management and/or drug development. MD/PhD will be considered as 3 years' experience **Essential work experience:** • Significant experience of clinical trial or public health project management in a recognized organization /institute (academic clinical trials unit, CRO, clinical project management and/or clinical trial/study monitoring pharmaceutical, biotechnology, or device company) leading/directing a clinical study / R&D team. Demonstrable experience of line management, project management concepts and ability to understand, explain and communicate project concepts using standard tools and templates
	Job profile	Lead the clinical trial/studies conduct team with overall responsibility for project management including quality monitoring and clinical operations and training for clinical studies. Responsible to undertake overall coordination of medical review and writing support and cross functional coordination of the programme and work closely with the Project Management unit of National Biopharma mission (NBM) to develop and maintain the overall project plan and time lines. The roles & responsibilities of Senior Program Manager are as follows but not limited to: • Oversee and ensure Implementation and conduct of clinical trial protocols per project timelines and service level commitments. • Establishment of procedures to ensure adherence to trial protocols • Review the study proposal and/or protocol for design, conduct, and develop methods for clinical studies. • Responsible for training investigator sites in Good Clinical Practice as well as study conduct. • Ensure the investigators' compliance with the study protocol, Good Clinical Practice, SOPs, and all applicable regulatory requirements. • Support customization of protocols, design of case report forms and informed consent forms, statistical analysis plan (SAP), DMC charter, and other documents as required by the study, as applicable. • Responsible for the quality, quantity, and timeliness of clinical trial data. • Perform review of data generated by data listings or statistical analyses. • Ensure compliance with quality standards, safety reporting, cost and time metrics of the project. • Support Clinical Trial Application submissions, as applicable. • Provide supervision of central laboratory activities. • Oversee and ensure implementation of project plan, including all elements listed in the project plan template as appropriate for project (Roles & Responsibilities, Communication Plan, Risk Analysis etc.)

		• Literature review to advise PMU on how to modify aspects of the trial without undermining the validity and integrity of the trial for adaptive and seamless designs. • Support NBM-PMU for review of interim and final study report. • Conduct oversight monitoring, verify the adherence to the procedures outlined in the safety management plans, SOPs, and forms set up for the study. Ongoing review of safety data as well as comprehensive safety during on-site visit • Educating, training, and mentoring research teams in safety monitoring and reporting • Participate in study management team meetings, DMC, and technical review meetings, as per NBM recommendation/ requirement • Support PMU-NBM to align the constitution of DSMB and compilation of DSMB charter as per study requirements and ensure strict adherence to the DSMB recommendations. • Work with data management and other departments to track progress and milestones of the project • Support the Chief -Clinical Portfolio Management (CPM) in the development of overall strategy and business policies • Responsible for reviewing study protocols, investigator's brochure, clinical study reports, IND sections • Revise SOPs or suggest process improvements for consideration. • May draft new SOPs for review and act as reviewer for Clinical SOPs, as assigned and appropriate. • Provide or arrange for project-related training as needed for team members • Initiate the project following Best Practices in Project Management • Provide consulting services to assist in the development of new drugs ordevices under the direction of the senior management
	Professional Skills	• Ability to gain trust and confidence with stakeholders. • Operational skills including focus and commitment to quality management and problem-solving • Influencing skills including negotiation and teamwork • Effective communication skills, the provision of timely and accurate information to stakeholders • Understanding and applied knowledge of GCP, clinical trial regulations, and ICMR guidelines on ethical standards for biomedical health research • Knowledge of adverse medical event investigation, analysis, and reporting procedures and standards • Fair and ethical. Creates a culture that fosters high standards of ethics. • Basic business computer skills (MS Word, Excel, e-mail)

- Last date of receipt of online application: **24th May 2023**
- The application will be scrutinized/shortlisted and processed for further selection.

SUBMISSION OF APPLICATION WILL BE THRU ONLINE MODE ONLY OTHERWISE IT WILL GET REJECTED OR IGNORED.

GENERAL TERMS & CONDITIONS: -

a) This is short-term positions and extension will be granted subject to satisfactory performance of the incumbents and tenure of the project for which they are selected. Those appointed to these positions will not have any claim for regularization of their employment.

b) All educational, professional and technical qualification should be from a recognized Board/University.

c) The experience requirement specified above shall be the experience acquired after obtaining the minimum educational qualifications specified for the post.

d) Closing date of online application will be the CRUCIAL DATE for determining eligibility with regard to age, essential qualification etc.

e) The age limit, qualification, experience and other requirements may be relaxed at the discretion of the competent authority, in case of candidates who are otherwise suitable. In case candidates are not found suitable for the posts notified, they can be offered lower post / lower emoluments on the recommendation of the Selection Committee.

f) Age and other relaxations for direct recruits and departmental candidates: 1. By five years for candidates belonging to SC/ST communities. 2. By three years for candidates belonging to OBC communities. 3. For Persons with Benchmark Disabilities (PWBD) falling under the following categories: (i) UR - ten years, ii) OBC - 13 years (iii) SC/ST - 15
4. Age is relaxable for Central Government servants up to five years in accordance with the instructions or orders issued by the Central Government, from time-to-time. 5. There is no upper age limit for the Institute employees who are treated as departmental candidates. 6. For Ex-servicemen up to the extent of service rendered in defense forces (Army, Navy & Air force) plus 3 years provided they have put in a minimum of 6 months attested service.

g) All results will be published on our website and all future communications will be only through email.

h) In case a large number of applications are received, screening will be done to limit the number of candidates to those possessing higher/relevant qualification and experience.

i) With regard to any provisions not covered in this notification, the bye laws of THSTI / Govt. of India rules / guidelines shall prevail.

j) Canvassing in any form will be a disqualification.

HOW TO APPLY:

1. **Documents to be kept handy before filling up the online application:** (all the documents except (i) should be in pdf format):

   i) A soft copy of your passport size photo and signature. (jpeg/jpg/png format)
   ii) A comprehensive CV containing details of qualification, positions held, professionalexperience

/ distinctions etc.

iii) Matriculation certificate (equivalent to 10th Standard) / Mark sheet
iv) Intermediate certificate (equivalent to 12th Standard) / Mark sheet
v) Graduation/Diploma degree certificate / Mark sheet
vi) Post-Graduation degree certificate & Mark sheet (if applicable)
vii) PhD/MD Degree (if applicable)
viii) Relevant experience certificates (if applicable)
ix) Caste / Disability certificate in the format prescribed by the Govt. of India, if applicable

2. Procedure for filling up online application:

i) The eligible and interested candidates may apply online at the Institute's website www.thsti.res.in/career. Applications through any other mode will not be accepted.
ii) The following will be the step wise procedure-
A) Step 1 : Details of applicant
B) Step 2 : Uploading of documents
C) Step 3 : Payment of application fee
- The payment can be made by using Debit Card / Credit Card / Internet Banking / UPI.
- Once payment is made, no correction / modification is possible
- Candidates are requested to keep a copy of the provisional receipt for future reference.
- Fee once paid shall not be refunded under any circumstances.
- Details of fees to be paid are as shown below:

S. No	Applying on direct recruitment	Applicationfee amount
1.	Unreserved, OBC & EWS candidates	Rs 590/-
2.	SC/ST/Women/PwBD	Rs 118/-

D) Step 4 : Submission of application form.

iii) On successful submission of application, an auto-generated email containing the reference number will be sent to the email address provided. Please keep a note of the reference number for future correspondence.
iv) Candidates are required to keep a printout of the online application form by using the print button on the dashboard for future reference.
v) Candidates must ensure that he / she fulfils all the eligibility criteria as stipulated in the advertisement. If it is found that he / she does not fulfil the stipulated criteria during the recruitment process, the candidature of the candidate will be cancelled. If the same is noticed after the appointment, the candidate will be terminated following due process.
vi) Incomplete applications shall be summarily rejected and no correspondence in this regard shall be entertained.
vii) In case of difficulty in filling up the online form, please send e-mail to **HR.CDSA@THSTI.RES.IN** along with the screenshot of the error displayed (if any).

"Government strives to have a work force which reflects gender balance and women candidates are encouraged to apply"

(M.V.Santo)
Head-Administration

==========End of the document==========