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/06/2023 **Dated: 25th 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**	**Head, Clinical Science** **(equivalent to Principal Scientist I - Medical)**
	Number of posts	One
	Emoluments	Rs. 1,65,000/-
	Age	55 years
	Duration	One Year
	Essential Functions	Lead the study design, research method, medical aspects and conduct of clinical trial/studies. Overall responsibility to lead the team on development of protocol, study design, grant application, coordinate conduct of clinical trial/ studies. Serve as medical liaison to all stakeholders – funding agencies, investigators, project teams
	Minimum Educational Qualification and Experience	MD/DNB or equivalent from a recognized university with at least five years of post-qualification clinical research experience especially in protocol development, site set up, trial/ study conduct, safety reporting and management
	Job profile	**Leadership and Strategy:** • Provide leadership on study design, research method, medical aspects and conduct of clinical trials and clinical study projects. • Contribute to drafting policies and standard operating procedures • Contribute to developing the clinical trials / studies portfolio • Responsible for dissemination of information for CDSA staff on best practices for clinical research • Serve as a liaison for research methods and medical functions to all stakeholders – funding agencies, sponsor, investigators, project teams and provides medical and regulatory guidance throughout the life cycle of trials/studies. **Clinical Science** • Provide leadership to clinical trial and clinical study projects on research methods, medical and safety aspects. • Participate in clinical review meetings and document preparation for meetings as required • Guide the project teams in the preparation and review of study documents like o clinical protocols, informed consent forms etc. o integrated clinical and statistical summary reports, o meeting presentations o journal articles, and other documents • Review all documents assigned for research methods relevant issues including safety • DSMB: Develop/ review DSMB charter, support constitution of DSMB for clinical trials, organize and coordinate DSMB meetings

		• Provide input as necessary to Feasibility Studies, Data and Safety Monitoring Committees (DSMC) and other committees, clinical/ product development planning meetings • Assist in the preparation of client proposals • 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. **Training** • Oversee development of training modules and project specific and protocol specific training • Faculty for training programs conducted by CDSA.
	Skills / Knowledge / Aptitude	• Leadership skills that include the ability to build effective medical and project teams, ability to motivate others, delegation, drive and timely/quality decision making • Demonstrated understanding of clinical research methods, conduct of regulatory and non-regulatory trials. • Good organizational skills with ability to prioritize to meet multiple deadlines • Ability to multi-task and problem solve • Demonstrated ability to successfully manage multiple projects and cross-functional teams • Flexible to adapt to and manage change • Personal qualities that include the ability to gain trust and confidence with a variety of clients, good learning ability, managerial courage, action oriented and resilience in a fast-paced and rapidly changing environment • Effective communication skills that include the provision of timely and accurate information to stakeholders, proficient in English, strong written and oral communication skills • Ability to develop and deliver presentations, prepare technical reports and contribute effectively in the manuscripts • Familiarity with basic computer software: MS Word, E-mail, Excel, Internet • Ability to travel for business purpose.
2.	**Name of the post & Project**	**Head -Training**
	Number of posts	**01**
	Emoluments	Rs. 1,65,000/-
	Age	50 years
	Duration	One Year
	Minimum Educational Qualification and Experience	**Essential Qualifications and Experience**: MD/ PhD in life sciences or related discipline from a recognised university with at least 5 years of post-qualification work experience **OR** MBBS with MPH or BDS with MPH from a recognised university with at least 7 years of post-qualification work experience

		OR MBBS or BDS or MSc in life sciences or related discipline from a recognized university with at least 8 years of post-qualification work experience **Work experience** • Demonstrated experience and capability in planning and coordinating academic course(s) at the post-graduate level • Experience in developing course content, training material, etc. for professional courses and/ or trainings • Proven competency and experience in developing online resources in clinical research • Working knowledge of relevant national and international guidelines and regulations • Demonstrated experience in developing online and/ or offline resources for clinical research in India • Demonstrated experience in management and coordination of multi-stakeholder projects **Desirable experience:** • Working knowledge of design, development, and execution of high-quality training programs • Experience in clinical research • Experience in initiating scientific/medical education or training programs will be useful • Experience of managing an online platform in clinical research, will be useful
	Job profile	This position is responsible for taking lead during the planning and conduct of the M.Sc. Clinical Research Course offered by THSTI and other such courses. The position will report to Principal Scientist II- Training. The role and responsibilities of this position are described in detail below: • **Leadership and strategy** • Provide support to the senior management in development of overall strategy • Contribute to the development of programs for capacity and capability building in area of clinical development and translational research as per the national mandate and as guided by the senior management • Lead on drafting relevant training-related policies and standard operating procedures. • Develop and implement strategies for the design, development, and conduct of the M.Sc. Clinical Research (specialization in Clinical Trials) programme, ensuring the highest standard of delivery and quality • Develop and implement strategies for evaluating the M.Sc. course and its impact • Act on behalf of CDSA-THSTI for M.Sc. Clinical Research-related activities, meeting with internal and external partners (academic,

		industry collaborations, vendors, regulators, etc.) • Ensure consistent application of core CDSA-THSTI policies and operating procedures, across all the deliverables • Continually review, improve, and respond to all the changes necessary to uplift the quality standards of the M.Sc. course • Implement new and innovative approaches to conduct the M.Sc. course • Participate in workshops to learn about various methodologies and assessment methods related to the conduct of a professional, post-graduate course, thereby contributing towards its continued improvement • With the Head Services, oversee and/ draft Agreements, Memorandums of Understanding (MoUs), or other documents related to the M.Sc. course • Contribute as a resource person in key areas of clinical development like current ethical and regulatory requirements for conducting clinical trials in India, Good Clinical Practice, etc., and represent CDSA-THSTI in national & international forums • Ensure the dissemination of information for CDSA-THSTI • staff on the CDSCO/ ICMR Clinical Trials Regulations and its implications, regulatory requirements, research governance and Good Clinical Practice (GCP) **B. Building the Clinical Research Ecosystem** • Contribute to the development of online and offline resources for clinical research in India, at CDSA-THSTI • Ensure the maintenance and updates of all existing resources on clinical research, developed by CDSA-THSTI • Contribute towards the development and enhancement of online platforms offered by CDSA-THSTI, for clinical research in India **C. Technical/ Academic** • **Contribute as a resource person and steer the Master of Science (MSc) in Clinical Research with a specialization in clinical trials program being initiated at CDSA-THSTI in collaboration with THSTI partners and Regional Centre for Biotechnology, Faridabad.** **D.GCPPCS scheme management** • **Oversee the Good Clinical Practice Professional Certification Scheme (GCPPCS) owned by CDSA-THSTI** • **Lead on the technical (GCP) part of GCPPCS and contribute to the certification expertise related to ISO 17024 compliance requirements.** • **Lead in Troubleshooting and finding pragmatic solutions when issues or concerns are raised by the team or its users or other stakeholders.** • **Ensure GCPPCS awareness is spread across India and beyond borders.** • **Support the GCPPCS Secretariat and all Training Institutions, and Personnel Certification Bodies working with CDSA-THSTI.** **Administrative** • **Lead training vertical meetings** • **Communicate to the CDSA head regarding training needs or**

		performance issues • **Participate in performance evaluation reviews for direct reports** • **Contribute to strategic direction of the Trainings group.** • **Participate in the recruitment and hiring process.** • **Other responsibilities assigned by management** **Financial** • Review budget forecasts and management reports for the M.Sc. Course • Contribute to budget preparation for the M.Sc. Course and other department needs, if required.
3.	**Name of the post & Project**	**Data Scientist** **(Equivalent to Research Scientist)**
	Number of posts	One Post
	Emoluments	Rs. 1,10,000/-
	Age	40 years
	Duration	One Year
	Essential Functions	This position is responsible for supporting Head Data Science during planning of data management for assigned clinical studies and trials, contributing to grant application in terms of data management, data protection and data security; budgeting for data management. The Data Scientist will have direct line reports like, but not limited to data manager, Quality Analyst, data coordinator and data entry operator. The post will work closely with the Faculty In charge of CDSA and Head Data Science with the following duties
	Minimum Educational Qualification and Experience	**Essential Qualifications and Experience:** Post graduate degree from a recognized university preferably in Computer application/ Computer science/ Data science with experience of working in a research or healthcare environment and at least 6 years of work experience in clinical data science and/ or data management **OR** Post graduate professional degree preferably in Computer application/ Computer science/ Data science with experience of working in a research or healthcare environment and at least 5 years of work experience in clinical data science and/ or data management **OR** Professional graduate degree preferably in Computer science/ Computer application with experience of working in a research or healthcare environment and at least 7 years of work experience in clinical data science and/ or data management **OR** Graduate in any discipline with one-year diploma in computers with experience of working in a research or healthcare environment and at least 8 years of work experience in clinical data science and/ or data management **Essential:**

		• Working knowledge in software design and development, techniques, testing and validation methodologies and software documentation. • Strong IT skills • Experience in Clinical Data Management, and Software Development **Desirable:** • Degree/ diploma or an equivalent degree in systems management or information technology from a reputed institution. • Should be well versed with technologies: SQL, MS Dot.Net, JavaScript, HTML, Web services, Content Management System.
	Responsibilities	**Database development** • Interact with study teams (including Data Management, CPM and Statistics) to understand the data and project management needs and develop appropriate solutions • Support study team members in developing CRF annotation & designing, data management plans and other study specific documentation as required • Provide guidance and training on metadata completion and maintenance • Support study team during the database user acceptance testing process • Support in procurement of clinical data management and monitoring tools • Support software validation (performance qualification) • Support integration and upgradation of Medical dictionaries within the application if necessary. **Data management support** • Ensure all sensitive data is secured in dedicated server /server space • Plan and develop study specific DM requirements (storage/archival) in consultation with study team. • Support the study teams in setting up paper/ remote or electronic data capture at the site • Support data managers in the development and maintenance of Data Management Plans • Assist with data quality assurance and auditing • Oversee DM activities at the assigned clinical site • Lead in preparation of datasets for analysis including data cleaning and ensuring compliance with the data protection. **Data quality and methodology** • Support CPM team in developing and implementing procedures for central data monitoring.

		• Provide efficient approaches to quality control through supporting project teams in the identification of missing data, inconsistencies in the data over time, protocol deviations and reliability of data. • Working in conjunction with the study teams to achieve these deliverables.

- **For Sr. No. 1 & 2 Interested candidates fulfilling the criteria as mentioned above may walk-in for written test/skill test/interview on 31st May 2023 at 10:00 am & 01:00 pm respectively at THSTI, NCR Biotech Science Cluster, 3rd Milestone, Faridabad-Gurugram Expressway, Faridabad - 121001**
- **For Sr. No. 3 Last date of receipt of online application: 14th June 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) The positions will be hired initially for a period of one year with a probation period of six months. The 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 number of positions to be hired, 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 postsnotified, 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.

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 numberof 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 wrong 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, professional experience / 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
   x) Forwarding letter / NOC from the current employer in the case of candidates working in Govt. / PSUs / autonomous bodies.

2. Procedure for filling up online application:

i) The eligible and interested candidates may apply online at the Institute's website https://thsti.res.in/en/Jobs. 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

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