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/02/2023 **Dated: 13th February 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**	**Clinical Data Manager (DTRC)**
	Number of posts	One
	Emoluments	Up to Rs 90,000/-
	Age	45 years
	Duration	03 Months (likely to be extended)
	Minimum Educational Qualification and Experience	**Essential qualification and work experience:** • Educated to Graduation degree level in healthcare field, IT, Computer Applications with 6-8 years in clinical data management (Clinical Data Manager/ Data Validation Associate/ Data Quality Manager). OR • Educated to Graduation degree level in healthcare field, IT, Computer Applications with 6-8 years in clinical data management (Clinical Data Manager/ Data Validation Associate/ Data Quality Manager). **Desirable qualification and work experience:** Diploma in Clinical research and clinical data management. Familiarity with industry standard CDMS and some programming skills: • Preparation of Clinical Study Data Management documents
	Job profile	**Responsibilities** • Clinical Study Protocol understanding and experience in the preparation of Data Management documents - DMP (Data Management Plan), DVP (Data Validation Plan/ Edit Checks Document), Annotated CRF, Data Entry Guideline etc. • Quality Check of Database Design, Validation Program, Annotated CRF, Data Extract Views, Laboratory Details, Site and Investigators and Final Data Listings • Good experience and working knowledge of CRF designing • Preparation of Data transfer guidelines for external data load and self-evident correction chart. • Working knowledge of Query management, data cleaning, data freezing and data archival. • Change Requests and takes approval from sponsor • Global library review and approval for changes • Interact with other project team members to support the set-up, maintenance, and closure of the Data Management aspects of the project • Sound knowledge of Clinical Database Development tools, logics and techniques and GCDMP • Working knowledge of database standards and study development process, CDM SOPs, CDISC & SDTM standards

		• AE/SAE reconciliation • Knowledge of medical dictionaries integration and medical coding in the databases. • Preparing interim reports and review of listings of data for clinical trial status and data extraction in collaboration with the statistician • Maintaining and archiving of clinical study related documents • Participates in cross functional team meetings & external client meetings as DM representative • Generate ad-hoc reports as needed • The data manager will ensure that security of all data is maintained and confidentiality of participants is protected. • Managing requests for data from external third parties – including liaising with internal staff and external collaborators to provide data in a timely and appropriate manner and maintenance of a database detailing the status of such external data requests. • Knowledge of Laboratory Information Management Systems (LIMS) to track requisition and specimen status to ensure prompt turnaround time of sample results. • Maintain stringent standards for quality, identifying any issues which might adversely impact the quality of test results and immediately communicating these to the appropriate management representatives to ensure prompt resolution • Create and/or update laboratory standard operating procedures, as needed • Verification of information fidelity in the specimen medical record and the electronic database. • Review information relating to the correlation of test results and final reports. • Releasing test results to physicians in a report format. • Effective interaction with intra-departments to ensure all required, vital information and documentation is acquired in a timely manner. • Clinical Lab Support as needed and not limited to: Biorepository functions, Regulatory Audit support, Sample Accessioning and Receiving. • Lead in preparation of datasets for analysis including data cleaning and ensuring compliance with the data protection. • Development of Standard Operation Procedures and training to the study team for the implementation of medical coding in the CDMS. • Supervise DM activities at the clinical site.

		Skills • Good management & leadership skills • Familiarity with GCP, US-FDA 21 CFR 11, regulatory requirements and data standardization guidelines. • IT literate (experience with Microsoft based applications and other CDMS applications) • Must have experience in handling EDC tools • Validation programming • Must have understanding of clinical trials and familiarity with clinical data management functions. • Good interpersonal, verbal and written communication skills. • Client focused approach to work. • A flexible attitude with respect to work assignments and new learning. • Meticulous attention to detail. • Effective time management in order to meet metrics or team objectives. • Commitment to project and team goals. • Must be able to work independently but seek guidance when necessary. • Team player with outstanding inter-personal, negotiation skills and organizational skills. • Sense of urgency in completing assigned tasks. • Exhibits a sense of urgency about solving problems and completing work. • Shows commitment to and performs consistently high quality work. • Ability to model behaviors and ethics in line with CDSA Mission and Vision.
➢ **Interested candidates fulfilling the criteria as mentioned above may walk-in for written test/skill test/interview on 22nd February 2023 at 11:00 am at THSTI, NCR Biotech Science Cluster, 3rdMilestone, Faridabad-Gurugram Expressway, Faridabad - 121001**		

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) 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.

e) 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.

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

g) 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.

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

i) Canvassing in any form will be a disqualification.

"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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