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/RN/45/2021. **Dated: 18th November 2021**

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) centre. CDSA is a niche centre 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

- 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
- Build research capacity and capability through high quality training in the area of clinical development/trials and regulation
- Support and strengthen clinical research environment in the country
- Regulatory science and policy support: provide tools and approaches to support researchers, regulators, health policy makers & industry

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

1.	**Name of the post: Chief- Clinical Portfolio Management** **Number of posts:** One **Emoluments:** Up to Rs 2,11,200/- **Age:** 55 years **Minimum Educational Qualification and Experience** Medical professional qualification (MBBS OR BDS or equivalent qualification) from a recognized university with at least 12 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 15 years of work experience in clinical project management and/or drug development. Significant experience of clinical trial or public health project management in a recognized organization /institute (academic clinical trials unit, CRO, pharmaceutical, biotechnology, or device company) leading/directing a clinical study / R&D team. **Job profile** Lead the clinical trial/studies conduct team with overall responsibility for project management including quality monitoring and clinical operations for clinical studies. **A. Leadership and Strategy** • Support the CDSA Head in the development of overall strategy • Lead on drafting relevant policies and standard operating procedures • Contribute to developing the clinical trials/studies portfolio • Lead on the development of systems/processes for conduct and reporting on clinical trials / studies and medical device portfolio (including mechanisms for prioritizing clinical trials/ studies and for ensuring full cost recovery and income generation). • Analyze and formally report data and information on trends related to research sponsorship activities • Ensure consistent application of core CDSA policies and operating procedures across the CDSA sponsored trials/ studies portfolio • Act as the lead on behalf of CDSA for projects and committees, meeting with internal and external partners (academic and industry collaborations, vendors, sponsors and manufacturers and regulators) • Continually review and respond to changes required to shape the infrastructure, functionality and standards of clinical trials/ studies management, including the development and implementation of systems, operating procedures and policies. • Effect change and/or ensure dissemination of regulatory effective change management systems are implemented to facilitate the changing clinical trials environment in India and CDSA, in particular the operational implications of new clinical trials and CDSCO/ ICMR regulations and policies. • Provide expert support to projects with regards to compliance, policy, sponsorship and high-risk studies • Represent CDSA at regulatory inspections and meetings as required • Act as a key advisor on, collating project reports and writing position papers as well as advising on “higher risk” studies • With the Administrative Manager and Head Regulatory Science and Medical Affairs, oversee and draft Memorandum’s of Understanding (MoU’s) or other documents to outline the delegation of duties from the sponsor office to CDSA and other stakeholders of the projects • Actively contribute to or lead on initiatives related to the development of CDSA including

resourcing, skills and training, systems and aligned risk assessments and strategies

- Lead in trouble shooting and finding solutions when issues or concerns are raised by researchers with regards to trials and "higher" risk studies
- Ensure the dissemination of information for CDSA staff on the CDSCO/ ICMR Clinical Trials Regulation and its implications, regulatory requirements, research governance and Good Clinical Practice (GCP).

B. Operations Management

- Oversee the preparation of proposals
- Participate in business development activities.
- Participate in clinical review meetings (teleconferences and /or face to face) and document preparation for meetings as required
- Solicit expert advice, develop collaborative relationship with key experts and investigators
- Organize meeting with investigators to understand the scope of work
- Ensure that any relevant Master Services agreement is in place for individual projects
- Review the Project contract with appropriate functional heads to identify staff necessary for the project team
- 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.)
- Oversee preparation of initial budget for the project
- Review and provide input for responses to IEC and regulatory agencies
- 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 input as necessary to Feasibility Studies, Data Safety Monitoring Committee (DSMC) and other committees, clinical/ product development planning meetings
- Provide or arrange for project-related training as needed for team members
- Initiate the project following Best Practices in Project Management
- Ensure the project is progressing according to quality standards, SOPs, regulations, and guidelines
- Use project plan as a management tool to record and measure progress, updating as necessary
- Track resources and actual time spent on each project task for all team members to evaluate project progress and profitability
- Review metrics reports regularly and follow through on actions required
- Determine the cause of project overruns, recommend and institute corrective action, with input from functional Primaries
- Attend and represent project management/ contracted services at internal meetings and investigator meetings
- Ensure information entered into management system is accurate, and updated on a regular basis
- Ensure the project is completed within the budget, schedule, and according to contract specifications
- Provide consulting services to assist in the development of new drugs or devices under the direction of the Head of Organization.

C. Quality Monitoring

- Work with investigators prior to start of project on incorporation of quality management processes into the scientific and operational design of the trial
- Develop a monitoring plan with project investigators that is tailored to the specific human subject protection and data integrity risks of the trial

	• Agree predefined quality tolerance limits to identify systematic issues that can impact participant safety or reliability of trial results • Be responsible for leading the contracted projects or oversee the studies whenever a designated project lead is assigned to a study. • Oversight for quality monitoring as per the approved plans. • Visit sites and participating institutes as and when required. **D. Communications** • Serve as primary contact for the project • Communicate to team members the scope of work, timeline and project goals, technical information, and input from client throughout the project • Inform team members of any new information or modification of project-related issues which may affect specific responsibilities of team members • Work with appropriate Managers on any anticipated need for addition or re-assignment of resources • Communicating with study investigators for evaluation of status of participant recruitment and progress to study timelines; supporting safety reporting and IEC submissions; maintaining and reporting metrics for clinical site performance • Provide Line Manager with input regarding team members' performance as needed for employees' periodic Performance Review • Prepare administrative reports and submit to clients as required by the contract exhibit, and other resource reports • Communicate fiscal, contractual, resource, deliverable and client- related issues to HoD as appropriate. **E. Training** • Develop project specific and protocol specific training • Provide guidance and operational area training for project team members and staff as required • Act as mentor for CPM staff and oversight for their training and development. •Faculty for training programs conducted by CDSA.
2.	**Name of the post**: Head Data Science **Number of posts**: One **Emoluments:** Up to Rs 1,65,000/- **Age**: 55 years **Minimum Educational Qualification and Experience** Post graduate degree from a recognized university preferably in Computer application/ Computer science/ Data science or relevant branch 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 **OR** Post graduate professional degree preferably in Computer application/ Computer science/ Data science or relevant branch 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 degree preferably in Computer science/ Computer application or relevant branch with experience of working in a research or healthcare environment and at least 10 years of work experience in clinical data science and/ or data management **OR** Professional graduate degree preferably in Computer science/ Computer application or relevant branch with experience of working in a research or healthcare environment and at least 9 years of work experience in clinical data science and/ or data management. • Experience of working across a range of interventional and observational study designs

- A comprehensive understanding of ICH Good Clinical Practice, Best practices for clinical data management and working knowledge of data sharing and the Data Protection guidance's
- An understanding of clinical trials methodology
- Experience of Electronic Data Management Systems

Job profile

Lead the Data Science division at CDSA-THSTI. The remit of the Data Science group is to provide clinical database systems development and support for the studies undertaken at the unit, as well as data management support. This includes initiatives to develop and promote best practice in a number of areas including database development, adherence to regulatory requirements, standardization and simplification, data management methods, quality control and assurance. CDSA & THSTI uses a number of different database approaches depending on the needs of the study, including Redcap, a commercial Clinical Data Management System, and bespoke systems-based MS SQL Server with front end development in .NET. The Data Science group also support the study websites, and develop systems to support unit processes.

The primary role of the post holder is to establish, implement and support delivery of high-quality clinical trials/ studies. To ensure data management in CDSA-THSTI is performed to the highest standards, meets GCP and other regulatory requirements.

Leadership and Strategy:

- Provide leadership and oversee the data science and data management activities in CDSA-THSTI.
- Lead the development and implementation of data management standards and procedures tailored to ensure that optimal use is made of the clinical data management systems and monitoring tools.
- Ensure implementation of data management standards and procedures to support study teams and database programmers in the development, deployment and maintenance of study databases.
- Contribute to developing the clinical trials / studies portfolio
- Participate in business development activities
- Serve as a liaison for database development & management functions to all stakeholders – funding agencies, sponsor, investigators, project teams and provide database development and management guidance throughout the life cycle of trials/studies.
- Develop and support trials with the clinical investigators from grant application stage.
- Oversee those trials that have successfully received funding through to delivery.
- Review and improve CDSA-THSTI data management methods to improve the quality, reliability, timeliness and cost effectiveness of clinical trials/ studies at the CDSA_THSTI in collaboration with the IT team, Statisticians and other members of the Trial & Study Management team.
- Encourage dissemination of best practices in data management to optimise the completeness and validity of study data.
- Support the CDSA Director and Chief of Clinical Portfolio Management to achieve and maintain the data management standards required of a Clinical Research Unit.
- Oversee the development and implementation of CDSA-THSTI Policies and Standard Operating Procedures (SOPs) for Data Management processes.
- Assist the CDSA Director and Chief of Clinical Portfolio Management in the review of relevant contracts and agreements.

Contributing to the database development life cycle

- Interact with stakeholders to understand the data management needs and develop appropriate solutions
- Provide oversight and guidance on development process of systems used within the organization (such as cross-study platforms, study websites, portfolio management, etc.)
- Oversee and provide guidance on procurement of clinical data management and monitoring

	tools • Ensure software validation (performance qualification) Review and provide guidance on possible design solutions and evaluate against the project requirements and decide on the most effective design for the application • Oversee the creation of the software development environment liaising with server administration as required **Data management support** • Ensure timely review and approval Data Management plans, and other relevant documentation for CDSA-THSTI trials. • Ensure project milestones and deliverables are provided in a timely manner. • Ensure data are adequate and available to be shared with internal and external stakeholders, review data sharing requests and oversee data sharing processes. • Along with the IT Manager ensure robust measures are in place for data security and confidentiality throughout the study lifecycle, including managing user access to trial databases • Advise and assist with data quality assurance and auditing • Provide guidance and review the preparation of datasets for analysis including data cleaning and ensuring compliance with the data protection. • Maintain a working knowledge of, and assure compliance with, applicable ICH & CDSCO Guidelines, Regulatory Agency requirements, and CDSA SOPs. **Technical Leadership** • Provide technical leadership for projects as required. This may include, but not be limited to, provide planning information; estimates and task dependencies for budget preparation. **Data quality and methodology** • Ensure development and implementation of mechanisms for central data monitoring of data in CDSA-THSTI • Provide efficient approaches to quality control in the identification of missing data, inconsistencies in the data over time, protocol deviations and reliability of data. **Support the operations and users of applications** • Work with IT department for applications within the team's remit as required • Provide guidance to team to work with IT department to perform Root Cause Analysis of major incidents and recurring problems with application services and recommend corrective actions • Work with IT to perform application upgrades of commercial software in line with CDSA-THSTI requirements **Standards and training** • Ensure Good Clinical Practice and Information Governance standards are maintained in relation to data management in clinical studies • Support Chief of CPM in the implementation of systems for: resource planning, trial administration and document management, data management and quality assurance. • Ensure development of relevant Standard Operation Procedures and Working Practice Documents including the training of staff. • Oversee training to CDSA data managers, project managers and CRAs in Clinical data management and monitoring tools.
3.	**Name of the post: Head Regulatory Science and Medical Affairs** **Number of posts:** One Post **Emoluments:** Up to Rs 1,65,000/- **Age:** 55 years

Minimum Educational Qualification and Experience
Medical professional qualification (MD OR MBBS or equivalent qualification) from a recognized university with at least 10 years of work experience in clinical research especially in clinical operations (start- up activities), regulatory function, medical affairs including medical monitoring, medical writing, pharmacovigilance and medical coding and systems for adverse event review and reporting, safety reporting and management.

Job profile
Lead the medical and regulatory aspects of clinical trial/studies. Overall responsibility to lead the team on development of protocol, study design, regulatory pathway, medical affairs and safety reporting.
Serve as medical liaison to all stakeholders – funding agencies, investigators, project teams.

Leadership and Strategy:
- Provide leadership on medical and regulatory aspects of clinical trials and clinical study projects.
- Participate in business development activities
- Contribute to drafting policies and standard operating procedures
- Contribute to developing the clinical trials / studies portfolio
- Act as a key advisor on regulatory matters, and writing position papers as well as advising on "higher risk" studies.
- Responsible for dissemination of information for CDSA staff on all CDSCO/ ICMR Clinical Trials Regulation and its implications, regulatory requirements, research governance and Good Clinical Practice (GCP)
- Serve as a liaison for medical and regulatory functions to all stakeholders – funding agencies, sponsor, investigators, project teams and provides medical and regulatory guidance throughout the life cycle of trials/studies.
- Provide guidance and oversees safety management, medical monitoring/coding and medical writing functions.
- Responsible for start-up activities inclusive of regulatory submission dossiers, wherever applicable, and managing the regulatory compliance of the clinical studies.
- With the Administrative Manager and Chief of Clinical Portfolio Management, oversee and draft Memorandum's of Understanding (MoU's) or other documents to outline the delegation of duties from the sponsor office to CDSA and other stakeholders of the projects

Medical Affairs (50%)
- Provide leadership to clinical trial and clinical study projects on 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
  - clinical protocols, informed consent forms etc.
  - integrated clinical and statistical summary reports,
  - meeting presentations
  - therapeutic area training material
  - journal articles, and other documents
- Review all documents assigned for scientific/ medically relevant issues including drug safety
- Review and sign off technical documents written with respect to medically relevant matters with particular attention to those relating to drug 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
- Act as medical liaison with clients and solicit expert advice, develop collaborative relationship

	with key experts and investigators • Assist in the preparation of client proposals • Oversee the medical monitoring and medical coding function for all the clinical studies in which CDSA is involved. • Train/mentor and provide leadership to the medical monitor(s) and coders assigned to the clinical studies/trials • Oversee and ensure accurate interpretation of single and or grouped adverse events, serious adverse events, drug effect and attribution of causality, and disease condition • Oversight / review of clinical narrative reports prepared by the Investigators describing the event; advise on individual participant cases as identified by the study team and identifying queries for the local monitors to complete. • Ensure compliance with clinical safety and good pharmacovigilance practices and requirements • Review and provide support in finalizing Periodic Safety Update Reports (PSURs) • Review and edit CSR for clinical consistency with data and standard of practice • Review and sign off Data Management listings of safety data (including adverse events, laboratory data, vital signs data, medical history, physical examination, concomitant medication), • Assist the PI and DSM in establishing the presence or absence of clinically meaningful trends and, if noted, assisting in follow up as appropriate with the project team, sponsor, and Regulatory Authorities • Review and provide input for AEs (coded), past medical history, concomitant medications or other medical data listings to verify and medically vet clinical data. • Provide consulting services to assist in the development of new drugs or devices under the direction of the Head of Organization **Regulatory Science (40%)** • Act as regulatory lead to projects by coordinating regulatory work flow for DCGI and Institutional Ethics Committee submission and approvals, ensuring sufficient regulatory project coverage, providing regulatory support to the team. • Review and approve investigator site regulatory package documents (Statement of Investigator, investigator CVs, IRB/IEC approval documentation, consent forms, etc.). Work with the appropriate project team members to resolve queries. • Maintain a working knowledge of, and assure compliance with, applicable ICH & CDSCO Guidelines, Regulatory Agency requirements, and CDSA SOPs.

- Last date for receipt of online application : **10th December 2021**
- **THOSE WHO HAVE ALREADY APPLIED IN RESPONSE TO RECRUITMENT NOTICE NO. THS/RN/31/2021 NEED NOT TO APPLY AGAIN.**
- The applications will be scrutinised/shortlisted and processed for further selection.

GENERAL TERMS & CONDITIONS:

a) For positions at S.No. 1 to 3, the incumbent will be permitted to undertake consultancy services on behalf of the institute and retain a percentage of the consultancy fees as per the Bye-laws of the institute.

b) The appointment will be initially for two years 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.

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

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

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

f) 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.

g) 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 relax able 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.

h) Age relaxation as per government norms will be provided duly ensuring at least 5 years remaining service for superannuation (60 years).

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

j) 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.

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

l) 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, 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

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 forfuture 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**	**Application fee 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 **personnel@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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