

(An Autonomous Institute of the Department of Biotechnology, Govt. of India)

NCR Biotech Science Cluster, 3<sup>rd</sup> Milestone, Faridabad – Gurugram Expressway, P.O. Box No. 04, Faridabad - 121001

**Recruitment notice no.: THS-C/RN/16/2023**

**Dated: 29 September 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.	<b>Name of the post &amp; Project</b>	<b>Chief – Clinical Portfolio Management</b>
	<b>Number of posts</b>	01 post
	<b>Emoluments</b>	Rs.2,11,200.00 consolidated per month
	<b>Age</b>	55 Years
	<b>Duration</b>	One Year
	<b>Minimum Educational Qualification and Experience</b>	<p><b>Essential qualification and work experience:</b></p> <p>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.</p> <p>OR</p> <p>Post graduate degree in a Science or health related discipline with at least 15 years of work experience in clinical project management &amp; monitoring and/or drug development.</p> <p>AND</p> <p>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&amp;D team.</p>
	<b>Job profile</b>	<p>Lead the clinical trial/studies conduct team with overall responsibility for project management including quality monitoring and clinical operations for clinical studies.</p> <p><b>A. Leadership and Strategy</b></p> <ul style="list-style-type: none"> <li>• Support the CDSA Head in the development of overall strategy</li> <li>• Lead on drafting relevant policies and standard operating procedures</li> <li>• Contribute to developing the clinical trials/studies portfolio</li> <li>• 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).</li> <li>• Analyze and formally report data and information on trends related to research sponsorship activities</li> <li>• Ensure consistent application of core CDSA policies and operating procedures across the CDSA sponsored trials/ studies portfolio</li> <li>• 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)</li> <li>• 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.</li> <li>• Effect changes and/or ensure dissemination of regulatory effective change management systems are implemented to facilitate the</li> </ul>

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

		<p>issues to HoD as appropriate.</p> <p><b>E- Training</b></p> <ul style="list-style-type: none"> <li>• Develop project specific and protocol specific training</li> <li>• Provide guidance and operational area training for project team members and staff as required</li> <li>• Act as mentor for CPM staff and oversight for their training and development.</li> <li>• Faculty for training programs conducted by CDSA.</li> </ul>
	<b>Skills / Knowledge / Aptitude</b>	<ul style="list-style-type: none"> <li>• Leadership skills include the ability to drive programs, build effective teams, the ability to motivate others. Possess self-initiative. Able to take a timely decision, strong decisions making skills.</li> <li>• Business/ Operational skills that include customer focus, commitment to quality management and problem solving</li> <li>• Influencing skills including negotiation and teamwork</li> <li>• Possess critical thinking, problem-solving, planning skills, time management, attention to detail.</li> <li>• Effective communication skills that include the provision of timely and accurate information to stakeholders, proficient in English, strong written and oral communication skills</li> <li>• Ability to develop and deliver presentations, prepare technical reports and contribute effectively in the manuscripts</li> <li>• Good interpersonal communication skills, reliable, able to work with multiple stakeholders</li> <li>• Demonstrated ability to prioritize workload in order to meet multiple deadlines</li> <li>• Familiarity with basic computer software: MS Word, E-mail, Excel, Internet</li> <li>• Ability to travel for business purpose</li> <li>• 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</li> </ul>
2.	<b>Name of the post &amp; Project</b>	<b>Head, Clinical Science (equivalent to Principal Scientist I - Medical)</b>
	<b>Number of posts</b>	One
	<b>Emoluments</b>	Rs. 1,65,000/-
	<b>Age</b>	55 years
	<b>Duration</b>	One Year
	<b>Essential Functions</b>	<p>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.</p> <p>Serve as medical liaison to all stakeholders – funding agencies, investigators, project teams</p>
	<b>Minimum Educational Qualification and Experience</b>	MD/DNB or equivalent from a recognized university with five years of post-qualification clinical research experience especially in protocol development, site set up, trial/ study conduct, safety reporting and management

<p><b>Job profile</b></p>	<p><b><u>Leadership and Strategy:</u></b></p> <ul style="list-style-type: none"> <li>• Provide leadership on study design, research method, medical aspects and conduct of clinical trials and clinical study projects.</li> <li>• Contribute to drafting policies and standard operating procedures</li> <li>• Contribute to developing the clinical trials / studies portfolio</li> <li>• Responsible for dissemination of information for CDSA staff on best practices for clinical research</li> <li>• 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.</li> </ul> <p><b><u>Clinical Science</u></b></p> <ul style="list-style-type: none"> <li>• Provide leadership to clinical trial and clinical study projects on research methods, medical and safety aspects.</li> <li>• Participate in clinical review meetings and document preparation for meetings as required</li> <li>• Guide the project teams in the preparation and review of study documents like <ul style="list-style-type: none"> <li>○ clinical protocols, informed consent forms etc.</li> <li>○ integrated clinical and statistical summary reports,</li> <li>○ meeting presentations</li> <li>○ journal articles, and other documents</li> </ul> </li> <li>• Review all documents assigned for research methods relevant issues including safety</li> <li>• DSMB: Develop/ review DSMB charter, support constitution of DSMB for clinical trials, organize and coordinate DSMB meetings</li> <li>• Provide input as necessary to Feasibility Studies, Data and Safety Monitoring Committees (DSMC) and other committees, clinical/ product development planning meetings</li> <li>• Assist in the preparation of client proposals</li> <li>• Revise SOPs or suggest process improvements for consideration.</li> <li>• May draft new SOPs for review and act as reviewer for Clinical SOPs, as assigned and appropriate.</li> </ul> <p><b><u>Training</u></b></p> <ul style="list-style-type: none"> <li>• Oversee development of training modules and project specific and protocol specific training</li> <li>• Faculty for training programs conducted by CDSA.</li> </ul>
<p><b>Skills / Knowledge / Aptitude</b></p>	<ul style="list-style-type: none"> <li>• Leadership skills include the ability to drive programs, build effective teams, the ability to motivate others. Possess self-initiative. Able to take a timely decision, strong decisions making skills.</li> <li>• Business/ Operational skills that include customer focus, commitment to quality management and problem solving</li> <li>• Influencing skills including negotiation and teamwork</li> <li>• Possess critical thinking, problem-solving, planning skills, time management, attention to detail.</li> </ul>

		<ul style="list-style-type: none"> <li>• Effective communication skills that include the provision of timely and accurate information to stakeholders, proficient in English, strong written and oral communication skills</li> <li>• Ability to develop and deliver presentations, prepare technical reports and contribute effectively in the manuscripts</li> <li>• Good interpersonal communication skills, reliable, able to work with multiple stakeholders</li> <li>• Demonstrated ability to prioritize workload in order to meet multiple deadlines</li> <li>• Familiarity with basic computer software: MS Word, E-mail, Excel, Internet</li> <li>• Ability to travel for business purpose</li> </ul> <p>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</p>
<p>➤ Last date of receipt of application: 20<sup>th</sup> October 2023.</p> <p>➤ The application will be scrutinized/shortlisted and process for further selection</p>		

**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 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.

- 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 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	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 [HR.CDSA@THSTI.RES.IN](mailto: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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