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/01/2022 **Dated: 21st Feb 2022**

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 Manager**
	Number of posts	Three
	Emoluments	Up to Rs 90,000/-
	Age	45 years
	Minimum Educational Qualification and Experience	**Essentialqualification and work experience:** • MBBS/ BDS/ Alliied Medical degree OR • Master's degree/ diploma in life sciences, pharmacy, public health, healthcare or other related discipline OR • Post graduate degree in a health-related discipline Essential work experience: 5 or more years of experience in clinical project management and/or clinical trial/ study monitoring. • Experience of clinical trial or public health project management in a recognized organization/institute (academic clinical trials unit, CRO, pharmaceutical, biotechnology, or device company). **Desirable qualification and work experience:** • Postgraduate degree in Public Health • MD/DNB from a recognized Indian University/recognized by MCI • PhD in a health-related discipline • Demonstrable experience of line management, project management concepts and ability to understand, explain and communicate project concepts using standard tools and templates.
	Job profile	The position is responsible for Responsible for oversight, management and operational execution of assigned clinical studies and trials. Timely delivery of key tasks, while maintaining high quality standards are: - • The project manager will manage the performance of project team working on projects. • The management and cross-functionalcoordination of the project and work closely to develop and maintain the overall project plan and timelines, communicate project expectations to the respective resource/consultant and manage the overall project budget. • Support the team in the implementation of systems for resource planning, study / trial administration, implementation, oversight monitoring, quality assurance and documentation and record keeping • Establishment of procedures to ensure adherence to trial protocols and administrative requirements • Develop project specific and protocol specific training or as requested. • Monitoring the trial progress to ensure compliance with and adherence to the project plan and to identify, evaluate and rectify problems • Understand the requirements of the various controlling bodies,agencies and frameworks, guiding the project in conforming to those requirements and coordinating any necessary audit processes • Liaison with Steering Committee and DSMB with a particular view on compliance with Research Governance, Good Clinical Practice, Data Protection and Ethical Requirements

		• Work with the Investigators to ensure that the trial is meeting its targets, is producing meaningful output and to predict and plan any changes that warrant requests to changes in protocol, funding, or timelines • Development, approval, and distribution of study-related documents including Case Report Forms (CRF's), study protocols, study manuals, and other study tools to investigational sites and review committees • Manage distribution, collection and tracking of regulatory documentation to ensure compliance with regulatory and project requirements and audit readiness • Work with data management and other departments to track progress, milestones and the challenges • Communicate to team members the scope of work, timeline and project goals, technical information or update. • Provide guidance and operational area training for projectteam members and staff as required • Faculty for training projects conducted by CDSA • Any other assignment with Clinical Portfolio Managementteam, based on project deliverables or exigencies. **Skills: -** • Leadership skills that include the ability to build effective project teams, ability to motivate others, delegation, drive and timely/quality decision making • 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 • Comprehensive understanding of Indian Clinical Trials Regulations, ICH and CDSCO Good Clinical Practice • Business/ Operational skills that include commitment to quality management and problem solving • Influencing skills including negotiation and teamwork • Effective communication skills that include the provision of timely and accurate information to stakeholders, proficient in English, strong written and oral communication skills • Computer literacy in Word, Excel, PowerPoint, Access or other trial management systems • Ability to develop and deliver presentations, prepare technical reports and contribute effectively in the manuscripts • Ability to develop and implement monitoring plans and SOPs • Ability to make evaluative judgments, remain flexible asprojects and priorities change • Demonstrated ability to prioritize workload in order to meetmultiple deadlines • Ability to work independently with minimal guidance as wellas collaboratively within a team setting • Knowledge of regulations and guidelines pertaining to theconduct of clinical trials/ studies on human subjects
2.	**Name of the post**	**Sr. Clinical Research Associate**
	Number of posts	One
	Emoluments	Up to Rs 75,000/-

	Age	45 years
	Minimum Educational Qualification and Experience	• Bachelor's in medical sciences or Master's degree/ diploma, life sciences, pharmacy, public health, MBBS, BDS, BHMS, BAMS, BPT healthcare or other related discipline • At least 4-5 years of relevant clinical trial monitoring experience
	Job profile	Sr. CRA will conduct monitoring visits for assigned trial protocol and trial sites. Overall responsibilities are to ensure that the trial is being conducted in accordance with the protocol, standard operating procedures, good clinical practice, and applicable regulatory requirements. • Performs site monitoring throughout the trial which involves visiting the trial sites on a regular basis (site initiation to site closeout) in accordance with contracted scope of work • Performs quality functions and executing quality programs (clinical operations, clinical laboratory) as per GCP/GCLP and regulations • Completes appropriate therapeutic, protocol and clinical research training to perform job duties. • Setting up the trial sites such that each center has the trial materials, including the trial drug while ensuring all trial supplies are accounted for • Administers protocol and related trial training to assigned sites and establishes regular lines of communication with sites to manage ongoing project expectations and issues. • May provide training and assistance to junior clinical staff • Creates and maintains appropriate documentation regarding site management, monitoring visit findings and action plans by submitting regular visit reports and other required trialdocumentation. • Manages the progress of assigned studies by tracking regulatory/ IEC submissions and approvals, recruitment and enrolment, CRF completion and submission, and data query generation and resolution. • Verifying that data entered on to the CRFs is consistent with participant clinical notes (source data/ document verification); continuous central monitoring and ensuring the timely resolution of queries by site team • Writing visit reports and follow-up letters within timeline • Filing and collating trial documentation and reports. • Archiving trial documentation and correspondence • Evaluates the quality and integrity of trial site practices related to the proper conduct of the protocol and adherence to applicable regulations. • Escalates quality issues to the Quality Manager, Project Manager and/ or senior management • Work with Clinical Portfolio Management on other projects as directed and other internal departments on their requirements as and when required. **Skills: -** • Computer skills including proficiency in use of Microsoft Office applications • Basic knowledge and ability to apply GCP and applicableregulatory guidelines. • Strong written and verbal communication skills including goodcommand of English required. • Excellent organizational and problem-solving skills.

		• Effective time management skills and ability to managecompeting priorities
3.	**Name of the post**	**Clinical Research Associate**
	Number of posts	Five
	Emoluments	Up to Rs 65,000/-
	Age	35 years
	Minimum Educational Qualification and Experience	• Bachelor's in medical sciences or Master's degree/ diploma, life sciences, pharmacy, public health, healthcare or other related discipline • MBBS/ BDS/ BHMS/ BAMS/ BPT preferred • At least 3 years of relevant clinical trial monitoring experience
	Job profile	The Study Monitor/ CRA conduct monitoring visits for assigned trial protocol and trial sites. Overall responsibilities are to ensurethat the trial is being conducted in accordance with the protocol, standard operating procedures, good clinical practice, and applicable regulatory requirements. • Performs site monitoring throughout the trial which involves visiting the trial sites on a regular basis (site initiation to site closeout) in accordance with contracted scope of work. • Performs quality functions and executing quality programs (clinical operations, clinical laboratory) as per GCP/GCLP and regulations • Completes appropriate therapeutic, protocol and clinical research training to perform job duties. • Setting up the trial sites such that each centre has the trial materials, including the trial drug while ensuring all trial supplies are accounted for • Administers protocol and related trial training to assigned sites and establishes regular lines of communication with sites to manage ongoing project expectations and issues. • May provide training and assistance to junior clinical staff. • Creates and maintains appropriate documentation regarding site management, monitoring visit findings and action plans by submitting regular visit reports and other required trial documentation. • Manages the progress of assigned studies by tracking regulatory/ IEC submissions and approvals, recruitment and enrolment, CRF completion and submission, and data query generation and resolution. • Verifying that data entered on to the CRFs is consistent with participant clinical notes (source data/ document verification) • Writing visit reports. • Filing and collating trial documentation and reports. • Archiving trial documentation and correspondence. • Evaluates the quality and integrity of trial site practices related to the proper conduct of the protocol and adherence to applicable regulations. • Escalates quality issues to the Quality Manager, Project Manager and/ or senior management. • Work with Clinical Portfolio Management on other projects as directed and other internal departments on their requirements as and when required. **Skills: -** • Computer skills including proficiency in use of Microsoft Office applications • Basic knowledge and ability to apply GCP and applicableregulatory

		guidelines. • Strong written and verbal communication skills including goodcommand of English required. • Excellent organizational and problem-solving skills. • Effective time management skills and ability to managecompeting priorities.
➢ Last date for receipt of online application : 10th March 2022 ➢ The applications will be scrutinised/shortlisted and processed for further selection.		

GENERAL TERMS & CONDITIONS: -

a) These are short-term positions (period of 03 months to 01 year) 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, 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 236/-
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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