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/10/2022 **Dated: 15th September 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:

2.	**Name of the post & Project**	**Clinical Research Associate/Study Monitor** **GARBH-Ini/POD**
	Number of posts	Three
	Emoluments	Rs. 52,080/- (1 Position) & Rs. 55,000/-(2 positions)
	Age	30 years
	Minimum Educational Qualification and Experience	• MBBS/ BDS/ BHMS/ BAMS/ BPT/Bachelor's in medical sciences or Master's degree/ diploma, life sciences, Pharmacy, public health, healthcare or other related discipline At least 2 years of relevant Clinical Research experience
	Job profile	The Study Monitor/ CRA 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 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 withparticipant 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 Officeapplications • Basic knowledge and ability to apply GCP and applicable regulatory

		guidelines. • Strong written and verbal communication skills including good Command of English required. • Excellent organizational and problem-solving skills. • Effective time management skills and ability to manage competingpriorities.
Interested candidates fulfilling the criteria as mentioned above may walk-in for written test/skill test/interview on 23rd September 2022 at 10:30 am at THSTI, NCR Biotech Science Cluster, 3rdMilestone, Faridabad-Gurugram Expressway, Faridabad - 121001		

GENERAL TERMS & CONDITIONS: -

a) These are 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) 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.

"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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