ब्रिक–ट्रांसलेशनल स्वास्थ्य विज्ञान और प्रौद्योगिकी संस्थान
BRIC-Translational Health Science and Technology Institute
(An Institute of the Biotechnology Research and Innovation Council, 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/05/2024 **Dated: 21 March 2024**

1. BRIC - Translational Health Science and Technology Institute (THSTI) is an autonomous Institute ofthe 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 & No.**	**Quality Manager (01 Position)**
	Name of the Study	**DTRC**
	Age	45 years
	Emoluments	Rs 80,000/-
	Duration	03 Months (June 2024) (can be extended further)
	Minimum Educational Qualification and Experience	**Essential qualification and work experience**: • Master's Degree or PG Diploma in Life Sciences or Biomedical Sciences or Pharmacy or Public Health or Clinical Research. • At least 4 years of demonstrated experience in clinical trial monitoring or clinical site management experience. • GCP Certification. **Desirable**: • GCLP Certification or experience of monitoring of laboratory-based activities/ research. • Two years of work experience in the area of Quality Control and Quality Assurance in clinical research.
	Job profile	• Oversees quality management processes and provides guidance and support to project teams to meet quality standards. • Actively lead or assist activities in the areas of Internal Quality improvements and CAPA (Corrective and Preventive Actions). • Ensure that the assigned study is conducted in accordance with study protocols, GCP guidelines, and applicable regulatory requirements. • Lead or assist with identifying non-conformances with requirements, provide suitable recommendations, and facilitate ongoing quality improvements using a risk-based methodology. • Proactively identify the project risks and assist in providing training to study staff in good clinical and documentation practices. • Maintain GCP-compliant processes that control the quality of work at the study site. • Conduct source document verification and case record forms for assessing the study trends. • Develop quality monitoring plan and processes for clinical activities of data collection, laboratory-based activities of sample processing and storage, and running of the biorepository.

		• Overseeing and/or performing quality functions and executing quality programs (clinical operations, clinical laboratory, data management review) • Collaborate with clinical and project management teams to ensure compliance with quality standards, timelines, and appropriate follow-up in areas of deficiency. • Coordinate expert monitoring visits/ audits as per project requirements. • Work with the Clinical Portfolio Management department and other internal departments on their requirements as and when required. • Work with data management and other key departments (laboratory, etc.) to track the process, and progress, and to ascertain the foreseen challenges proactively.
	Skills:	• Good understanding of needs for projects and job responsibilities. • Extensive knowledge of GCP/GLP, observational studies, and appropriate regulations and guidelines. • Ability to develop and implement clinical and laboratory monitoring plans, SOPs, database concepts, and formats. • Ability to build effective project teams, ability to motivate others, delegate, drive, and timely/ quality decision-making. • Operational skills including focus and commitment to quality management and problem solving. • Influencing skills including negotiation and teamwork. • Effective communication skills to provide timely and accurate information to all stakeholders. • Ability to assess non-compliance situations and recognize the potential or real wider strategic risk to the project, escalate when needed. • Ability to identify systematic causes of complex quality problems and recommend long-term solutions. • Create fair and ethical culture that fosters high standards of ethics. • Basic business computer skills (MS Word, Excel, e-mail).
2	**Name of the post & No.**	**Clinical Research Associate (01)**
	Name of the Project	**DTRC**
	Emoluments	**Rs. 55,000/-**
	Age	**35 Years**
	Duration	**03 Months (June 2024) (can be extended further)**
	Minimum Educational Qualification and Experience	• Bachelor in Life Sciences with a minimum of three (3) years of relevant clinical trial monitoring or clinical site coordinator experience. OR • Master's degree/ PG diploma, life sciences, pharmacy, public health, healthcare, or other related disciplines with a minimum of two (2) years of relevant clinical trial monitoring or clinical site coordinator experience. • MBBS/ BDS/ BHMS/ BAMS/ BPT preferred (Experience as above)

	Skills	• Basic knowledge and ability to apply GCP and applicable regulatory guidelines. • Computer skills including proficiency in the use of Microsoft Office applications. • 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 competing priorities.
	Job profile	• The Study Monitor/ CRA conducts 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 the contracted scope of work. • Performs quality functions and executes 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 in the study. • 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 into the CRFs is consistent with participant clinical notes (source data/ document verification) • Writing monitoring visit reports. • Filing and collating trial documentation and reports. • Archiving trial documentation and correspondence. • Evaluate 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 the Clinical Portfolio Management department on other projects as directed and with other internal departments on their requirements as and when required.

- **Interested candidates fulfilling the criteria as mentioned for Sr. No. 1 Post may walk-in for a written test/skill test/interview on 04th April @10:30 AM for CRA at THSTI, NCR Biotech Science Cluster, 3rd Milestone, Faridabad-Gurugram Expressway, Faridabad – 121001. (Note - The candidate must report by 09:30 AM to be interviewed otherwise the candidate will not be interviewed by the selection committee).**
- **Interested candidates fulfilling the criteria as mentioned For Sr. No. 2. May walk-in for written test/skill test/interview on 04th April 2024 @02:30 PM at THSTI, NCR Biotech Science Cluster, 3rd Milestone, Faridabad-Gurugram Expressway, Faridabad – 121001. (Note - The candidate must report by 12:00 PM to be interviewed otherwise the candidate will not be interviewed by the selection committee).**
- **Candidates can apply for both positions but they will have to appear for the interview separately**

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 lowerpost / lower emoluments on the recommendation of the Selection Committee.

e) Age and other relaxations for direct recruits and departmental candidates: 1. By five yearsfor candidates belonging to SC/ST communities. 2. By three years for candidates belonging to OBC communities. 3. For Persons with Benchmark Disabilities (PWBD) fallingunder the following categories: (i) UR - ten years, ii) OBC - 13 years (iii) SC/ST - 15
1. 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. Thereis 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.

j) You are requested to bring 2 passport size photograph & one set of photocopies of your education/qualification certificate/documents along with the originals at the time of interview

"Government strives to have a work force which reflects gender balance and women candidates are encouraged to apply"

(M.V.Santo)
Head-Administration

==========End of the document==========