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ब्रिक–ट्रांसलेशनल स्वास्थ्य विज्ञान और प्रौद्योगिकी संस्थान
BRIC a DBT Organization
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/10/2024 **Dated: 27 May 2024**

1. BRIC-Translational Health Science and Technology Institute (THSTI) is an Institute of the Biotechnology Research and Innovation Council, Department of Biotechnology, Ministry of Science & 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. BRIC-THSTI has built several inter-institutional collaborations and connectivity with industry supported by well-trained teams of research and laboratory staff. THSTI has established various centres namely (a) Centre for Maternal and Child Health, (b) Centre for Viral Therapeutics and Vaccines (c) Centre for Tuberculosis Research (d) Centre for Microbial Research, (e) Centre for Immunobiology and Immunotherapy (f) Centre for Drug Discovery (g) Clinical Development Services Agency (h) Computational and Mathematical Biology Centre (i) Centre for Bio-design and Diagnostics. These centres are strengthened by many core facilities viz. Bioassay Laboratory, Biorepository, Biosafety Level -3 Lab, Data Management Centre, Immunology Core laboratory, Multi-OMICS facility, Experimental Animal Facility, Vaccine design and Development facility, School of Innvoation in Biodesign etc that serve as huge resources for the research programmes of THSTI and 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 developmentas 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**	**Quality Manager (GARBH -INI)**
	Number of posts	**01**
	Emoluments	**Rs. 67,000/- + 16,080 (24% HRA) = Rs. 83,080/-**
	Age	**Up to 45 years**
	Duration	**03 Months**
	Minimum Educational Qualification and Experience	**Essential qualification:** • MBBS/ BDS/ Allied health degree OR • Master's degree in life sciences or pharmacy or public health or 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 or a PhD in a health-related discipline • Experience of clinical trial or public health project management in a recognized organization/institute (academic clinical trials unit, CRO, pharmaceutical, biotechnology, or device company). • Demonstrable experience of line management, project management • Ability to understand, explain and communicate project concepts using standard tools and templates
	Job profile	• The Quality Manager is responsible for the oversight, management and operational execution of assigned clinical studies and trials. • Ensure high-quality standards on delivery of key tasks with adherence to project timelines and deliverables. • Understand the requirements and frameworks of the various regulatory bodies such as DBT, ICMR, HMSC etc, and guide the project conforming to those requirements. • Responsible for the establishment of quality assurance procedures and time points across various aspects of the overall project functioning. • Prepare a risk assessment and mitigation plan for the study and, ensure its implementation. • 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. • 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. • 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 project team members and staff as required • Responsible for the training, task allocation and evaluation of the performance of the study monitors. • Any other assignments with the Clinical Portfolio Management team, based on project deliverables or exigencies.
	Skills	• Ability to work independently with minimal guidance as well as collaboratively within a team setting. • Leadership skills that include the ability to build effective project teams, ability to motivate others, delegate, drive and timely/quality decision-making • Business/ Operational skills that include a commitment to quality management and problem-solving. • Effective communication skills that ensure the provision of timely and accurate information to stakeholders. Proficient in English, Strong written and oral communication skills. • Proficient in computer literacy in Excel, Word, PowerPoint, and Access. • Good writing skills, including the ability to develop and deliver presentations, prepare technical reports, manuscripts, monitoring plans and SOPs. • Comprehensive understanding of Indian Clinical Trials Regulations, ICH and CDSCO Good Clinical Practice • Knowledge of regulations and guidelines pertaining to the conduct of clinical trials/ studies on human subjects. • Personal qualities that include the ability to gain trust and confidence with a variety of clients, good learning ability, managerial courage, ability to prioritize workload, action-oriented and flexible to accommodate in changing environment. • Influencing skills including negotiation and teamwork.
2.	**Name of the post & Project**	**Study Monitor (GARBH-INI)**
	Number of posts	**04**
	Age	**35 years**
	Emoluments	**Rs. 42,000/- + 10,080 (24% HRA) = Rs, 52,080/-**
	Duration	**03 Months**
	Minimum Educational Qualification and Experience	• Bachelors in medical sciences with minimum three years of relevant clinical trial monitoring experience. OR • Master's degree/ diploma, life sciences, pharmacy, public health, healthcare or other related discipline with minimum 2 years of relevant clinical trial monitoring experience.

		• MBBS/ BDS/ BHMS/ BAMS/ BPT (Experience as above)
	Job profile	The Study Monitor conduct monitoring visits for assigned trial protocol and trial sites. Overall responsibilities are to ensure that the trial isbeing 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/ orsenior 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 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 competing priorities.

➢ **Interested candidates fulfilling the criteria as mentioned above may walk-in for written test/skill test/interview on 30th May 2024 at 10:30 am 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).**

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
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. 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

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