

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

Dated: 05th May 2025

RECRUITMENT NOTICE NO.: THS-C/RN/09/2025

- 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, 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 under the project of Clinical Development Services Agency (CDSA), a unit of BRIC-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.

4. <u>Educational Qualification and Experience required for the post</u>:

Name of the post & No.	Research Associate (Quality Assurance) (01)		
Name of the Project	Sepsis-related mortality in neonates in India: A multi-disciplinary, multi-institutional research program for context-specific solutions		
Emoluments	Rs. 58,280/-		
Age	35 Years		
Minimum Educational Qualification and Experience	Bachelor's in Life Sciences with a minimum of three years of relevant clin trial monitoring experience. OR		
zaperience	 Master's degree/ diploma, life sciences, pharmacy, public health, healthcare or other related discipline with a minimum of 2 years of relevant clinical trial monitoring experience. MBBS/ BDS/ BHMS/ BAMS/ BPT preferred (Experience as above). 		
Skills	 Proficient in computer applications, with demonstrated expertise in Microsoft Office Suite (Word, Excel, PowerPoint, Outlook). Strong knowledge of ICH-GCP, GCLP, and regulatory guidelines. Excellent documentation, communication, and organizational skills. Ability to travel frequently to assigned trial sites. Detail-oriented with effective time management skills and ability to manage multiple tasks and priorities efficiently. 		
Job profile	 The Research Associate is responsible for the oversight of clinical trial sites to ensure adherence to study protocols, Good Clinical Practice (GCP), and applicable regulatory requirements. This position involves conducting regular monitoring visits, supporting site operations, and maintaining data quality and compliance across all phases of the clinical trial lifecycle. Conduct site monitoring visits from initiation through closeout, ensuring trials are conducted in compliance with the study protocol, GCP guidelines, SOPs, and applicable regulatory requirements. Set up trial sites, ensuring that investigational products and essential trial supplies are delivered, stored, and documented appropriately. Perform quality checks and execute quality assurance process across clinical operations and clinical laboratories in accordance with GCP/GCLP standards. Provide training on protocols and trial procedures to site staff and maintain ongoing communication to support study execution and address issues. Support clinical staff through guidance and training as and when needed. 		

		Create, maintain, and submit all required documentation related to site		
		management, monitoring visits, findings, and follow-up actions.		
		Track and manage study progress, including regulatory and ethics		
		submissions, patient recruitment and enrolment, CRF completion, and data		
		query resolution.		
		 Verify data accuracy through source data/document verification to ensure consistency between CRFs and clinical records. 		
		Prepare detailed monitoring visit reports and contribute to the preparation and each initial of exceptial trial decuments.		
		and archiving of essential trial documents.		
		Assess trial site compliance and escalate quality or protocol deviations to		
		the Project Manager or Senior Leadership as appropriate.		
		Collaborate with Clinical Portfolio Management and other internal departments on cross-functional initiatives and project requirements.		
	Name of the post &	Clinical Research Associate (01)		
	No.			
		Sepsis-related mortality in neonates in India: A multi-disciplinary, multi-		
		institutional research program for context-specific solutions		
		Rs. 49,000/- +HRA		
	Age	35 Years		
	Minimum	Bachelor's degree in Life Sciences with a minimum of three years of relevant		
Educational experience in clinical site management or clinical trial m		experience in clinical site management or clinical trial monitoring.		
	Qualification and Experience	OR		
		Master's degree or diploma in Life Sciences, Pharmacy, Public Health,		
		Healthcare, or a related discipline with at least two years of relevant experience.		
• MBBS, BDS, BHMS, BAMS, or BPT with a minimum o		MBBS, BDS, BHMS, BAMS, or BPT with a minimum of two years of relevant		
		clinical site management or monitoring experience		
	Skills	Proficient in computer applications, particularly Microsoft Office Suite		
		(Word, Excel, PowerPoint, Outlook).		
		Working knowledge of ICH-GCP, GCLP, and applicable regulatory guidelines.		
		Excellent documentation, communication, and organizational skills.		
		Ability and willingness to travel frequently to assigned trial sites.		
		Detail-oriented with strong time management skills and the ability to		
		manage multiple priorities effectively.		
	Job profile	The Study Monitor/ CRA is responsible for overseeing clinical research sites to ensure		
		adherence to study protocols, Good Clinical Practice (GCP), and applicable regulatory		
		requirements. This position involves conducting regular monitoring visits, supporting		
		site operations, and maintaining data quality and compliance across all phases of the		
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	clinical trial lifecycle.
	Conduct site monitoring visits from initiation to closeout to ensure trials
	comply with the protocol, GCP guidelines, SOPs, and regulatory requirements.
	Set up trial sites and ensure proper delivery, storage, and documentation of
	investigational products and essential supplies.
	Perform quality checks and support the implementation of quality assurance
	processes in line with GCP/GCLP standards.
	Provide training and ongoing support to site staff on protocol adherence and
	trial procedures.
	Maintain detailed documentation of site visits, findings, follow-ups, and site
	management activities.
	 Monitor and manage study progress, including regulatory submissions, patient
	recruitment, CRF completion, and query resolution.
	Verify data accuracy through source data/document verification.
	 Prepare monitoring visit reports and assist with archiving trial documents.
	Report protocol deviations and quality issues to the Project Manager or senior
	leadersnip.
	 leadership. Collaborate cross-functionally with internal departments on project initiatives
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No. Name of the Project Emoluments	Collaborate cross-functionally with internal departments on project initiatives and operational requirements. Assistant Data Manager (01) Burden and Sequelae of Influenza, SARS-CoV-2 and other respiratory viruses associated severe Acute Respiratory Infections among Indian adult population aged 18-60 yrs Upto Rs. 71,120/- 35 Years
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- IT literate (experience with Microsoft based applications and other CDMS applications).
 Must understand clinical research and familiarity with clinical data management functions.
 - Good interpersonal, verbal and written communication skills.
 - A flexible attitude with respect to work assignments and new learning.
 - Effective time management in order to comply to timelines.
 - Commitment to project and team goals.
 - Must be able to work independently but seek guidance when necessary.
 - Demonstrated ability to solve complex tasks and complete work on time
 - Must be a team player
 - Ability to model behavior and ethics in line with CDSA Mission and Vision

Job profile

- Assist data manager in drafting, maintenance and update of Data Management Plan and any other relevant documentation (Edit Checks Document, Annotated CRF, Data Entry Guidelines, Standard Operating Procedures etc.) for ensuring efficient database creation and maintenance.
- Assist data manager in creating dashboards using data visualization tools like Microsoft Power BI and Tableau.
- Designing of the paper case report forms
- Support data science team in database development and edit checks implementation.
- Assist in creation and enter test data for Clinical Database for screen validation.
- Working knowledge of query management, data cleaning, data freezing and data archival.
- Interact with other project team members to support the set- up,
 maintenance, and closure of the data management aspects of the project
- Assist data manager in preparing interim reports and data extraction
- Working knowledge of database standards and study development process, CDM SOPs, CDISC & SDTM standards
- Should be able to provide training to site data entry operators, if required
- Assist with data entry and reconciliation as needed or assigned
- Assist data manager in preparation of datasets for analysis including data cleaning and ensuring compliance with the data protection.
- Assist data manager in report preparations and dashboard creation.
- Assist the data science team in other miscellaneous activities as required

- Interested candidates fulfilling the criteria for the posts as mentioned at Sr. No. 1 & Sr. No. 2 may walk-in for a written test/skill test/interview on 15th May 2025 @09:00 AM at THSTI, NCR Biotech Science Cluster, 3dl Milestone, Faridabad-Gurugram Expressway, Faridabad 121001.
- ➤ Interested candidates fulfilling the criteria for the post as mentioned at Sr. No. 3 may walk-in for written test/skill test/interview on 20th May 2025 @09:00 AM at THSTI, NCR Biotech Science Cluster, 3_{rd}Milestone, Faridabad-Gurugram Expressway, Faridabad 121001.

NOTE: 1) The candidates must bring their latest resume, one set of photocopy of documents in support of their educational qualification and experience along with originals and a valid ID cards for verification. 2) Candidates coming after the time slot mentioned will not be entertained. 3) All the candidates coming for written test/skill test/interview will be mandatorily required to deposit their mobile phone along with a valid Identity proof at the reception and the same will only be returned back on completion of the entire selection process.

GENERAL TERMS & CONDITIONS:

- a) These are the 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. The candidates are required to satisfy themselves, before applying /appearing for the selection process, that they possess the minimum eligibility criteria as laid down in the recruitment advertisement. No query will be entertained with regard to eligibility criteria.
- d) Closing date of online application will be the **CRUCIAL DATE** for determining eligibility with regard to age, essential qualification, experience 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.
- 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. Institute employees will get the age relaxation to the extent of the service rendered by them as on closing date of advertisement. 6. For Exservicemen upto the extent of service rendered in defence forces (Army, Navy & Air force) plus 3 years provided they have put in a minimum of 6 months attested service.
- g) All results/notifications will only be published on our website. Therefore, the candidates should essentially visit THSTI website, regularly.
- h) All communications will only be made through email.
- i) 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.
- j) The no. of vacancy indicated above may change subjected to the actual requirement at the time of Written test/skill test/interview.
- k) With regard to any provisions not covered in this notification, the bye laws of THSTI / Govt. of India rules / guidelines shall prevail.
- 1) Canvassing wrong information in any form will be a disqualification.

HOW TO APPLY FOR POSTS MENTIONED IN ABOVE TABLE:

- 1. <u>Documents to be kept handy before filling up the online application:</u> (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 degree/certificate (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. 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** 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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