# BRIC-Translational Health Science and Technology Institute

ब्रिक–ट्रांसलेशनल स्वास्थ्य विज्ञान और प्रौद्योगिकी संस्थान

**BRIC**
a DBT Organization

**O thsti**

(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/07/2024**                                    **Dated:  16 April 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 | Data Manager (Equivalent to Project Scientist II) |
|---|---|---|
| | **Number of posts** | One |
| | **Emoluments** | Rs. 67,000 + 27% HRA = Rs. 85,090/- |
| | **Age** | 45 years |
| | **Duration** | One Year and likely to be continued |
| | **Minimum Educational Qualification and Experience** | **Essential qualification and work experience:**<br>• Master's degree in any field preferably in science, with 6 years of experience in clinical data management/clinical research/operations/MIS/data analysis/IT/computer science/healthcare field<br><br>**OR**<br><br>• Graduation degree in any field preferably in science, with 8 years of experience in clinical data management/clinical research/operations/MIS/data analysis/IT/computer science/healthcare field<br><br>**Desirable qualification and work experience:**<br><br>Diploma in Information Technology/ Computer Applications/ Clinical Data Management. Familiarity with industry standard CDMS and some programming skills.<br><br>Demonstrated experience of developing Clinical Study Data Management documents |
| | **Job profile** | • Overall responsible for all the activities of assigned CDM project and one point contact with the sponsor and clinical sites<br>• Manage all data management activities from study start to database close.<br>• Interact with other project team members to support the set-up, maintenance, and closure of the data management aspects of the project<br>• Perform database testing and database audit as part of Quality Control<br>• Prepare or perform review of Data Management documents - DMP (Data Management Plan), DVP (Data Validation Plan/ Edit Checks Document), Annotated CRF, Data Entry Guidelines etc.<br>• Working knowledge of query management, data cleaning, data freezing and data archival<br>• Clean, organize, and transform raw data to ensure accuracy, consistency, and completeness of the data<br>• Lead in preparation of datasets for analysis including data cleaning and ensuring compliance with the data protection.<br>• Prepare interim reports for clinical study status and participating in data extraction in collaboration with the sponsor and coordinating site<br>• Generate ad-hoc reports as needed<br>• Sound knowledge of logics and data management techniques<br>• Working knowledge in data visualization tools (e.g., Tableau, Power BI) and should be able to create dashboards as per the project requirement<br>• Create charts, graphs, dashboards, and other visual representations to present data<br>• Coordinate the archiving of study databases and related documents<br>• Develop standard operation procedures (SOPs) and working practice documents including the training of staff |

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|---|---|---|
| | | • Effective interaction with intra-departments to ensure all required, vital information and documentation is acquired in a timely manner.<br>• Good experience and working knowledge of paper CRF and eCRF development<br>• Participate in cross functional team meetings & external client meetings as DM representative<br>• Prepare data transfer guidelines for external data load and self-evident correction chart.<br>• Ensure that security of all data is maintained and confidentiality of participants protected<br>• Working knowledge of database standards and study development process, CDM SOPs, CDISC & SDTM standards<br>• Develop Standard Operation Procedures and train study staff<br>• Supervise of DM activities at sites |
| | Skills | • Good management & leadership skills.<br>• IT literate (experience with Microsoft based applications, data visualization tools and other data management applications).<br>• Must have experience in handling databases and query management.<br>• Client focused approach to work<br>• Meticulous attention to detail.<br>• Must be able to work independently but seek guidance when necessary.<br>• Team player with outstanding inter-personal, negotiation skills and organizational skills.<br>• A flexible attitude with respect to work assignments and new learning.<br>• Effective time management in order to meet metrics or team objectives.<br>• Commitment to project and team goals.<br>• Demonstrated ability to solve complex tasks and complete work on time<br>• Commitment to deliver high-quality work consistently<br>• Ability to model behavior and ethics in line with CDSA Mission and Vision |
| 2. | Name of the post | **Assistant Data Manager (Equivalent to Project Scientist I** |
| | Number of posts | One |
| | Age | Rs. 56,000 + 27% HRA = Rs. 71,120/- |
| | Emoluments | 45 years |
| | Duration | One Year and likely to be continued |
| | Minimum Educational Qualification and Experience | **Essential:**<br><br>• Master's degree in any field preferably in science, with 3 years of experience in clinical data management/clinical research/operations/MIS/data analysis/IT/computer science/healthcare field<br><div align="center">OR</div><br>• Graduation degree in any field preferably in science, with 5 years of experience in clinical data management/clinical research/operations/MIS/data analysis/IT/computer science/healthcare field<br><br>**Desirable:**<br>Diploma in Information Technology/ Computer Applications |
| | Job profile | **Responsibilities**:<br>• 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.<br>• Designing of the paper case report forms<br>• Support data science team in database development and edit checks |

| | | implementation. |
|---|---|---|
| | | • Assist in creation and enter test data for Clinical Database for screen validation.<br>• Working knowledge of query management, data cleaning, data freezing and data archival.<br>• Interact with other project team members to support the set- up, maintenance, and closure of the data management aspects of the project<br>• Assist data manager in preparing interim reports and data extraction<br>• Working knowledge of database standards and study development process, CDM SOPs, CDISC & SDTM standards<br>• Should be able to provide training to site data entry operators, if required<br>• Assist with data entry and reconciliation as needed or assigned<br>• Assist data manager in preparation of datasets for analysis including data cleaning and ensuring compliance with the data protection.<br>• Assist data manager in report preparations and dashboard creation.<br>• Assist the data science team in other miscellaneous activities as required |
| | **Skills** | • Familiarity with GCP, US-FDA 21 CFR 11, regulatory requirements and data standardization guidelines.<br>• IT literate (experience with Microsoft based applications and other CDMS applications).<br>• Must understand clinical research and familiarity with clinical data management functions.<br>• Good interpersonal, verbal and written communication skills.<br>• A flexible attitude with respect to work assignments and new learning.<br>• Effective time management in order to comply to timelines.<br>• Commitment to project and team goals.<br>• Must be able to work independently but seek guidance when necessary.<br>• Demonstrated ability to solve complex tasks and complete work on time<br>• Must be a team player<br>• Ability to model behavior and ethics in line with CDSA Mission and Vision |

➢Last date of receipt of online application: **07th May 2024.**

➢The application will be scrutinized/shortlisted and processed for further selection.

**SUBMISSION OF APPLICATION WILL BE THRU ONLINE MODE ONLY OTHERWISE IT WILL GET REJECTED OR IGNORED.**

**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)  Closing date of online application will be the **CRUCIAL DATE** for determining eligibility with regard to age, essential qualification etc.

e)  Number of positions to be hired, 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 postsnotified, 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.

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 wrong in any form will be a disqualification.

k) The candidate may be transfer to site location as per the project requirement and management discretion.

**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.
   x) Forwarding letter / NOC from the current employer in the case of candidates working in Govt. / PSUs / autonomous bodies.

2. **Procedure for filling up online application:**

   i) The eligible and interested candidates may apply online at the Institute's website https://thsti.res.in/en/Jobs. 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 | Applicationfee 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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