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/12/2022 **Dated: 07 October 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:

1	**Name of the post & Project**	Program Manager (Public Health) "NBM Program"
	Number of posts	01
	Emoluments	Rs. 85,000/- Consolidated
	Age	45 years
	Minimum Educational Qualification and Experience	Essential qualification: •MBBS/ BDS/ Alliied Medical degree **OR** •Master's degree/ diploma in life sciences, pharmacy, public health, 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 • MD/DNB from a recognized Indian University/ recognized by MCI PhD in a health-related discipline • Demonstrable experience of line management, project management concepts and ability to understand, explain and communicate project concepts using standard tools and templates
	Job Profile	Responsible for the management and cross-functional coordination of the program and work closely with Project Management Unit (PMU) of National Biopharma Mission (NBM) to develop and maintain the overall project plan and timelines, communicate project expectations to the respective resource / consultant and manage the overall project budget. • To oversee the management of a portfolio of trials / studies including project management, quality monitoring and/or safety monitoring and guiding the study teams to achieve successful completion of all assigned activities in the program. • This position may also be required to participate, manage and oversee capacity building at sites for clinical trials as planned by MIU-NBM. This would involve being responsible for completion of all the objectives set out for the sites to ensure they are ready and capable of participating in clinical trials. • Support the team in the implementation of systems for resource planning, study / trial administration, implementation, oversight monitoring, quality assurance and documentation and record keeping Particulars Details • 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 • Understand the requirements of the various controlling bodies, agencies and frameworks, guiding the project in conforming to those requirements and coordinating any necessary audit processes • Liaison with Steering Committee and DSMB with a particular view on compliance with Research Governance, Good Clinical Practice, Data Protection and Ethical Requirements • 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 • Assists Clinical management with the development, negotiation, and execution of the site contract, budget and payment plan • Management of the trial budget(s) and maintenance of the accounts • 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 • Supervise the study start up activities, trial monitoring and reporting • Manage distribution, collection and tracking of regulatory documentation to ensure compliance with regulatory and project requirements and audit readiness • Oversight for planning, preparing, and distributing materials for investigator and coordinator meetings, and for study related training • Work with data management and other departments to track progress, milestones and the challenges • Works Closely with: Project Team at CDSA, NBM and the site, Sponsors, clinical collaborators, Expert groups / Committee, Regulatory Affairs, Medical Affairs, Data Management, Biostatistics, Laboratory team, key Institute staff on finance, administration, contracts and personnel matters. • Continually review and respond to changes required to shape the infrastructure, functionality and standards of the program management
2	**Name of the post & Project**	Consultant Data Manager
	Number of posts	01
	Emoluments	Rs. 75,000/- (Consolidated)
	Age	45 years
	Minimum Educational Qualification and Experience	Educated to Graduation degree level in healthcare field, IT, Computer Applications with 4 years' experience in clinical data management and/ or data analysis OR Master's degree in healthcare field, IT, Computer Science, Computer Applications with 2 years' experience in clinical data management and/ or data analysis.
	Job Profile	• Providing data management services for the project • Providing exploratory data analysis support as per requirement of the group • Providing technical support to the consortium. • Working knowledge of Query management, data cleaning, data freezing and data archival. Sound knowledge of Clinical Database Development tools, logics and techniques and GCDMP • Working knowledge of database standards

		• AE/SAE reconciliation • Preparing interim reports and review of listings of data for clinical trial status and data extraction in collaboration with the statistician • Lead in preparation of datasets for analysis including data cleaning and ensuring compliance with the data protection. • Preparation of Data transfer guidelines for external data load and self-evident correction chart. Interact with other project team members to support the set-up, maintenance, and closure of the Data Management aspects of the project. • Working knowledge of Quality Check of Database Design, Validation Program, Annotated CRF, Data Extract Views, Laboratory Details, Site and Investigators and Final Data Listings • Working knowledge of study development process, CDM SOPs, CDISC & SDTM standards • Any other responsibility assigned by the PI. **Skills: -** • IT literate (experience with Microsoft based applications and other CDMS applications) • Must have experience in handling EDC tools • Demonstrated knowledge of validation programming Demonstrated knowledge of query management and data cleaning • Must understand clinical trials and familiarity with clinical data management functions. • Good interpersonal, verbal and written communication skills. • Client focused approach to work. • A flexible attitude with respect to work assignments and new learning. • Meticulous attention to detail. Effective time management in order to meet team objectives. • Commitment to project and team goals. • Must be able to work independently but seek guidance when necessary. • Team player with outstanding inter-personal, negotiation skills and organizational skills. • Sense of urgency in completing assigned tasks • Exhibits a sense of urgency about solving problems and completing work. • Shows commitment to and performs consistently high- quality work. Ability to model behaviors and ethics in line with CDSA Mission and Vision.
3	**Name of the post & Project**	Clinical Research Associate (Indigo)
	Number of posts	01
	Emoluments	Rs.49000+16 % HRA
	Age	35 years
	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 preferred

	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 with participant 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 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.
4	**Name of the post & Project**	Project Associate -II (DBT Neo Sepsis and Indigo)
	Number of posts	02
	Emoluments	Rs.28000+ 24 % HRA and Rs 35000+ 16 % HRA
	Age	35 Years
	Minimum Educational Qualification and Experience	• Bachelor's degree in Bio-technology or medicine or Life Science related field from a recognized institute / equivalent OR Master's degree in Life Sciences from a recognized institute / equivalent. • A minimum of 3 years' work experience after graduation OR at least one year of work experience after the post graduate degree

		• Relevant experience of handling clinical site management, support to clinical site operations and administrative work for clinical research will be preferred Skills: - • Strong communication skills both verbal and written in English. • Proficient in Microsoft Office, including Word, Excel, PowerPoint, Outlook etc. and working experience with project management software • Ability to work under pressure, exhibit integrity in behavior and action. • Ability to remain flexible and work independently with minimal guidance as well as collaboratively within a team setting
	Job Profile	• Project tracking activities for efficient management of the SoW for respective assignment related projects/ assignments. • Responsible for supporting clinical study documents development for start-up activities and other study documents / dossiers as per project requirement and assist in collation and preparation of clinical study documents for submission for regulatory and EC approvals. • Supports creation, maintenance and periodic review of Trial Master Files, Tools and Systems for accuracy and completeness as per the regulatory and GCP requirements. • Participate in project related meetings and assist in preparation of agendas, presentation materials, minutes, and tracking of action items. • Assist project team in the preparation, handling, distribution, filing, and archiving of clinical study documentation as per departmental SOPs and project requirements. • Provide support for administrative tasks and office operations which may include but not limited to: - Coordinate with cross-functional departments for travel and accommodation arrangements for delegates of project meetings, investigator meetings etc. - Assist project teams in vendor payments and maintain tracking of payments. - Assist in administrative tasks of manpower recruitment and coordinate candidate interviews. • Creation of administrative notes as per project/operational requirements and tracking of approvals. • Work with Clinical Portfolio Management and other internal departments on their requirements as and when require.
5	**Name of the post & Project**	Project Assistant "NBM Program"
	Number of posts	01
	Emoluments	Rs. 35,000/-
	Age	35 Years
	Minimum Educational Qualification and Experience	Graduate with 3 years' experience OR Post graduate with one-year experience of handling administrative work Candidate with clinical research experience as from a recognized institute / organization will be preferred. Skills: - • Strong communication skills both verbal and written in English. • Proficient in Microsoft Office, including Word, Excel, PowerPoint, Outlook etc. and working experience with project management software • Ability to work under pressure, exhibit integrity in behavior and action.

		Ability to remain flexible and work independently with minimal guidance as well as collaboratively within a team setting.
	Job Profile	• Provide support to the consultancy granted to us through NBM, in administrative tasks, office operations and project tracking activities for efficient management of the SoW for respective assignment related to allocated NBM projects/ assignments.: • Provide the support for accurate forecasts for the project, procurement, planning, and tracking • Implement and maintain effective administrative and project tracking systems / tools. • Creation of administrative notes as per project requirements and tracking of approvals. • Responsible for creation / providing inputs of clinical study documents for start-up activities and other study documents / dossiers as per project requirement. • Supports creation, maintenance and period review of Trial Master Files, Tools and Systems for accuracy and completeness as per the regulatory and GCP requirements. • Assist in collation and preparation of clinical study documents for submission for regulatory and EC approvals. • Participate in CDSA- NBM and Project Team meetings and assist in preparation of agendas, presentation materials, minutes, and tracking of action items. • Liaise with CDSA team on consultancy services for NBM programs, admin department and finance department for arrangements of monitoring visits, conferences, workshops etc. • Coordinate with cross-functional departments for travel and accommodation arrangements for delegates of project meetings, investigator meetings etc. • Assist project teams in vendor payments and maintain tracking of payments. • Assist project team in the preparation, handling, distribution, filing, and archiving of clinical study documentation as per departmental SOPs and project requirements. • Work with Clinical Portfolio Management and other internal departments on their requirements as and when required • Work closely with NBM BIRAC and CDSA teams for monitoring the grant allocated to the sites and help ensure resources are used efficiently. • Coordinate efforts within the team and with outside consultants efficiently. • Keep records of all information and communications related to project for documentation, clarification and presentation to the management.
➢ Call for application will remain open till suitable candidate are found. ➢ Deadline for receipt of application is 28th October 2022.		

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.

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

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

i) The eligible and interested candidates may apply online at the Institute's website www.thsti.res.in/career. 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 forfuture 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**
For Program Manager and Consultant Data Manager		
1.	Unreserved, OBC & EWS candidates	Rs 590/-
2.	SC/ST/Women/PwBD	Rs 118/-
For all other positions		
1.	Unreserved, OBC & EWS candidates	Rs 236/-
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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