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/04/2023 **Dated: 28th March 2023**

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**	**Head Regulatory Science and Medical Affairs**
	Number of posts	One
	Emoluments	Rs. 1,65,000/-
	Age	55 years
	Duration	One Year
	Minimum Educational Qualification and Experience	Medical professional qualification (MD OR MBBS or equivalent qualification) from a recognized university with at least 08 years of work experience in clinical research especially in clinical operations (start- up activities), regulatory function, medical affairs including medical monitoring, medical writing, pharmacovigilance and medical coding and systems for adverse event review and reporting, safety reporting and management
	Job profile	Lead the medical and regulatory aspects of clinical trial/studies. Overall responsibility to lead the team on development of protocol, study design, regulatory pathway, medical affairs and safety reporting. Serve as medical liaison to all stakeholders – funding agencies, investigators, project teams. **Leadership and Strategy:** • Provide leadership on medical and regulatory aspects of clinical trials and clinical study projects. • Participate in business development activities • Contribute to drafting policies and standard operating procedures • Contribute to developing the clinical trials / studies portfolio • Act as a key advisor on regulatory matters, and writing position papers as well as advising on "higher risk" studies. • Responsible for dissemination of information for CDSA staff on all CDSCO/ ICMR Clinical Trials Regulation and its implications, regulatory requirements, research governance and Good Clinical Practice (GCP) • Serve as a liaison for medical and regulatory functions to all stakeholders – funding agencies, sponsor, investigators, project teams and provides medical and regulatory guidance throughout the life cycle of trials/studies. • Provide guidance and oversees safety management, medical monitoring/coding and medical writing functions. • Responsible for start-up activities inclusive of regulatory submission dossiers, wherever applicable, and managing the regulatory compliance of the clinical studies. • With the Administrative Manager and Chief of Clinical Portfolio Management, oversee and draft Memorandum's of Understanding (MoU's) or other documents to outline the delegation of duties from the sponsor office to CDSA and other stakeholders of the projects. **Medical Affairs (50%)** • Provide leadership to clinical trial and clinical study projects on medical and safety aspects. • Participate in clinical review meetings and document preparation for meetings as required •Guide the project teams in the preparation and review of study documents like o clinical protocols, informed consent forms etc. o integrated clinical and statistical summary reports, o meeting presentations o therapeutic area training material o journal articles, and other documents

		• Review all documents assigned for scientific/ medically relevant issues including drug safety • Review and sign off technical documents written with respect to medically relevant matters with particular attention to those relating to drug safety •DSMB: Develop/ review DSMB charter, support constitution of DSMB for clinical trials, organize and coordinate DSMB meetings • Provide input as necessary to Feasibility Studies, Data and Safety Monitoring Committees (DSMC) and other committees, clinical/ product development planning meetings •Act as medical liaison with clients and solicit expert advice, develop collaborative relationship with key experts and investigators •Assist in the preparation of client proposals •Oversee the medical monitoring and medical coding function for all the clinical studies in which CDSA is involved. • Train/mentor and provide leadership to the medical monitor(s) and coders assigned to the clinical studies/trials •Oversee and ensure accurate interpretation of single and or grouped adverse events, serious adverse events, drug effect and attribution of causality, and disease condition •Oversight / review of clinical narrative reports prepared by the Investigators describing the event; advise on individual participant cases as identified by the study team and identifying queries for the local monitors to complete. • Ensure compliance with clinical safety and good pharmacovigilance practices and requirements • Review and provide support in finalizing Periodic Safety Update Reports (PSURs) • Review and edit CSR for clinical consistency with data and standard of practice • Review and sign off Data Management listings of safety data (including adverse events, laboratory data, vital signs data, medical history, physical examination, concomitant medication), •Assist the PI and DSM in establishing the presence or absence of clinically meaningful trends and, if noted, assisting in follow up as appropriate with the project team, sponsor, and Regulatory Authorities • Review and provide input for AEs (coded), past medical history, concomitant medications or other medical data listings to verify and medically vet clinical data. • Provide consulting services to assist in the development of new drugs or devices under the direction of the Head of Organization. **Regulatory Science (40%)** • Act as regulatory lead to projects by coordinating regulatory work flow for DCGI and Institutional Ethics Committee submission and approvals, ensuring sufficient regulatory project coverage, providing regulatory support to the team. • Review and approve investigator site regulatory package documents (Statement of Investigator, investigator CVs, IRB/IEC approval documentation, consent forms, etc.). Work with the appropriate project team members to resolve queries. • Maintain a working knowledge of, and assure compliance with, applicable ICH & CDSCO Guidelines, Regulatory Agency requirements, and CDSA SOPs
2.	**Name of the post & Project**	**Research Scientist (Bioinformatics)**
	Number of posts	One
	Emoluments	Rs. 1,10,000/-
	Age	40 years

	Duration	One Year
	Minimum Educational Qualification and Experience	**Essential qualification and work experience:** MD or MVSc or M. Tech with minimum 2 years' relevant post qualification research experience **OR** PhD in Life Sciences/ Computational Science/ Bioinformatics/ Genomics from a recognized University with minimum 6 months relevant post qualification research experience. **Desirable:** Work experience in metagenomics and bacterial genomics.
3	**Name of the post & Project**	**Consultant Data Manager (POD)**
	Number of posts	One
	Emoluments	Rs. 75,000/-
	Age	45 years
	Duration	**Dec 2023**
	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 standard • 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 standard **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.
4	**Name of the post & Project**	**Clinical Research Associate**
	Number of posts	One
	Emoluments	Rs. 55,000/-
	Age	35 Years
	Duration	One Year
	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.
5	**Name of the post & Project**	**Research Nurse (DBT Neo-Sepsis)**
	Number of posts	One
	Emoluments	Rs. 31,500/-

	Age	18-30 years
	Duration	One Year
	Minimum Educational Qualification and Experience	Standard 12 and Diploma in Nursing & Midwifery (3 years course) + Registration as "A" Grade Nurse / BSc (Nursing) / Nursing "A" Certificate with 3 years' experience in hospital / Nursing Assistant Class III & above from the Armed Forces. Desirable: At least with 1 year of experience in research projects, Work experience in research/newborn nursery/ NICU
	Job profile	The study nurse (round the clock shift duties) will be responsible for: • Pre-screening of all mothers for eligibility • Taking consent from eligible mothers • Giving all information about study to parents/Guardians and to explore whether they are interested in participating in the study • Sample collection from mother before delivery (rectovaginal swabs and blood sample), sample collection at the time of delivery (cord blood, cord tissue, vernix) • To fill CRF form for all enrolled mothers and neonates • To monitor the babies for occurrence of sepsis • To collect blood samples, urine, stool, oral and nasopharyngeal swab in neonates with suspect sepsis • To collect breast milk sample from enrolled mothers in the postnatal wards • To follow all the neonates till discharge or 28 days of life whichever is greater must be able to evaluate the material and work effectively with other researchers Data collection • To coordinate with lab personnel to transport and process the samples from NICU to the NICU side lab and microbiology lab • Collection of lab results and coordinating with RO for final labelling of sepsis Coordinate with RO for smooth flow of CRFs.
➢ Last date of receipt of online application: **17th April 2023** ➢ 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) The positions will be hired initially for a period of one year with a probation period of six months. The 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 05 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 numberof 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

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 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	For Sr. No. 1 to 4 Rs 590/- For Sr. No. 5 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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