



ब्रिक-ट्रांसलेशनल स्वास्थ्य विज्ञान  
और प्रौद्योगिकी संस्थान



## BRIC-Translational Health Science and Technology Institute

(An Institute of the Biotechnology Research and Innovation Council, Govt. of India)

NCR Biotech Science Cluster, 3<sup>rd</sup> Milestone, Faridabad – Gurugram Expressway,  
P.O. Box No. 04, Faridabad – 121001

भर्ती नोटिस सं. : टीएचएस-सी/आरएन/14/2025

दिनांक: 14 अगस्त 2025

**RECRUITMENT NOTICE NO.: THS-C/RN/14/2025**

**Dated: 14<sup>th</sup> August 2025**

### **भर्ती अधिसूचना/ RECRUITMENT NOTIFICATION**

1. BRIC-Translational Health Science and Technology Institute (THSTI), जैव प्रौद्योगिकी अनुसंधान और नवाचार परिषद, जैव प्रौद्योगिकी विभाग, विज्ञान और प्रौद्योगिकी मंत्रालय, भारत सरकार का एक संस्थान है। भारत का यह संस्थान फरीदाबाद में स्थित इंटरडिसिप्लिनरी एनसीआर बायोटेक साइंस क्लस्टर का एक अभिन्न अंग है, जिसमें अभिनव ट्रांसलेशनल अनुसंधान करने और मानव स्वास्थ्य में सुधार के लिए अवधारणाओं को उत्पादों में ट्रांस्लेट करने के लिए विषयों और व्यवसायों में अनुसंधान सहयोग विकसित करने का मिशन है।

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. ब्रिक-टीएचएसटीआई ने अनुसंधान और प्रयोगशाला कर्मचारियों की प्रशिक्षित टीमों द्वारा समर्थित उद्योग के साथ कई अंतर-संस्थागत सहयोग और कनेक्टिविटी का निर्माण किया है। टीएचएसटीआई ने विभिन्न केंद्रों की स्थापना की है जैसे (क) मातृ और बाल स्वास्थ्य केंद्र, (ख) वायरस अनुसंधान, चिकित्सा और टीका केंद्र (ग) तपेदिक अनुसंधान केंद्र (घ) माइक्रोबियल अनुसंधान केंद्र, (ङ) इम्युनोबायोलॉजी और इम्युनोथेरेपी केंद्र (च) ड्रग डिस्कवरी केंद्र (छ) नैदानिक विकास सेवा एजेंसी (ज) कम्प्यूटेशनल और गणितीय जीव विज्ञान केंद्र (झ) बायो-डिजाइन और निदान केंद्र। इन केंद्रों को कई मुख्य सुविधाओं द्वारा मजबूत किया गया है जैसे कि बायोएसे लेबोरेटरी, बायोरेपोजिटरी, बायोसेफ्टी लेवल-3 लैब, डेटा मैनेजमेंट सेंटर, इम्युनोलॉजी कोर लेबोरेटरी, मल्टी-ओमिक्स सुविधा, प्रयोगात्मक पशु सुविधा, वैक्सीन डिजाइन और विकास सुविधा, बायोडिजाइन में नवाचार का स्कूल आदि। जो THSTI के अनुसंधान कार्यक्रमों और राष्ट्रीय राजधानी क्षेत्र बायोटेक साइंस क्लस्टर और अन्य शैक्षणिक और औद्योगिक भागीदारों के लिए विशाल संसाधनों के रूप में काम करते हैं। ब्रिक-टीएचएसटीआई कई महत्वाकांक्षी और वैश्विक रूप से प्रतिस्पर्धी शैक्षणिक पाठ्यक्रमों के माध्यम से वैज्ञानिक लीडर की अगली पीढ़ी को प्रशिक्षित करता है जो बहु-विषयक शिक्षाविदों-उद्योग साझेदारी के माध्यम से अनुसंधान और नवाचार को बढ़ावा देता है।

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 Virus Research, 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 Innovation in Bio design 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. BRIC-THSTI trains the next generation of scientific leaders through many ambitious and globally competitive academic courses which promotes research and innovation through multi-disciplinary academia-industry partnerships.

3. यह भर्ती क्लिनिकल डेवलपमेंट सर्विसेज एजेंसी (CDSA) केंद्र में परियोजना पदों की रिक्तियों को भरने के लिए की जा रही है। CDSA, THSTI का एक विशेष केंद्र है, जिसे सार्वजनिक स्वास्थ्य रोगों के लिए किफायती स्वास्थ्य उत्पादों के विकास को सुविधाजनक बनाने के उद्देश्य से स्थापित किया गया है। यह देश का एकमात्र सार्वजनिक केंद्र है जिसे लाभ-न कमाने वाले तकनीक-आधारित प्रीक्लिनिकल और क्लिनिकल उत्पाद विकास के साथ-साथ सार्वजनिक एजेंसियों द्वारा किए जाने वाले क्लिनिकल अनुसंधान को समर्थन और पोषण देने के उद्देश्य से बनाया गया है। यह प्रशिक्षण और सीखने के एक इको-सिस्टम के विकास की दिशा में काम करता है और सार्वजनिक क्षेत्र की संस्थाओं तथा छोटे और मध्यम उद्यमों (SME) के साथ मिलकर नवाचारपूर्ण तकनीकों को जनहित में चिकित्सीय उत्पादों में बदलने का कार्य करता है। 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.

**CDSA के मुख्य उद्देश्य निम्नलिखित हैं:**

- एक अकादमिक क्लिनिकल रिसर्च यूनिट के रूप में, अध्ययन योजना, सेटअप, संचालन, परियोजना प्रबंधन, निगरानी, डेटा प्रबंधन, सुरक्षा रिपोर्टिंग, विश्लेषण और रिपोर्ट लेखन में अन्वेषकों और SMEs को अंत-to-अंत क्लिनिकल अध्ययन समर्थन प्रदान करना।
- क्लिनिकल विकास/प्रयोजन और नियमन के क्षेत्र में उच्च गुणवत्ता वाले प्रशिक्षण के माध्यम से शोध क्षमता और क्षमता का निर्माण करना।
- देश में क्लिनिकल रिसर्च पर्यावरण का समर्थन और सुदृढ़ करना।
- नियामक विज्ञान और नीति समर्थन: शोधकर्ताओं, नियामकों, स्वास्थ्य नीति निर्माताओं और उद्योग को समर्थन देने के लिए उपकरण और दृष्टिकोण प्रदान करना।

**The main objectives of CDSA are:**

- 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
- Build research capacity and capability through high quality training in the area of clinical development/trials and regulation
- Support and strengthen clinical research environment in the country
- Regulatory science and policy support: provide tools and approaches to support researchers, regulators, health policy makers & industry.

4. यह भर्ती निम्नलिखित परियोजनाओं के तहत ब्रिक-टीएचएसटीआई की रिक्तियों को भरने के लिए है:

This recruitment is to fill up the vacancies of BRIC-THSTI under the following projects:

**पद के लिए आवश्यक शैक्षिक योग्यता और अनुभव / Educational Qualification and Experience required for the post:**

1.	पद का नाम/Name of the post	प्रोग्राम मैनेजर/Program Manager
	पदों की संख्या/Number of the post	01
	परियोजना का नाम/Name of the Project	Improving maternal and neonatal outcomes using imaging data science
	वेतन/Emoluments	Rs. 67,000/- + HRA
	उम्र/Age	Up to 40 years
	न्यूनतम शैक्षिक योग्यता और अनुभव/Minimum Educational Qualification and Experience	<p><b>Essential qualifications and work experience:</b></p> <ul style="list-style-type: none"> <li>• MBBS/BDS/BVSc with a minimum of three (3) years of experience in clinical project management and/or clinical trial/ study monitoring.</li> </ul> <p style="text-align: center;"><b>OR</b></p> <ul style="list-style-type: none"> <li>• Master's Degree / PG Diploma in Life Sciences / Biomedical Sciences / Pharmacy / Public Health / Clinical Research with at least five (5) years of experience in clinical project management and/or clinical trial/ study monitoring.</li> </ul> <p style="text-align: center;"><b>AND</b></p> <ul style="list-style-type: none"> <li>• Experience in clinical trial or public health project management in a recognised organisation/institute (academic clinical trials unit, CRO, pharmaceutical, biotechnology, or medical device company)</li> </ul> <p><b>Desirable qualifications and work experience:</b></p> <ul style="list-style-type: none"> <li>• Postgraduate degree in Public Health</li> <li>• MD/DNB from a recognised Indian University/recognised by MCI</li> <li>• PhD in a health-related discipline</li> <li>• Demonstrable experience of line management, project management concepts, and ability to understand, explain and communicate</li> <li>• Project concepts using standard tools and templates.</li> </ul>
	नौकरी का प्रोफाइल/Job profile	<p>The Program Manager is responsible for overseeing, managing, and executing the operational aspects of assigned clinical studies and trials, ensuring the timely delivery of milestones while upholding the highest standards of quality, compliance, and scientific integrity. The role demands cross-functional leadership, operational excellence, and a strategic mindset to support complex clinical research programs</p> <p><b><u>Key Responsibilities:</u></b></p> <ul style="list-style-type: none"> <li>• Oversee and manage the performance of the project team, ensuring effective collaboration and accountability across functions.</li> <li>• Maintain the integrity of clinical trials by monitoring data, processes, and documentation through both onsite visits and remote oversight.</li> <li>• Conduct site qualification, initiation, monitoring, and close-out visits for assigned clinical trials/research studies. Must be willing to travel to</li> </ul>

		<p>clinical sites across India on short notice and stay for extended durations as needed.</p> <ul style="list-style-type: none"> <li>• Lead cross-functional coordination efforts, working closely to develop, implement, and maintain comprehensive project plans and timelines. Clearly communicate project expectations to all relevant team members and consultants.</li> <li>• Manage overall project budgets to ensure alignment with scope and financial objectives.</li> <li>• Support the implementation and maintenance of systems related to resource planning, study administration, monitoring, quality assurance, and documentation, under the supervision of the Chief - Clinical Portfolio Management (CPM).</li> <li>• Undertake additional responsibilities within the Clinical Portfolio Management team as required by project deliverables or organisational needs.</li> <li>• Establish and enforce procedures to ensure adherence to study protocols, regulatory requirements, and organizational standards.</li> <li>• Ensure adherence to applicable regulatory and ethical frameworks, including oversight by regulatory authorities, ethics committees, and other governing bodies.</li> <li>• Coordinate and support audit readiness and audit processes, including the development of Corrective and Preventive Actions (CAPAs).</li> <li>• Liaise with the Steering Committee and Data Safety Monitoring Board (DSMB) to ensure compliance with Research Governance, Good Clinical Practice (GCP), Data Protection, and Ethical Guidelines.</li> <li>• Prepare or oversee regulatory and ethics submissions, amendments, and responses to regulatory queries, ensuring timely approvals and renewals.</li> <li>• Develop and deliver project-specific and protocol-specific training, as well as additional training as requested.</li> <li>• Provide ongoing guidance, mentorship, and operational training to project staff as needed.</li> <li>• Serve as trainer for training initiatives conducted by CDSA.</li> <li>• Collaborate with Investigators to monitor study progress, ensure meaningful outputs, and support necessary protocol or funding amendments based on study findings or operational needs.</li> <li>• Facilitate partnerships with sponsors, collaborators, and regulatory bodies to support compliance, reporting, and trial visibility.</li> <li>• Engage external stakeholders such as funding bodies and governmental agencies to enhance trial impact and reach.</li> <li>• Oversee the development, approval, and distribution of essential study documents, including study protocols, Case Report Forms (CRFs), study manuals, and tools for investigational sites and review boards.</li> <li>• Manage regulatory documentation workflows, including distribution, collection, and tracking, ensuring compliance and audit readiness.</li> <li>• Collaborate with data management and other departments to monitor project milestones, assess challenges, and drive progress.</li> <li>• Evaluate, implement, and oversee clinical trial management systems (CTMS), electronic data capture (EDC), and eTMF systems.</li> <li>• Act as the point of contact for clinical systems integration, troubleshooting, and training.</li> </ul>
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	<b>कौशल /Skills</b>	<ul style="list-style-type: none"> <li>• Demonstrated ability to build, lead, and mentor high-performing project teams. Skilled in motivating and inspiring others, effectively delegating responsibilities, and making timely, high-quality decisions in complex clinical settings.</li> <li>• Recognized for earning the trust and confidence of diverse stakeholders. Possesses a quick learning aptitude, managerial courage, emotional resilience, and a proactive mindset, particularly in dynamic and fast-paced environments.</li> <li>• Deep knowledge of Indian clinical trial regulations and a comprehensive understanding of global standards, including ICH-GCP and CDSCO guidelines. Committed to upholding the highest standards of regulatory and ethical compliance.</li> <li>• Strong grasp of clinical operations, project budgeting, and resource management. Demonstrates a continuous improvement mindset, with a focus on quality assurance, operational efficiency, and pragmatic problem-solving.</li> <li>• Exceptional ability to negotiate, influence, and align cross-functional teams and external partners. Approaches challenges with a collaborative, solution-oriented mindset that fosters consensus and drives results.</li> </ul>
<b>वॉक-इन साक्षात्कार की तिथि/ Date of walk-in interview:</b>		26 <sup>th</sup> August 2025
2.	<b>पद का नाम/Name of the post</b>	<b>नैदानिक अनुसंधान सहयोगी/ Clinical Research Associate</b>
	<b>पदों की संख्या/Number of the post</b>	01
	<b>परियोजना का नाम/Name of the Project</b>	Sepsis-related mortality in neonates in India: A multi-disciplinary, multi-institutional research program for context-specific solutions
	<b>वेतन/Emoluments</b>	Rs. 49,000/- + HRA

उम्र/Age	35 years
न्यूनतम शैक्षिक योग्यता और अनुभव/Minimum Educational Qualification and Experience	<ul style="list-style-type: none"> <li>Bachelor's in Life Sciences with a minimum of three years of relevant clinical trial monitoring experience or clinical trial/study coordinator, or clinical trial/study associate experience.</li> </ul> <p style="text-align: center;"><b>OR</b></p> <ul style="list-style-type: none"> <li>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 or clinical trial/study coordinator, or clinical trial/study associate experience</li> </ul> <p style="text-align: center;"><b>OR</b></p> <ul style="list-style-type: none"> <li>MBBS/ BDS/ BHMS/ BAMS/ BPT with a minimum of 2 years of relevant clinical trial monitoring or clinical trial/study coordinator, or clinical trial/study associate experience.</li> </ul>
नौकरी का प्रोफाइल/ Job profile	<p>The Clinical Research Associate (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 clinical trial lifecycle.</p> <ul style="list-style-type: none"> <li>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.</li> <li>Set up trial sites, ensuring that investigational products and essential trial supplies are delivered, stored, and documented appropriately.</li> <li>Perform quality checks and execute quality assurance process across clinical operations and clinical laboratories in accordance with GCP/GCLP standards.</li> <li>Provide training on protocols and trial procedures to site staff and maintain ongoing communication to support study execution and address issues.</li> <li>Support clinical staff through guidance and training as and when needed.</li> <li>Create, maintain, and submit all required documentation related to site management, monitoring visits, findings, and follow-up actions.</li> <li>Track and manage study progress, including regulatory and ethics submissions, patient recruitment and enrolment, CRF completion, and data query resolution.</li> <li>Verify data accuracy through source data/document verification to ensure consistency between CRFs and clinical records.</li> <li>Prepare detailed monitoring visit reports and contribute to the preparation and archiving of essential trial documents.</li> <li>Assess trial site compliance and escalate quality or protocol deviations to the Project Manager or Senior Leadership as appropriate.</li> <li>Collaborate with Clinical Portfolio Management and other internal departments on cross-functional initiatives and project requirements.</li> </ul>
कौशल /Skills	<ul style="list-style-type: none"> <li>Proficient in computer applications, with demonstrated expertise in Microsoft Office Suite (Word, Excel, PowerPoint, Outlook).</li> <li>Strong knowledge of ICH-GCP, GCLP, and regulatory guidelines.</li> <li>Excellent documentation, communication, and organizational skills.</li> <li>Ability to travel frequently to assigned trial sites.</li> <li>Detail-oriented with effective time management skills and ability to manage multiple tasks and priorities efficiently.</li> </ul>

<b>वाक-इन साक्षात्कार की तिथि/ Date of walk-in interview:</b>		28 <sup>th</sup> August 2025
3.	<b>पद का नाम/Name of the post</b>	प्रधान परियोजना सहयोगी /Principal Project Associate
	<b>पदों की संख्या/Number of the post</b>	01
	<b>परियोजना का नाम/Name of the Project</b>	INDIGO Effective and Affordable flu Vaccine for the world
	<b>वेतन/Emoluments</b>	Rs. 49,000/- + HRA
	<b>उम्र/Age</b>	35 years
	<b>न्यूनतम शैक्षिक योग्यता और अनुभव/Minimum Educational Qualification and Experience</b>	<ul style="list-style-type: none"> <li>Bachelors in medical sciences with minimum three years of relevant clinical trial monitoring experience or clinical trial/study coordinator, or clinical trial/study associate experience.</li> </ul> <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> <li>Master's degree/ diploma, life sciences, pharmacy, public health, healthcare or other related discipline with minimum 2 years of relevant clinical trial monitoring experience or clinical trial/study coordinator, or clinical trial/study associate experience.</li> </ul> <p style="text-align: center;">OR</p> <ul style="list-style-type: none"> <li>MBBS/ BDS/ BHMS/ BAMS/ BPT with a minimum of 2 years of relevant clinical trial monitoring or clinical trial/study coordinator, or clinical trial/study associate experience.</li> </ul>
	<b>नौकरी का प्रोफ़ाइल/ Job profile</b>	<ul style="list-style-type: none"> <li>The Principal Project Associate/ Clinical Research Associate conducts monitoring visits for the 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.</li> <li>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.</li> <li>Performs quality functions and executing quality programs (clinical operations, clinical laboratory) as per GCP/GCLP and regulations</li> <li>Completes appropriate therapeutic, protocol and clinical research training to perform job duties.</li> <li>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</li> <li>Administers protocol and related trial training to assigned sites and establishes regular lines of communication with sites to manage ongoing project expectations and issues.</li> <li>May provide training and assistance to junior clinical staff.</li> <li>Creates and maintains appropriate documentation regarding site management, monitoring visit findings and action plans by submitting regular visit reports and other required trial documentation.</li> <li>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.</li> <li>Verifying that data entered on to the CRFs is consistent with participant clinical notes (source data/ document verification)</li> <li>Writing visit reports.</li> </ul>

		<ul style="list-style-type: none"> <li>Filing and collating trial documentation and reports.</li> <li>Archiving trial documentation and correspondence.</li> <li>Evaluates the quality and integrity of trial site practices related to the proper conduct of the protocol and adherence to applicable regulations.</li> <li>Escalates quality issues to the Quality Manager, Project Manager and/ or senior management.</li> <li>Work with Clinical Portfolio Management on other projects as directed and other internal departments on their requirements as and when required.</li> </ul> <p>Skills: -</p> <ul style="list-style-type: none"> <li>Computer skills including proficiency in use of Microsoft Office applications</li> <li>Basic knowledge and ability to apply GCP and applicable regulatory guidelines.</li> <li>Strong written and verbal communication skills including good command of English required.</li> <li>Excellent organizational and problem-solving skills.</li> <li>Effective time management skills and ability to manage competing priorities.</li> </ul>
<b>वॉक-इन साक्षात्कार की तिथि/ Date of walk-in interview:</b>		28 <sup>th</sup> August 2025
4.	<b>पद का नाम/Name of the post</b>	डाटा प्रबंधक/Data Manager
	<b>पदों की संख्या/Number of the post</b>	01
	<b>परियोजना का नाम/Name of the Project</b>	INDIGO Effective and Affordable flu Vaccine for the world
	<b>वेतन/Emoluments</b>	67,000 + HRA
	<b>उम्र/Age</b>	40 years
	<b>न्यूनतम शैक्षिक योग्यता और अनुभव/Minimum Educational Qualification and Experience</b>	<p><b>Essential:</b></p> <ul style="list-style-type: none"> <li>Master's degree in any field preferably in science, with 6 years of post-qualification experience in clinical data management/ clinical research/ operations/MIS/data analysis/IT/computer science/ healthcare field</li> </ul> <p style="text-align: center;"><b>OR</b></p> <ul style="list-style-type: none"> <li>Graduation degree in any field preferably in science, with 8 years of post-qualification experience in clinical data management/ clinical research/operations/MIS/data analysis/IT/computer science/ healthcare field</li> </ul> <p><b>Desirable:</b></p> <ul style="list-style-type: none"> <li>Diploma in Clinical research and clinical data management.</li> <li>Familiarity with industry standard CDMS and some programming Skills</li> <li>Preparation of Clinical Study Data Management documents</li> </ul>
	<b>नौकरी का प्रोफाइल/ Job profile</b>	<p><b>Responsibilities</b></p> <ul style="list-style-type: none"> <li>Clinical Study Protocol understanding and experience in the preparation of Data Management documents - DMP (Data Management Plan), DVP (Data Validation Plan/ Edit Checks Document), Annotated CRF, Data Entry Guidelines etc.</li> <li>Prepare data transfer guidelines for external data loads and self-evident correction charts.</li> </ul>



	<ul style="list-style-type: none"> <li>• Manage change requests and coordinate approvals from sponsors and stakeholders.</li> <li>• Design and review Case Report Forms (CRFs/eCRFs) aligned with protocol requirements.</li> <li>• Oversee and quality check of clinical database setup, validation programming, annotated CRFs, data extract views, and final data listings.</li> <li>• Ensure adherence to standards such as CDISC, SDTM, and institutional SOPs.</li> <li>• Reconcile adverse event (AE/SAE) data and integrate medical coding dictionaries (e.g., MedDRA, WHODrug).</li> <li>• Preparation of Data transfer guidelines for external data load and self-evident correction chart.</li> <li>• Working knowledge of Query management, data cleaning, data freezing and data archival.</li> <li>• Maintain strict compliance with GCP, ICH, and data protection regulations.</li> <li>• Ensure participant confidentiality and secure handling of all clinical trial data.</li> <li>• Train and supervise site staff in data entry and protocol compliance.</li> <li>• Sound knowledge of Clinical Database Development tools, logics and techniques and GCDMP</li> <li>• Generate interim reports and review of listings of data for clinical trial status and data extraction in collaboration with the statistician</li> <li>• Generating ad-hoc reports as needed to support project oversight and decision-making.</li> <li>• Maintain oversight of data status reports for internal and external communication.</li> <li>• Maintaining and archiving of clinical study related documents</li> <li>• Participates in cross functional team meetings &amp; external client meetings as DM representative</li> <li>• The data manager will ensure that security of all data is maintained and confidentiality of participants is protected.</li> <li>• Managing requests for data from external third parties – including liaising with internal staff and external collaborators to provide data in a timely and appropriate manner and maintenance of a database detailing the status of such external data requests.</li> <li>• Knowledge of Biorepository Management Systems (BMS) for tracking specimen status and turnaround time.</li> <li>• Effective interaction with intra-departments to ensure all required, vital information and documentation is acquired in a timely manner.</li> <li>• Lead in preparation of datasets for analysis including data cleaning and ensuring compliance with the data protection.</li> <li>• Development of Standard Operation Procedures and training to the study team</li> <li>• Supervise DM activities at the clinical site.</li> </ul>
<b>कौशल /Skills</b>	<ul style="list-style-type: none"> <li>• Good management &amp; leadership skills</li> <li>• Familiarity with GCP, US-FDA 21 CFR 11, regulatory requirements and data standardization guidelines.</li> <li>• IT literate (experience with Microsoft based applications and other CDMS applications)</li> <li>• Must have experience in handling EDC tools</li> <li>• Validation programming</li> <li>• Must have understanding of clinical trials and familiarity with clinical data management functions.</li> </ul>

		<ul style="list-style-type: none"> <li>• Good interpersonal, verbal and written communication skills.</li> <li>• Client focused approach to work.</li> <li>• A flexible attitude with respect to work assignments and new learning.</li> <li>• Meticulous attention to detail.</li> <li>• Effective time management in order to meet metrics or team objectives.</li> <li>• Commitment to project and team goals.</li> <li>• Must be able to work independently but seek guidance when necessary.</li> <li>• Team player with outstanding inter-personal, negotiation skills and organizational skills.</li> <li>• Sense of urgency in completing assigned tasks</li> <li>• Exhibits a sense of urgency about solving problems and completing work.</li> <li>• Shows commitment to and performs consistently high-quality work.</li> <li>• Ability to model behaviors and ethics in line with CDSA Mission and Vision.</li> </ul>
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**उपरोक्त पदों के लिए /For posts mentioned above-**

- ऑनलाइन आवेदन प्राप्त करने की अंतिम तिथि: **03 सितम्बर 2025**/Last date for receipt of online application for posts: **03 September 2025**.
- आवेदनों की जांच/छंटनी की जाएगी तथा आगे की चयन प्रक्रिया हेतु उन्हें अग्रेषित किया जाएगा। **The applications will be scrutinised/shortlisted and processed for further selection**

5.	पद का नाम/Name of the post	मेडिकल मॉनिटर/Medical Monitor
	पदों की संख्या/Number of the post	01
	परियोजना का नाम/Name of the Project	INDIGO Effective and Affordable flu Vaccine for the world
	वेतन/Emoluments	78,000 + HRA
	उम्र/Age	45 years
	न्यूनतम शैक्षिक योग्यता और अनुभव/Minimum Educational Qualification and Experience	<p><b>Essential Qualifications and Experience</b></p> <ul style="list-style-type: none"> <li>• MD/MS or Postgraduate Diploma in a medical discipline from a recognized university with a minimum of 1 year of relevant research &amp; development (R&amp;D) experience in clinical research</li> </ul> <p style="text-align: center;"><b>OR</b></p> <ul style="list-style-type: none"> <li>• MBBS/BDS or an allied medical degree with a minimum of 4 years of R&amp;D experience in clinical research</li> </ul> <p><b>Desirable Experience</b></p> <ul style="list-style-type: none"> <li>• Prior experience in medical monitoring and/or medical affairs in clinical studies</li> <li>• Exposure to vaccine trials or regulatory studies is highly preferred</li> </ul>
	नौकरी का प्रोफाइल/Job profile	<p>The Medical Monitor will oversee the medical and safety aspects of ongoing clinical trials, ensuring compliance with protocol, GCP, and regulatory guidelines. This role plays a critical part in participant safety oversight and scientific data integrity, notably for regulatory and vaccine-focused study. This position reports to the Head – Clinical Sciences at CDSA-THSTI.</p> <p><b><u>RESPONSBLITY</u></b></p> <ul style="list-style-type: none"> <li>• Provide medical and safety oversight for clinical trials in line with the Safety Management Plan</li> <li>• Review and interpret adverse events (AEs/SAEs), assess causality, drug effect, and clinical relevance</li> <li>• Participate in data review, safety listings, and statistical analyses</li> </ul>

		<ul style="list-style-type: none"> <li>• Support protocol development, CRF design, SAP, and DMC charters</li> <li>• Conduct on-site medical monitoring visits and generate visit reports</li> <li>• Assist Principal Investigators with expedited and periodic safety reports</li> <li>• Review and finalize clinical narratives for safety events</li> <li>• Collaborate with investigators, study teams, and external stakeholders on medical queries</li> <li>• Participate in study team meetings, DMC reviews, and database lock procedures</li> <li>• Ensure accurate MedDRA coding of safety data</li> <li>• Contribute to Clinical Study Reports (CSR), abstracts, and publications</li> <li>• Provide mentorship on safety monitoring and GCP compliance</li> <li>• Perform other duties as assigned by the faculty-in-charge or project lead</li> <li>• May require travel to clinical sites or sponsor meetings</li> </ul>
	<b>कौशल /Skills</b>	<ul style="list-style-type: none"> <li>• Strong foundation in Good Clinical Practice (GCP) and clinical trial regulations</li> <li>• Understanding of adverse event analysis, reporting standards, and risk mitigation</li> <li>• Proficiency in medical coding (MedDRA) and safety review processes</li> <li>• Excellent communication, team collaboration, and problem-solving abilities</li> <li>• Ability to influence stakeholders and work cross-functionally</li> <li>• Ethical, dependable, and committed to quality-driven results</li> <li>• Basic computer skills (MS Word, Excel, Email)</li> <li>• Familiarity with EDC systems, safety databases and data visualisation tools are a plus</li> </ul>

उपरोक्त पदों के लिए /For posts mentioned above-

- ऑनलाइन आवेदन प्राप्त करने की अंतिम तिथि: **03 सितम्बर 2025/Last date for receipt of online application for posts: 03 September 2025.**
- आवेदनों की जांच/छंटनी की जाएगी तथा आगे की चयन प्रक्रिया हेतु उन्हें अग्रणी किया जाएगा। **The applications will be scrutinised/shortlisted and processed for further selection**

**नोट:1) उम्मीदवारों क्रम संख्या 1, 2 और 3 के पदों के लिए आवेदनको अपना नवीनतम रिज्यूमे, शैक्षिक योग्यता और अनुभव के समर्थन में दस्तावेजों की एक प्रति, मूल दस्तावेज और सत्यापन के लिए एक वैध आईडी कार्ड लाना होगा। 2) जो उम्मीदवार निर्धारित समय के बाद आएंगे, उन्हें प्रवेश नहीं दिया जाएगा। 3) लिखित परीक्षा/कौशल परीक्षण/साक्षात्कार के लिए आने वाले सभी उम्मीदवारों को अनिवार्य रूप से अपनी मोबाइल फोन और वैध पहचान प्रमाण रिसेप्शन पर जमा करना होगा, और यह केवल चयन प्रक्रिया पूरी होने के बाद ही वापस किया जाएगा।**

**NOTE: 1) The candidates applying for the post of S.No. 1,2 & 3 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.**

#### **सामान्य नियम व शर्तें/ GENERAL TERMS & CONDITIONS:**

- 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.
- 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 the 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 Ex-servicemen 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.
- l) Canvassing wrong information in any form will be a disqualification.

**उपरोक्त तालिका 4 -5 में उल्लिखित पदों के लिए आवेदन कैसे करें/ HOW TO APPLY FOR POSTS MENTIONED IN ABOVE TABLE 4 & 5:**

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 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:

D) 4 :	<b>S. No</b>	<b>सीधी भर्ती पर आवेदन करना/ Applying on direct recruitment</b>	<b>आवेदन शुल्क राशि/ Application fee amount</b>	Step
	1.	Unreserved, OBC & EWS candidates	Rs 590/-	
	2.	SC/ST/Women/PwBD	Rs 118/-	

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](mailto: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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