CLINICAL DEVELOPMENT SERVICES AGENCY

An extra mural unit of THSTI,
An autonomous organization of Department of Biotechnology
Ministry of Science & Technology, Govt. of India
3rd Floor, THSTI Building, 3rd Milestone, Gurgaon-Faridabad Expressway,
Faridabad – 121001 (Haryana)

Recruitment Notice No. CDS/RN/1/2021

Name of the Post & No.	**Clinical Research Associate– 1 position**
Name of the Study	(A Phase III, Multicenter, Randomized, Double-blind, Three arm Placebo controlled Trial to Evaluate the Efficacy and Safety of two vaccines in Preventing Tuberculosis (TB) in Healthy Household Contacts of Newly Diagnosed Sputum Positive Pulmonary TB Patients funded by ICMR in Six States of India)
Emoluments	**(upto Rs. 55,000/- per month consolidated)**
Duration	**12 Months, extension of contract is based on the performance.**
Age Limit	**Upto 45 Years**
Location	**Faridabad or across any clinical site (in India).**
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 and regulations • Completes appropriate therapeutic, protocol and clinical research training to perform job duties. • Setting up the trial sites such that each centre 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
Qualifications and Experience	• Bachelor's in medical sciences or Master's degree/ diploma, life sciences, pharmacy, public health, healthcare or other related discipline • MBBS/ BDS/ BHMS/ BAMS/ BPT preferred • Atleast 2 years of relevant clinical trial monitoring experience
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

GENERAL TERMS & CONDITIONS:

1. All educational professional and technical qualification should be from a recognized Board/ University and full-time.
2. The experience requirement specified should be experience acquired after obtaining the minimum educational qualifications required for the post.
3. Persons working in Govt. or Public Sector undertaking should produce "No Objection Certificate" at the time of Interview.
4. The qualification, experience and the number of position and other requirements for the post can be relaxed at the discretion of the Chairman of the Interview Committee, in case candidates are otherwise well qualified.
5. Only shortlisted candidates will be contacted for interview
6. Incomplete applications will stand summarily rejected without assigning any reasons

7. The salary is a consolidated sum as per sanctioned order without any other benefits. Salary mentioned against the position is the maximum and can be lesser based on candidate's experience, qualifications, skill set, etc. A 10% annual increase in salary is based on the performance
8. **This position is strictly project-based.**
9. All results will be published on our website and all future communications will be only through email
10. Candidates (Including SC/ST and other backward classes) are not entitled for the travel reimbursement or any other reimbursement for attending the interview.
11. This position will be placed in CDSA Faridabad office at NCR Biotech Science Cluster at **Faridabad Gurgaon Expressway, Faridabad or National Institute of Tuberculosis and Respiratory Diseases, Delhi.**
12. Canvassing in any form will be a disqualification.
13. **Submission of application will be thru online mode only otherwise it will get rejected or ignored.**

Procedure for filling online application:

a. Before filling up the online application, keep the following documents handy:

i) A soft copy of your passport size photo and signature. (only jpeg/jpg format, file size 50 kb maximum)

ii) A comprehensive CV (PDF format only, file size 1 mb maximum) containing details of qualification, positions held, professional experience/distinctions etc.

iii) Candidates are requested to use Google Chrome internet browser for best results in submission of online application.

b. Once online application is submitted, no correction/ modification is possible.
c. In case of difficulty in filling up the online form, please send an e-mail to **mahendersingh.cdsa@thsti.res.in**
d. Those who have applied once need not to apply again.
e. Only technical queries will be resolved (if any), other than technical will not be entertained.
f. On successful submission of your application, an auto-generated email containing a reference number will be sent to the email address provided. Please keep a note of the reference number for future correspondence.

NOTE: **THIS IS A ROLLING OUT ADVERTISEMENT ON CDSA WEBSITE ONLY. THE APPLICATION WILL BE SCREENED ON WEEKLY BASIS. IN CASE A SUITABLE CANDIDATE IS NOT FOUND, THE CALL FOR APPLICATION WILL REMAIN OPEN TILL SUITABLE CANDIDATE IS FOUND. AS SOON AS SUITABLE CANDIDATE IS FOUND, THIS RECRUITMENT NOTICE WILL BE CLOSED ON OUR WEBSITE.**

"Government strives to have a work force which reflects gender balance and women candidates are encouraged to apply"