CLINICAL DEVELOPMENT SERVICES AGENCY

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

Recruitment Notice No. CDS/RN-iKMC/37/CRC/2018

Name of the Post	**Clinical Research Coordinator (iKMC Study), 01 Position**
Age Limit	**Upto 45 years (Study based Research Position)**
Emoluments/Duration	**Rs. 1,00,000/- per month consolidated, 12 Months (Depending on experience)**
Location	**Safdarjung Hospital, New Delhi**
Job profile	The Clinical Research Coordinator (CRC) will be leading the study team and will be primary point of contact for operational aspects of implementation of the clinical trial activities from study start-up through database lock, ensuring compliance with GCP and applicable guidance. He/ she will be the primary link between study team and investigators. The CRC will have an oversight responsibility for activities undertaken by study team. He/she will be responsible for: i. Providing input into and/or developing study related materials such as clinical operations plan, SOPS, CRF completion guidelines, informed consent, study logs/forms and other study related documents; ii. Supporting the submissions for relevant government / ethics approvals; iii. Developing training module and planning the initial and retraining sessions for the research study staff along with the site supervisors (called research officers) who will be medical doctors; iv. Structuring and supervising compliance for the study management plans; Ensuring compliance with the project requirements and cascading the issues/ updates to the relevant stakeholders; v. Supervising the study implementation at site and ongoing study and QC activities; vi. Reviewing protocol deviations and loss to follow up to ensure quality data is delivered; vii. Communicating with CROs and investigators for tracking patient recruitment and progress to study timelines; maintaining and reporting metrics for clinical site performance viii. Providing input and support to maintain appropriate documentation for adverse event safety monitoring, and collaborating in submission of safety reports to sponsor, Ethics Committees and other applicable authorities; ix. Liasoning with the QM team to ensure good quality of study data ;

	x. Providing support to site team to prepare for clinical audits and to respond to audit findings conducted by internal QA and external agencies; xi. Supervising the data management progress with data manager and the DM team; xii. Work with coordinating PI 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; xiii. Keeping stakeholders informed on study progress, risks and accomplishments.
Qualifications and Experience	MD/DNB preferably in Pediatrics/ Community Medicine from an accredited Indian University/ MCI with 3 years of experience after completing MD/DNB. Or DCH in Pediatrics from an accredited Indian University/ MCI with 4 years of experience after completing DCH. Or MBBS from an accredited Indian University/ MCI with atleast 7 years work experience after completing internship, preferably in the field of Pediatrics Or MBBS from an accredited Indian University/ MCI + MPH + 5 years of work experience in clinical research after completing MPH
Skills	• Ability to gain trust and confidence with stakeholders • Operational skills including focus and commitment to quality management and problem solving • Influencing skills including negotiation and teamwork • Effective communication skills, the provision of timely and accurate information to stakeholders • Ability to develop and implement clinical research monitoring plans, SOPs, database concepts, and formats • Understanding of GCP, regulations and guidelines • Excellent computer skills (MS word, excel, internet) • Knowledge of adverse medical event investigation, analysis, and reporting procedures and standards

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. **Candidates must bring their original documents at the time of interview.**
5. The qualification, experience and other requirements for the posts are relaxable at the discretion of the competent authority, in case of candidates who are otherwise suitable.

Candidates not found suitable for the posts notified, can be offered a lower post on the recommendation of the Selection Committee.

6. No TA/DA will be admissible to appear in the interview, including (SC/ST candidates).
7. **Candidates who can join immediately needs to apply, as the position is to be filled on an urgent basis.**
8. This position will be purely on temporary/contractual basis for the specified period of time and based on project.
9. In case large number of applications are received for each post, screening will be done to limit the number of candidates to those possessing higher/relevant qualification.
10. **Walk –in-Interview will be on 10th August 2018. The venue is at ward 20 Seminar room, H block, Safdarjung Hospital, New Delhi. Kindly bring along two sets of latest resume/CV and all the original documents. (For directions, please visit Safdarjung Hospital website at** http://www.vmmcsjh.nic.in/forms/contentpage.aspx?lid=1205
11. **Registration time 1:30 PM onwards. Candidates coming after 1:30 PM shall not be allowed.**
12. **Request for change interview schedule will not be entertained under any circumstances.**
13. The salary is a consolidated sum without any other benefits and it is based on experience, qualifications, skill set, etc. of the candidates.
14. Incomplete applications will stand summarily rejected without assigning any reasons thereof.
15. All results will be published on our website and all future communications will be only through email.
16. Canvassing in any form will be a disqualification.

Note: 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.