Clinical Development Services Agency

(An extramural unit of Translational Health Science and Technology Institute,
an Autonomous Institute of the Department of Biotechnology, Govt. of India)
470, Udyog Vihar Phase III, Gurgaon – 122 016
www.cdsaindia.in

Recruitment Notice No: CDS / RN /1 / 2014

CDSA invites applications from high performing professionals with a desire to serve public health needs of the country for the following positions:

Name of the post / Emoluments	**BIOSTATISTICIAN** (up to Rs. 1,00,000/- per month consolidated)
Qualifications and Skills	PhD in Statistics
Skills	• Good oral and written communication skills in English. • Demonstrated ability to work independently and in a multidisciplinary team. • Collaborates closely with investigators, sponsors, and other project leadership to ensure that research project results and conclusions are presented accurately and without bias. • Responsible for designing and validating analysis data sets, programs, and statistical output products (tables, listings, figures).
Experience	• 8-15 years' experience in handling clinical trial & epidemiological studies • Experience in using SAS software, especially base, statistics, and graphics; developing statistical analysis plans and statistical methods for protocols; demonstrated use of sample size estimation and power calculation tools/software. • Knowledge of clinical data management system (paper based and electronic data capturing) is desirable. Coding of data on adverse events and concomitant medication using MedRA an additional plus.
Job profile	The position will work on the design and conduct of clinical studies; the evaluation, interpretation, and reporting of study results; and regulatory submissions. Responsibilities: • Manages research project responsibilities on statistics independently. Handles multiple competing projects and deadlines, and coordinates all the statistical needs of each research project. • Performs intermediate and advanced statistical analysis and programming for research projects. • Documents analyses, creates summaries, and presents results in written and verbal form to requestors. Writes statistical text for study reports and clinical publications. Prepares methods sections and analysis plans for incorporation in abstracts, manuscripts, and grants.

	• Writes own SAS code, find errors, correct, and validate output and results. Performs complex programming efficiently. • Programs analysis datasets using SAS and/or reviews those programmed by others to ensure quality products; combines multiple disparate raw databases and derives analysis variables accurately. Considers alternative programming approaches to improve quality and/or efficiency. Experience with data management systems and collection of data following ICH guidelines
Name of the post / Emoluments	**MEDICAL DIRECTOR** Upto Rs 1,50,000/- (consolidated) per month
Qualifications and Skills	**Essential:** A postgraduate medical degree (e.g. MD in general medicine/ pharmacology/ community medicine or equivalent) **Desirable:** An advanced degree/diploma in public health.
Skills	▪ Proven ability to foster a collaborative team environment. ▪ Supervisory skills including clinical mentoring and coaching skills. ▪ Effective organizational and interpersonal skills, communication and presentation skills required. ▪ Excellent written and oral communications skills in English.
Experience	▪ Approximately Fifteen years of hands-on experience in community based clinical trials; epidemiological and observational studies and /or R&D experience in pharmaceutical/biotechnology industry. ▪ Demonstrated sound knowledge of clinical regulatory standards and guidelines. ▪ Experience in New drug/ biologics/vaccine development from Phase I onwards ▪ Experience in preparing study related documents: Protocol, IB and CSR ▪ Experience in safety reporting and management as per the applicable regulatory requirement. ▪ Experience in Pharmacovigilance.
Job profile	▪ Provides medical oversight to all the CDSA projects ▪ Provides medical input to clinical study documents and prepares them in conjunction with the clinical management and regulatory teams. ▪ Participates in the clinical/ product development planning meetings, and provide medical inputs. ▪ Performs the duties of Medical Monitor for all the clinical trials in which CDSA is involved ▪ Solicit expert advice, develop collaborative relationship with key experts and investigators in the COE consortium ▪ Engage medical experts as consultants / advisers in various therapeutic areas as per the need of research project. ▪ Provides project-specific medical /therapeutic training to project and site teams as needed. ▪ Represents CDSA at scientific meetings as required.

GENERAL TERMS & CONDITIONS:

1. These positions are under CDSA's contract career path. Please visit our website www.cdsaindia.in for more information.
2. Appointment will be made on contract subject to renewal based on good performance.
3. The salary is a consolidated sum without any other benefits.
4. Positions will be initially based in the CDSA's interim office at Gurgaon and will be shifted to its permanent campus in Faridabad when ready.
5. The experience requirement specified shall be experience acquired after obtaining the minimum educational qualifications required for the position.
6. The qualifications, experience, emoluments and other requirements for the positions may be modified at the discretion of the competent authority. In case candidates are not found suitable for the positions notified, they may be offered lower positions on the recommendation of the Selection Committee.
7. Persons working in Govt. or Public Sector undertaking should apply through proper channel or produce 'No Objection Certificate' at the time of Interview.
8. Incomplete applications will stand summarily rejected.
9. In case a 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. Only shortlisted candidates will be called for interview.
11. All correspondence shall be only through e-mail.
12. Number of positions filled will be as per the need and availability of the suitable candidates.
13. Canvassing in any form will be a disqualification.

Interested candidates may send their CV along with photo copies of all relevant educational qualifications and experience certificates with a cover letter indicating their motivation for the position (150 words) along with three references to Program Director, Clinical Development Services Agency, 470, Udyog Vihar Phase III, Gurgaon- 122 016, Haryana, India or email the same to **cdsa_admin@thsti.res.in**.

Applications will be accepted up to 21st April, 2014.