CLINICIAL DEVELOPMENT SERVICES AGENCY
An extra mural unit of Translational Health Science & Technology Institute
(an autonomous institute under the Department of Biotechnology (DBT),
Ministry of Science & Technology, Govt. of India)
NCR Biotech Science Cluster at Gurgaon-Faridabad Expressway, Faridabad.

Clinical Development Services Agency (CDSA) mission is to create, develop, nurture world class clinical product development capacity in India.

CDSA invites applications from high performing professionals with a desire to serve public health needs of the country for the below mentioned administrative position.

Recruitment No:	**CDS/RN/01/2015**
Name of the post / Emoluments and Age	**FULL TIME CONSULTANT – CLINICAL DATA MANAGEMENT** (up to Rs. 75,000/- per month consolidated) **Age Limit: 45 years**
Qualifications and Skills	Master's degree level (biological/ life science, pharmacy or other health related discipline preferred)
Skills	• Good oral and written communication skills in English. • Demonstrated ability to work independently and in a multidisciplinary team. • Demonstrated ability to manage and motivate direct reports • Excellent interpersonal, verbal and written communication skills, (including experience in making presentations at conferences, meetings, training sessions) • Able to role model behaviours and ethics in line with CDSA Mission, Vision and Values • IT literate • Knowledge of SOPs/ Guidelines/ System Life Cycle methodologies, GCP and any other • applicable local regulations and proven practical application. • Tenacity to work in an innovative environment. • Personal skills include ability to manage competing priorities, function independently, attention to detail, excellent organizational skills, and flexibility to change and fulfilling activities to completion. • Demonstrated ability to learn new systems and function in an evolving technical environment.
Experience	• 8-15 years in clinical data management with at least 5 years of management experience • Sound understanding of the global drug development process • Ability to develop/advise on training programs for Data Scientists/Technicians and data management workshops for Clinical Research staff • Ability to establish strong working relationships with others in the drug development process, particularly within Clinical Research • Familiarity with SAS programming • Well-versed in regulatory requirements for validation of data management systems, GxP, Good Clinical Data Management Practices (GCDMP) Experience in various phases of clinical trials with full project life cycle experience (CRF design to database lock and reporting); use of commercial and/ or proprietary clinical data management systems, coding dictionaries/encoding systems (e.g. MedDRA, WHODRL), other software in support of data management activities (e.g SAS, Access, SQL, Oracle), programming skills and experience with electronic data capture a definite plus

Job profile	• Take responsibility for managing Data Management. • Provide technical leadership, resource management and project management for the required technical aspects supporting clinical trial activities. • Ensure quality, timeline and productivity requirements are met or exceeded. Included in this are project planning and implementation, milestone tracking, organization and participation in team meetings, monitoring progress and providing updates as required • Create, direct and maintain strategies in line with the Clinical Operations and/or Biostatistics organization to help facilitate efficiencies within the department. • Manage a team local to a site to provide work direction task prioritization, supervision, assistance and career development to assigned tasks. • Manage all phases of data management activities from study start up to database close and not limited to database set-up, CRF design, data entry, validation/ edit checks, data transfer, and any ad-hoc programming required to support a clinical trial process • Lead cross-functional meetings and drive initiatives to ensure the delivery of milestones and timelines for clinical studies. • Identify and adequately resolve operational and technical problems. Manage process improvements. • Communicate with the other operational groups regarding workflow, process, timelines, and resource planning to ensure transparency between the all functions as well as any external support groups. • Define, develop and deploy appropriate operating procedures. • Work closely with the Quality Management Groups (QMG) to ensure compliance with SOPs/ Guidelines, GCP and any other applicable local regulations. • Provide relevant training/mentoring for staff to assist them in resolution of problems encountered in the conduct of their daily work or on application of Clinical Systems. • Co-ordinate the improvement and implementation of tools, including, but not limited to standard project directories and subdirectories, document file names and status reports that result in improved efficiencies and quality. • Attend (as appropriate) client facing meetings to represent the CDM group on activities including, but not limited to, progress reviews, technical updates on key milestones, bid defences, technical requirements collection. Represent the CDM group at internal and external audits and regulatory inspections, as required.

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 age limit, 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.

5. Number of positions filled will be as per the Institute's need and availability of the suitable candidates.
6. 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. Only shortlisted candidates will be contacted for further discussion.
7. The Consultancy fee for the position of **Consultant, Clinical Data Management** is a consolidated sum without any other benefits. Salaries mentioned against the position are indicative and actual salary will be based on experience, qualifications, skill set, etc. of the candidates.
8. Incomplete applications will stand summarily rejected without assigning any reasons.
9. All results will be published on our website and all future communications will be only through email.
10. This position will be placed in CDSA Faridabad office located at NCR Biotech Science Cluster at Faridabad Gurgaon-Expressway, Faridabad.
11. **Please ignore the Demand Draft (DD) part while filling the online form.**
12. Canvassing in any form will be a disqualification.
13. Interested candidates are requested to submit the online application on or before the last date and send the signed hard copy on or before the specified date.

The procedure for online application:

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

i. A soft copy of your passport size photo.

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

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

In case of difficulty in filling up the online form, please contact **admin@thsti.res.in**

d. 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.

Please do the following after submission of online application:

Take a print out of the application.

Please sign the application at the appropriate place and send the signed application with CV, self-attested copies of certificates / documents pertaining to educational qualification and experience by **speed post /registered post** so as to reach us on or before the last date at the address given below.

HR Department

Clinical Development Services Agency (CDSA)

(An extra mural unit of Translational Health Science and Technology Institute)

NCR Biotech Science Cluster, 3rd Milestone, Faridabad – Gurgaon Expressway,

P.O. Box No. 04, Faridabad – 121001

Please superscribe the post applied for on the envelope.

Please note that application without signature, or those received after due date or incomplete in any other respect will be summarily rejected.

Important dates:

Last date for submission of online application:**30.05.2015**

Last date for receiving the signed hard copy of application at CDSA: **30.05.2015**

Candidates who have applied for this position in response to the earlier advertisement need not apply again. Applications will be accepted up to May 30, 2015.