CLINICAL DEVELOPMENT SERVICES AGENCY
An extra mural unit of THSTI,
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/15/2017

Name of the post	**Quality Analyst (bOPV Study)**
Emoluments & Duration	Up to Rs. 60,000 per month, consolidated for 15 Months
Location	CDSA (THSTI), NCR BioScience cluster, Faridabad
Job profile	**Activities** • Manage all stages of data management quality management activities from study startup to database close • Development of database build specifications • Program procedures to validate the data in the database and perform testing of the same with test patient data (UAT) • Develop edit check and data derivation procedures to support implementation of new clinical trials • Test and execute validation procedures • Perform the database testing and database audit as part of Quality Control • To complete database close / lock / freeze checklists • To perform reconciliation of the clinical database against safety data, laboratory data and other third party data as appropriate • Review CRF / eCRF data entry conventions • Interact with other project team members to support the set-up, maintenance, and closure of the Data Management aspects of the project • Preparing interim reports for clinical trial status and participating in data extraction in collaboration with the statistician • Review interim listings for of data as needed • Maintaining clinical study documents • Testing new processes and systems for the management of clinical trials • Participates in cross functional team meetings & external client meetings as DM representative • Ensure data processing activities are performed according to protocol, GCP and SOPs • Generate ad-hoc reports as needed • Coordinate the archiving of study databases and related documents

	Work relations (context – main interfaces – functional report) • Interfaces with Director (Clinical Data Management), Data Manager, Project Manager, Database Administrator, Database Designer, SAS Programmer, Clinical Data Coordinator, Data Entry Operator, Medical Coder, Medical Affairs & Medical Writing, Biostatistics, Central Laboratory, other Heads of Departments and Administration team **Critical Deliverables** • Performing day-to-day clinical data quality control and data processing according to the principles of Good Clinical Practice • Resolving DCFs related to safety and efficacy panels enable data cleaning leading to qualitative database • Effective generation, resolution and updation of DCFs • Quality Check of Database Design, Validation Program, Annotated CRF, Data Extract Views, Laboratory Details, Site and Investigators and Final Data Listings
Qualifications and Experience	• Master's degree level in healthcare field or equivalent experience • Accredited residency training program or equivalent clinical experience • 5 years in clinical data management as Data Validation Associate/ Data Quality Analyst
Skills	• Familiarity with GCP, 21 CFR Part 11, regulatory requirements and data standardization guidelines • Must have experience in handling EDC tools • Validation programming • Must have understanding of clinical trials and familiarity with clinical data management functions • Good interpersonal, verbal and written communication skills. • Client focused approach to work • A flexible attitude with respect to work assignments and new learning. • Meticulous attention to detail • Effective time management in order to meet metrics or team objectives • Commitment to project and team goals • Must be able to work independently but seek guidance when necessary • Team player with outstanding inter-personal, negotiation skills and organizational skills • IT literate (experience with Microsoft based applications and general knowledge of PC functions)

	• Exhibits a sense of urgency about solving problems and completing assigned task • Shows commitment to and performs consistently high quality work • Ability to model behaviours and ethics in line with CDSA Mission and Vision

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 other requirements for the post can be relaxed at the discretion of the controlling authority, in case candidates are otherwise well qualified.
   Interested candidates may please send their current CV with a recent photo and cover letter indicating their motivation for the position applied for (150 words) and three references along with the attached datasheet and excel sheet posted in the website. E-mail should be submitted with subject line **Application for the post of "Quality Analyst (bOPV Study)**" to **cdsa_admin@thsti.res.in.**
5. Only shortlisted candidates will be contacted for further discussion
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 an actual and will be based on experience, qualifications, skill set, etc. of the candidates.
8. **This position is strictly project-based and hired only for 15 months.**
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.
11. This position will be placed in CDSA Faridabad office at NCR Biotech Science Cluster at Faridabad Gurgaon Expressway, Faridabad.
12. Canvassing in any form will be a disqualification.

Those who have applied earlier need not apply again.

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.