Senior Clinical Database Developer

Job ID
REQ-10059053

9   15, 2025

India

Provide timely & professional ongoing Mgmt of Data Mgmt/Coding/CDDRA-Database
Development/DAP deliverables and of clinical trial data with respect Provides comprehensive
expertise for multiple or complex global clinical studies ensuring consistent and high-quality
generation of specification, production, and validation of clinical data collection systems and
associated metadata with high quality, on time, and within budget in accordance with project budgets.
Interpret data collection requirements into data models of moderate complexity and uses relevant
programming language to build EDC &
warehouse setup.

About the Role

Major accountabilities:

- 1. Serves as the primary study lead ensuring timely and quality deliverables

- a. Leads the effective and timely development and implementation of clinical systems for assigned studies
- b. Uses advanced database programming techniques to solve study specific complex validation or custom development needs
- c. Understand and manages study metadata to compliment data provisioning in compliance with global standards.
- d. Coordinates database development and conducts database testing e. Develops data models to support data review and acquisition standards.
- 2. Establishes and maintains strong working relationships with study teams, and functional lines.
- 3. Acts as a technical consultant ensuring appropriate development, maintenance, and use of all system capabilities such as electronic data capture, database programming, edit check programming, report programming, electronic data load, interactive response technology, electronic patient reported outcomes, metadata management and other clinical database development activities.
- 4. Ensures that systems meet regulatory requirements, internal standards and are deployed with exceptional quality eliminating post production changes.
- 5. Lead independently or participate in improvement initiatives and/or non-clinical projects.
- 6. Communicate and ensure that study objectives and priorities are met according to agreed timelines, strategies, quality and scientific standards.
- 7. Responsible for multiple studies in parallel with minimal supervision/mentoring.
- 8. Coordinates resources to ensure study objectives are met.
- 9. Contributes to the development/updates of Clinical Systems processes and supports training on systems and processes to ensure compliance.

Key performance indicators:

- Achieve overall goals as set each year by Global Head Clinical Data Operations, GCO.
- Achieve high level of Quality, timeliness and customer satisfaction on Clinical Data Operations activities, deliverables and support.
- No critical findings as result of routine audits or health authority inspections relating to activities/deliverables supported by the Clinical Standards Group.

Minimum Requirements:
Work Experience:

- 1. At least 5 years of experience in setup of clinical databases/Data Warehouse using RAVE or OC-RDC or LSH.
- 2. Excellent interpersonal and written and oral communication skills, with the ability to effectively communicate cross-functionally
- 3. Advanced technical skills:
- a. Expert knowledge of EDC - Medidata RAVE preferred
- b. Excellent understanding of relational databases
- c. Microsoft Office Suite
- d. Knowledge of other programming languages such as SQL, PL/SQL, VBscript, SAS, C# or Java preferred
- e. Experience in Custom Functions is an added advantage.
- 4. Demonstrated ability to consistently produce detailed, high quality deliverables in a team environment
- 5. Excellent problem-solving, project management negotiation and conflict resolution skills

- 6. Good understanding of Drug Development Process, ICHGCP and Health Authority Guidelines & Regulations.
- 7. Ability to mentor within Clinical Sytems and cross functionally and coordinate internal and external training.
- 8. Ability to effectively lead and contribute to initiatives requiring Clinical Database acquisition tools and design expertise
- 9. Excellent planning, resource and project management skills.
- 10. Working knowledge of relevant industry standards including CDASH and SDTM is preferred.

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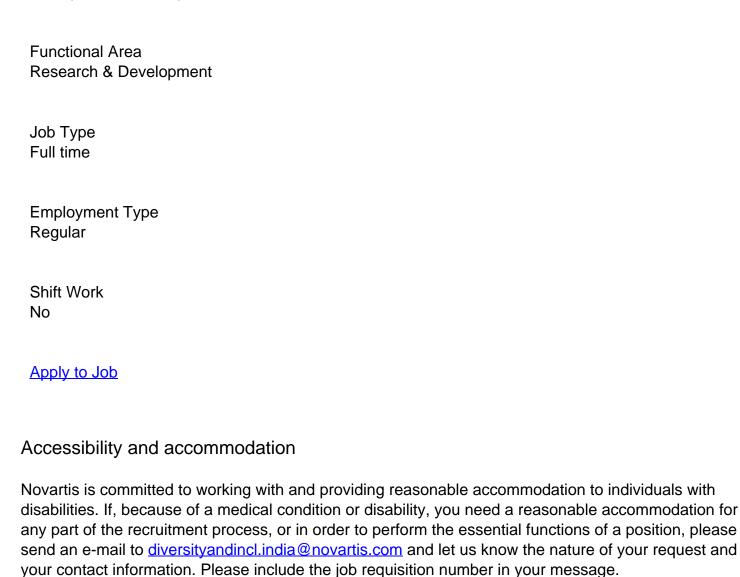
Development

Business Unit
Universal Hierarchy Node

India

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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