NOVARTIS

Non Drug Program Associate Director

Job ID
REQ-10030225
Jan 05, 2025
India

Summary

-Accountable for managing all Data Mgmt / CDDRA deliverables for one or more assigned projects. Direct, oversee and coordinate all activities, deliverables and manage optimal use of resources within respective group or disease area. This is a key leader position ensuring that pharmaceutical drug-development plans in Novartis Global Drug Development are executed efficiently with timely and high quality deleiverables. It is a leader role with a strong understanding of the drug development process with a track record of agile/lean process development and training strategy and delivery for end-to-end deliverables in data Mgmt and statistical programming. Follows and oversees Good Clinical Practices (GCP), data-handling procedures and guidelines, reporting and tracking relevant business measures/metrics; organizational budget Mgmt; resource Mgmt and vendor Mgmt. Work seamlessly with partner groups. Lead, contribute to and implement initiatives to establish and maintain Novartis Data Mgmt as best in class in the industry. Leads and manages the review of clinical research protocols, reports and statistical analysis plans.Lead DO in all sponsor related Audits and inspections. -Responsible for assessing and ensuring data and programming quality, process adherence, appropriate documentation, system compliance, Facilitate sharing of resources between groups inorder to meet company goals and objectives.

About the Role

Major accountabilities:

- Leads Data Mgmt activities for high priority/complex programs/projects -May act as local manager of global associates including providing supervision and advise to these data managers on functional expertise and processes -Accountable for all aspects of the Process and Training department to ensure full compliance to all applicable global regulatory requirements is maintained and business objectives are achieved.
- Drive functional excellence by contributing to the definition of the strategic goals and operating policies, and leading/contributing to strategic initiatives in line with the overall strategy.
- May define SLA and negotiate with partners to establish optimal Statements of Work.
- Lead the development, collection, coordination and implementation of metrics for for both internal associates and external (CRO, FSP) resources and activities.
- Represents and drives Quality and Compliance organization -Manages and measures organizational quality.
- Ensures appropriate exceptions requests, deviations and CAPA plans.
- Build and maintain effective working relationship with cross -Representative at project-level and in the Submission team, or in local leadership team.
- Esnures compliance with company, department and industry standards/processes, -Oversees and is responsible for quality control and audit readiness of all assigned data Mgmt deliverables as well as

accuracy and reliability of data within databases of assigned project(s).

- Maintain up-to-date advanced knowledge of industry software and reporting tools as well as industry requirements -Represent Data Mgmt at audits and in Health Authority (HA) meetings for assigned project(s), or on data amangement aspects in external conferences or groups -Mentors others to develop their own leadership capabilities and identifies/develops talent -Selects, recruits, develops, manages, motivates, coaches, develops talent and appraises the performance of direct reports to ensure high quality performance across his/her Clinical Data Mgmt Group -Leads and supports clinical and non - clinical special projects and initiatives -Propose creation of new SOPs, NIPs and WPs where appropriate, provide input to undertake implementation and maintenance of such documents , standards.
- Provide necessary help and support to address and resolve issues, Identifies solutions for remediation.
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- Achieve high level of quality, timeliness, cost efficiency and customer satisfaction across Data Mgmt activities and deliverables.
- No critical audit findings due to Data Mgmt -Effectiveness of participation in internal and external networks/initiatives.
- Effectiveness of recruitment, retention and development of talent.
- Efficiency of resource usage.
- Adequacy of resource estimation.
- Adherence to Novartis policy and guidelines -Customer / partner/ project feedback and satisfaction

Minimum Requirements:
Work Experience:

- Cross Cultural Experience.
- People Leadership.
- Project Management.

Skills:

- Clinical Data Management.
- Cross-Functional Team.
- Data Architecture.
- Data Governance.
- Data Management.
- Data Quality.
- Data Science.
- Data Strategy.
- Drug Development.
- Master Data.
- People Management.
- Project Management.

Languages :

- English.

Why Novartis: Helping people with disease and their families takes more than innovative science. It takes a

community of smart, passionate people like you. Collaborating, supporting and inspiring each other. Combining to achieve breakthroughs that change patients' lives. Ready to create a brighter future together? https://www.novartis.com/about/strategy/people-and-culture

Join our Novartis Network: Not the right Novartis role for you? Sign up to our talent community to stay connected and learn about suitable career opportunities as soon as they come up: https://talentnetwork.novartis.com/network

Benefits and Rewards: Read our handbook to learn about all the ways we'll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

Division
Development
Business Unit
Innovative Medicines
Location
India
Site
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
Apply to Job

Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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