

Non Drug Program Associate Director

Job ID
REQ-10030225
Nov 17, 2024
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 deliverables. 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 in order 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.
- Ensures 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 management 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

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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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