NOVARTIS

Technology Product Manager

Job ID
378428BR
Juni 19, 2024
Indien

Zusammenfassung

-Responsible and accountable for managing all Data Mgmt/Coding / CDD/DAP aspects of several studies, a medium to large sized project or project level activities at a consistently high standard. The position is a key collaborator and strategic partner with stakeholders ensuring that pharmaceutical drug development plans in Novartis Global Drug Developnment are executed efficiently with timely and high quality deliverables. Conceptualize and implement, in a scalable way, appropriate training delivery models and platforms for end-to-end deliverables. Follows and oversees -Good Clinical Practices (GCP), data-handling procedures and guidelines. Ensure consistency across assigned program to aid efficiencies for submissionsParticipates in the review of clinical research protocols, reports and statistical analysis plans. Leads quality deliverables across platforms. Develops simple and reproducible strategies to ensure quality deliverables,

About the Role

Major accountabilities:

- Lead functional activities for a medium to large sized project in phase I to IV clinical studies in Novartis Global Development Organization.
- Co-ordinate activities of Data Managers either internally or externally.
- Make data Mgmt decisions and propose strategies at study or project level.
- Ensure application of consistent data Mgmt processes, influence increased standardization and documentation across assigned project/programs -Comply with company, department and industry standards and processes.
- Provide and implement data Mgmt solutions; ensure knowledge sharing.
- Leads process and training deliverables within multiple platforms, franchises or therapeutic areasDevelops strategies to ensure effective training and knowledge retention.
- Progresses DO towards complete, compliant, agile and simple end to end processes and effective training (Protocol/Measure through Analysis and Reporting).
- Drives towards agreed deliverables, proactively addressing potential issues before they become problematic -Build and maintain effective working relationship with cross-functional teams, able to summarize and discuss status of deliverables and critical data Mgmt aspects.
- Represents DO in all audits and inspections, centralizing and aligning the team in audit preparation, readiness and response.
- Manages and measures quality -Coordinates exception requests, deviations and corrective/preventative action plansEnsure timely and quality development/ validation of CRFs and edit specifications for assigned studies/programs Responsible for quality control and audit readiness of all assigned data Mgmt deliverables as well as accuracy and reliability of the clinical database.
- Coaches & mentors associates as required -Act as subject matter expert (SME) or, as assigned, lead

process improvement/non clinical project initiatives.

- Develops risk Mgmt strategies to prevent data quality/coding issues from derailing projects -Manages effective escalation of issues in order to keep stakeholders appraised of DM activities and proposed resolutions -Represent Data Mgmt at audits & in Health Authority (HA) meetings for assigned project(s) -Provide Functional/technical Coding leadership for Therapeutic Area/Franchisee having multiple trials or mega trials in the role of Lead Coder ans ensures that Clinical Coding is performed at a consistently high standard.
- Serves as the primary program/therapeutic area lead ensuring timely & quality deliverables by es

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.
- Adherence to Novartis policy and guidelines -Customer / partner/ project feedback and satisfaction -

Minimum Requirements:
Work Experience:

- Cross Cultural Experience.
- Project Management.
- Functional Breadth.

Skills:

- Statistical Programming.
- Modeling & Simulation.
- Biostatistics.
- Compound to the Clinic - Preclinical and Translational Medicine.
- Post Authorization Data Safety.
- Over The Counter Product Development.
- Trial Planning and Feasibility.
- Regulatory Strategy.
- Clinical Trial Set-up, Management & Conduct.
- From Hit to Lead - Lead Discovery & Optimization.

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

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Development
Business Unit
Innovative Medicines
Ort
Indien
Website
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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