Principal Clinical Data Manager

Job ID
REQ-10011827

9月 26, 2024

Ireland

摘要

We are seeking a Principal Data Manager to be responsible and accountable for managing all Data Management activities using advanced data management tool and techniques with respect to cost, quality and timelines for all assigned trials/ project(s) within Clinical Data Acquisition and Management. The position is a key collaborator and strategic partner with stakeholders ensuring that data management activities for the clinical trials are executed efficiently with timely and high-quality deliverables (in alignment with the Novartis Clinical Data Quality Statement).

This role reports to the Director Data Management.

About the Role

Key Responsibilities:

- Lead data management activities as Trial Clinical Data Scientist for complex priority trial(s) or

as a Project/ Program Clinical Data Scientist for moderate complexity non-priority project(s)/ program in study set up and accountable for all conduct/close out deliverables.
- Co-ordinate activities of Data Scientist either internally or externally. Make data management decisions and propose strategies at study or project level.
- Ensures alignment with the TA level data strategy as defined by the TA Data Strategy Director
- Competent in relevant CDISC or other recognized industry standards and how these impact the programming team. Ensures consistency of program level standards
- Provides accelerated feedback to assure well written, stable protocols and amendments aligned with Program standards and requirements.
- Recognize and resolve protocol issues that may impact database design, data validation and/or analysis/reporting, minimizes the data footprint to focus on the trial endpoints and ensures utilization of available data standards.
- Build and maintain effective working relationship with cross-functional teams, able to summarize and discuss status of deliverables and critical data management aspects (timelines, scope, resource plan), e.g. as Clinical Data Acquisition & Management representative in study- or project-level team.
- Review eCRF, assess the need for additional study specific CRF, discuss data structures and review activities and ensure project-level standardization which allows pooling.

Essential Requirements:

- Strong leadership, collaboration and organizational skills with proven ability to successfully manage simultaneous trials and meet deadlines
- Excellent understanding of clinical trials methodology, GCP and medical terminology
- Proven ability to interrogate and view data through various programming/GUI techniques.
- Must be able to anticipate challenges and risks and proactively suggest/implement solutions
- Ability to work under pressure demonstrating agility through effective and innovative team leadership
- Excellent interpersonal skills and proven ability to operate effectively in a global environment. Ability to influence and communicate across functions and to external stakeholders
- Ideally 9+ years ' experience in Drug Development with at least 8 years' in Clinical Data Management
- Ability to transfer own knowledge to others. Experience as a Trial Data Scientist for several studies and some work performed at a project level

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Business Unit
Innovative Medicines

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Ireland

站点
Dublin (NOCC)

Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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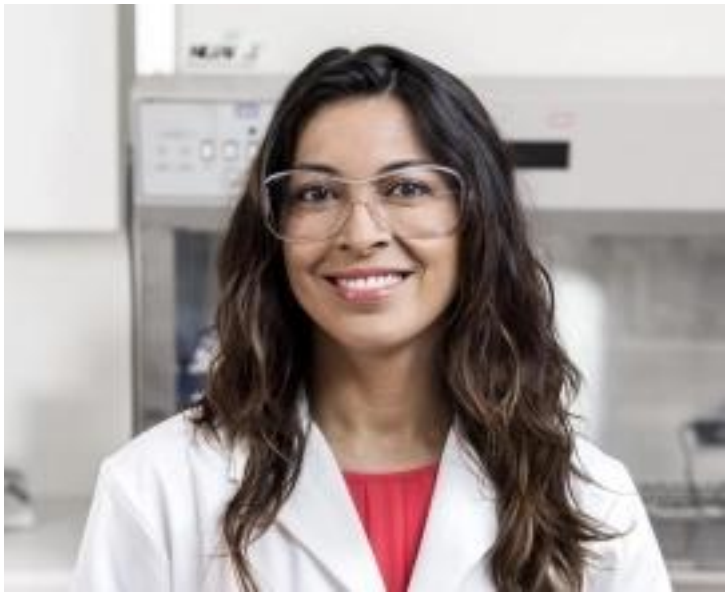

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