NOVARTIS

Principal Clinical Data Manager

Job ID
REQ-10011827
Sep 26, 2024
Ireland

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

Why Novartis? Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our

people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

You'll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards

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

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

Role Requirements

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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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

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List of links present in page

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2. https://www.novartis.com/about/strategy/people-and-culture
3. https://www.novartis.com/careers/benefits-rewards
4. https://talentnetwork.novartis.com/network
5. https://www.novartis.com/about/strategy/people-and-culture
6. https://talentnetwork.novartis.com/network
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