Senior Clinical Data Scientist (Trial Data Manager)

Job ID
394976BR
May 07, 2024
United Kingdom

About the Role

100,000+ That's how many patients participate in our clinical trials at any given time. GCO is Novartis' powerhouse of Global Clinical Operations, redesigned to enable faster trial recruitment and enhanced trial delivery resulting in more timely access for patients to potential novel treatments. Every day, we are the link between science and medicine – imagine the impact you could have as [Role]! #GCO

Using advanced data management tools and techniques, provide professional and lean execution of Data Management products and milestones with respect to cost, quality and timelines for all assigned trials within Clinical Data Acquisition and Management. Ensure consistently high-quality data delivery (in alignment with the Novartis Clinical Data Quality Statement) to analysis and reporting.

Your responsibilities include, but are not limited to:

• Provides DM leadership across assigned trial(s) Acts as the Trial Data Scientist where needed ensuring strong DM representation across the CTT.
• Demonstrates a business understanding of the compound(s) profile and data strategy to identify and assist in successful application of data management processes and documentation across assigned trials, i.e, ensuring consistency across data quality plans. 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.
• Provides accelerated feedback to assure well written, stable protocols and amendments. 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.
• Performs DM activities for study start up including preparing the architecture of the eCRF, CCG's, Data Quality Plan (DQP), Data Quality Plan Module (DQPM), Data Transfer Specification (DTS) and performing user acceptance testing (UAT)
• Manage local lab data flow and set up for the Clinical Database as applicable. Performs DM hands on activities during the course of the study, with a strong emphasis on quality, integrity and on-time delivery.
• Disseminates study level information to the Clinical Trial Team (CTT) and Program Clinical Data Scientist (PCDS). Supports and assists Junior staff for assigned trials. Ensures Third party and other necessary reconciliation activities are performed for the study in a timely manner. Provides effective input into DM initiatives and innovations for quality, efficiency and continuous improvement in scientific and operational excellence

• Tracks and reports status and progress for assigned trials, indications or programs. Is proactive to ensure milestones are met with quality (incl. Snapshots and interim/final locks). Ensures adherence to ICH GCP, DM standards, SOPs/WPS and process guidelines

Diversity & Inclusion / EEO

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

Role Requirements

What you'll bring to the role:

Required Experience & Qualifications:

• Ideally 4 years' experience in Drug Development with at least 3 years' in Clinical Data Management
• Fluent English (oral and written).
• 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 stakeholder
• Proven ability to interrogate and view data though various programming/GUI techniques Excellent problem solving skills
• Excellent verbal and written skills

Must have the right to work in the UK as we are unable to provide sponsorship

Desirable Experience & Qualifications:

• University or college degree in life science, computer science, pharmacy, nursing or equivalent relevant degree.

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

Division
Development
Business Unit
GCO GDD
Location
United Kingdom
Site
National
Company / Legal Entity
Novartis Pharmaceuticals UK Lt

Functional Area
Research & Development
Job Type
Full Time
Employment Type
Regular
Shift Work
No
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Senior Clinical Data Scientist (Trial Data Manager)

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