Clinical Data Specialist I

Job ID
REQ-10015172
Juli 10, 2024
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Summary

-Contributes, with appropriate oversight, to all relevant aspects of global clinical trial(s) activities to deliver study outcomes within schedule, budget, quality/compliance and performance standards. May lead specific aspects of global clinical trial(s). Core member of the Clinical Trial Team. - Applicable to Clinical Data Specialist I, The Clinical Data Specialist I (CDS I) provides clinical and scientific support through all phases of a clinical study under the guidance of the (A)CD(M)D in compliance with Novartis processes, ICH GCP and regulatory requirements. This role applies the principles of clinical data review excellence and identifies clinical data insights to ensure data is scientifically plausible and to identify trends, signals and risks associated to trial endpoints and patient safety. The CDS I is a core member of the Clinical Trial Team (CTT) and may support program level activities as assigned.

About the Role

Major accountabilities:

- Implementing issue resolution plans; -Assist with program level activities (e.g., tracking of program - Managing interactions with relevant line functions including data management, drug supply management, clinical development and/or Novartis Country Pharma Organizations; -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:

- Timely, efficient and quality execution of assigned trials and trial related activities within budget, and in compliance with quality standards.
- Proactive operational planning with effective contingency and risk mitigation plans.
- Applicable for Clinical Data Specialist I: -Performing clinical data review and insights consistently and accurately which meets the Novartis quality standards, timelines, and is inspection ready.
- High quality contributions to study documents (e.g. protocol, ICF, clinical sections of CTA) -Clearly demonstrates Novartis Values and Behaviors (i.e. Innovation, Quality, Collaboration, Performance, Courage and Integrity.

Minimum Requirements:
Work Experience:

- Cross Cultural Experience.
- Operations Management and Execution.
- Collaborating across boundaries.

- Project Management.

Skills:

- Clinical Research.
- Clinical Trial Protocol.
- Clinical Trials.
- Data Integrity.
- Learning Design.
- Lifesciences.
- Risk Monitoring.
- Trends Analysis.

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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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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Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the

recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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