NOVARTIS

Clinical Data Specialist II

Job ID
REQ-10015170
Juil 10, 2024
Inde

Résumé

-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, Contributes to operational excellence through process improvement and knowledge sharing and/or provide inputs to clinical development process. -Applicable to Clinical Data Specialist II, The Clinical Data Specialist II (CDS II) 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 II is a core member of the Clinical Trial Team (CTT). In addition, the CDS II supports/leads program level documents or activities as assigned.

About the Role

Major accountabilities:

- Contributes to all operational/clinical trial deliverables that are in scope of the specific JD, according to timelines, budget, operational procedures, quality /compliance and performance standards.
- Conduct/Contribute to study start-up activities such as overseeing protocol development, CRF development, Informed Consent Form development.
- Ensuring proper handling of all study conduct and close out activities including but not limited to site close out, final drug accountability and audit readiness of Trial Master File documentation (if in scope of the specific JD).
- Responsible for education, implementation and compliance to standards (SOPs) and best practices for clinical operations/clinical data review activities within assigned clinical trial(s) and within clinical program(s), including sharing lessons learned.
- 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.
- Adherence to Novartis policy and guidelines and external regulations -Applicable for Clincial Scientific Expert II: -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/ program level and/or submission documents (e.g. IDP, protocol, ICF, clinical sections of CTA).
- Strong leadership skills to be able to support management in team competency building, lead/contribute to local/global initiatives and best practice sharing across programs and/or departments -Clearly demonstrates Novartis Values and Behaviors (i.e. Innovation, Quality, Collaboration, Performance, Courage and Integrity.

Minimum Requirements:
Work Experience:

- Financial Management.
- Collaborating across boundaries.
- Operations Management and Execution.
- Project Management.

Skills:

- Budget Management.
- Clinical Research.
- Clinical Trial Protocol.
- Clinical Trials.
- Coaching.
- Data Analysis.
- 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

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

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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IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
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Job Type
Full time
Employment Type
Regular
Shift Work
No
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Accessibility and accommodation

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.

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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