NOVARTIS

Clinical Scientific Expert I

Job ID
REQ-10020654
Sep 25, 2024
India

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 Scientific Expert IThe Clinical Scientific Expert I (CSE 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 CSE I is a core member of the Clinical Trial Team (CTT) and may support program level activities as assigned.

About the Role

Major accountabilities:

Your responsibilities include, but are not limited to:

• Responsibility for ensuring high quality clinical trial data review/insights and analysis as directed by the Integrated Clinical Trial Team (iCTT)
• Perform high quality clinical data review and identify clinical data insights through patient level review and trends analysis, supporting Interim Analysis, Database and Post Lock activities and facilitate resolution of clinical data issues. Collaborate with relevant line functions to enhance the quality of clinical data review/insights with an emphasis on subject safety and eligibility, data integrity, trend identification, analysis and remediation, and identification of cases for medical review.
• Contributes to the development the Data Review/Quality Plan (DRP/DQP) and data review strategy, ensuring that protocol-level deviations, eligibility criteria, study assessments & other aspects of the protocol are implemented consistently across the study.
• In conjunction with the relevant line functions, may contribute to Case Report Form (CRF) development, and support the implementation of data capture tools.
• Contribute to and facilitate data review process improvements e.g. identification of delinquent/redundant reports and/or implementation of innovative data analysis processes and tools.
• May contribute (in collaboration with relevant line functions) to the development of

study-level documents, including clinical sections of key regulatory documents, such as Investigator's Brochures, briefing books, safety updates and submission dossiers. In collaboration with relevant line functions, review/write clinical trial documents for study CSR activities, and publications.
• May support pharmacovigilance activities (e.g., reviewing/contributing to aggregate reports/patient narratives, attendance of Safety Monitoring Meetings (SMT)), if required.
• Produce training materials and provide training to iCTT.

Minimum Requirements:

• Advanced degree in life sciences/healthcare (or clinically relevant degree) is required. Master's, PharmD, M.Pharma, PhD, MBBS, BDS, MD strongly preferable. Fluent English (oral and written).
• >1 year experience in pharmaceutical industry/ clinical research organization - Basic knowledge in planning, executing, reporting and publishing global clinical studies in a pharmaceutical company or contract research organization.
• Work experience in clinical operations preferable. Strong interpersonal skills - Ability to work under pressure
• Good negotiation and conflict resolution skills - Collaborates across boundaries for shared success - Resolve issues with minimal supervision and understands when to escalate - Fundamental knowledge of Good Clinical Practice, clinical trial design, statistics, regulatory processes, and clinical development process - Strong analytical / computational background - Demonstrates strong Medical / scientific writing skills.
• Demonstrates knowledge and application of statistical analysis methodology and can identify trends and analyze / interpret / report data effectively.

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

Commitment to Diversity & Inclusion:

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

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

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.

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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Site
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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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