

Clinical Scientific Expert I

Job ID
REQ-10009715
Aug 01, 2024
India

Summary

“150! Clinical scientific experts, globally, are part of Global Drug Development (GDD) team, working to ensure clinical trial data and regulatory reports are of highest quality throughout the life cycle of each program, across all disease areas. Be part of a dedicated, passionate team that is diligently providing clinical and scientific inputs at study and program level, thereby supporting Novartis in reimagining medicine for patients worldwide.”

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.Pharm, 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:

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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.

Division

Development

Business Unit

Innovative Medicines

Location

India

Site

Hyderabad (Office)
Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited
Functional Area
Research & Development
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.

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