U NOVARTIS

Clinical Data Specialist

Job ID 393921BR

May 07, 2024

India

Summary

-Contributes, with appropriate oversight, to all aspects of global clinical trial(s) 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

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.

- May/may not be involved in identifying new sites for clinical trials; analyze capability and make recommendation for trial inclusion.
- 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

Minimum Requirements: Work Experience:

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

Skills:

- Trial Planning and Feasibility.
- Over The Counter Product Development.
- Post Authorization Data Safety.
- Regulatory Strategy.
- Clinical Trial Set-up, Management & Conduct.

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? <u>https://www.novartis.com/about/strategy/people-and-culture</u>

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: <u>https://www.novartis.com/careers/benefits-rewards</u>

部門 Biomedical Research

部門 Pharma Research

国 India

勤務地 Hyderabad (Office)

Company / Legal Entity IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area Research & Development

職種 Full time

雇用形態 Regular

Shift Work No

Apply to Job.

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 <u>diversityandincl.india@novartis.com</u> 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.



Job ID 393921BR

Clinical Data Specialist

Apply to Job.

Source URL: https://prod1.novartis.com/jp-ja/careers/career-search/job/details/393921br-clinical-data-specialist-0

List of links present in page

- 1. https://www.novartis.com/about/strategy/people-and-culture
- 2. https://talentnetwork.novartis.com/network
- 3. https://www.novartis.com/careers/benefits-rewards
- 4. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Hyderabad-Office/Clinical-Data-Specialist<u>3</u>93921BR
- 5. mailto:diversityandincl.india@novartis.com
- 6. https://novartis.wd3.myworkdayjobs.com/en-US/NovartisCareers/job/Hyderabad-Office/Clinical-Data-Specialist<u>3</u>93921BR