

Clinical Data Specialist

Job ID
393921BR

5月 07, 2024

India

摘要

-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.

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部门

Biomedical Research

Business Unit

Pharma Research

地点

India

站点

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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