

# **Clinical Data Specialist**

Job ID 393921BR Mai 07, 2024 Indien

## **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? <a href="https://www.novartis.com/about/strategy/people-and-culture">https://www.novartis.com/about/strategy/people-and-culture</a>

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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

Biomedical Research

**Business Unit** 

Pharma Research

Standort

Indien

Site

Hyderabad (Office)

Company / Legal Entity

IN10 (FCRS = IN010) Novartis Healthcare Private Limited

**Functional Area** 

Research & Development

Job Type

Full time

**Employment Type** 

Regular

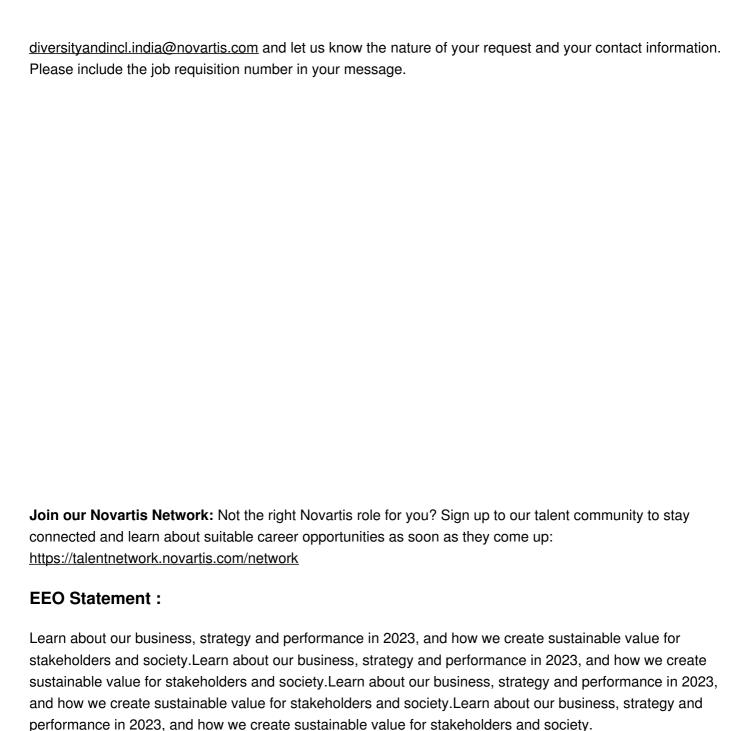
Shift Work

No

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