

Sr. Clinical Operations Specialist

Job ID
REQ-10037384
Jan 26, 2025
India

Summary

The Sr. Clinical Operations Specialist (Sr. COS) supports Clinical/Brand Teams on various operational aspects of assigned projects/activities: clinical studies (interventional and non-interventional, from early phase to late phase), other clinical services (e.g. managed access programs (MAP), Research Collaborations (RC), Investigator Initiated Trials (IITs), Digital Solutions etc...) or specific stand-alone services executed by Global Business Solutions on behalf of Novartis.

About the Role

Sr. Clinical Operations Specialist

Location – Hyderabad #LI Hybrid

About the Role:

The Administrative Assistant and Project Coordinator is responsible to provide administrative support to MKS Head and MKS Leadership team including managing schedules, arranging appointments, arranging travel, and scheduling meetings, MKS Townhalls and other key governance meetings/calls. The role also provides support to Global Medical Affairs activities and governance taking place in the Hyderabad office.

Key Responsibilities:

- Execute clinical services and meet planned deliverables in line with defined roles and responsibilities agreed with business colleagues.
- Support set-up and maintenance of information in Clinical Trial Management Systems (CTMS) and other systems as applicable, under responsibility of COS or CPM as applicable: Update data, timelines, milestones, Ethics Committee (EC)/Health Authority (HA) authorizations, etc. on an ongoing basis.
- Support (Sr.) Clinical Project Manager (CPM) with study budget management, ensuring accurate planning, tracking and reporting of clinical study budget and Grant Plan as applicable.
- Support set-up and maintenance of Trial Master File (TMF): Ensuring that all key documents are present and filed as appropriate in TMF, under responsibility of COS or CPM as applicable. Follow up with Clinical Trial Team at agreed frequency for TMF maintenance.
- Track clinical service progress, ensure CTMS, TMF and other systems as applicable are up to date, report to business colleague as per scope of work. Address questions; escalate issues or critical findings to project lead (Sr./CPM).
- Support in meeting set up, coordination and meeting minutes, running reports from systems, draft project documentation.

- Support and lead (where applicable) CTT in study start-up activities, recruitment and close-out activities as required. Takes ownership for specific tasks as delegated by project lead.
- Support (Sr.) CPM in set up and coordination of External Service Providers, ensuring all information, documentation and material in place for study start during study conduct and close-out. Follow-up with External Service Providers on day-to-day operations.

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.

Essential Requirements:

- *Bachelor's Degree or above in life sciences*) or equivalent combination of education, training and experience
- Approximately 5 to 6 years of operational experience of global clinical study execution in a pharmaceutical company or contract research organization.
- Experience in finance: forecast, actuals, cost reconciliation, a plus.
- Strong technical and organizational skills (Excel, PowerPoint)
- Thorough knowledge of Good Clinical practice.
- Demonstrated ability to establish effective working relationship in a matrix and multicultural environment.
- Able to manage priorities with minimum guidance. Willingness to act accountably in project/study management.

Desirable Requirements:

- Demonstrated ability to establish effective working relationship in a matrix and multicultural environment.
- Demonstrated presentation and diplomacy skills.
- Strong customer-oriented mindset.

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>

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Commitment to Diversity and Inclusion:

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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<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>

Division

Operations

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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