NOVARTIS

Senior Study Leader

Job ID
REQ-10084424
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Индия
Available in: English

Сводка

-Oversees all operational aspects of clinical trials end-to-end including the planning, execution, and interpretation of clinical trials research, data collection activities and clinical operations. -Complete oversight of budget and resource allocation within assigned trial. Drives operational excellence through process improvement and knowledge sharing across trials within program/franchise. Enables an empowered organization that can navigate in a matrix environment and adjust quickly to business needs. Point of escalation for resolution of trial management operational issues within assigned trial.

About the Role

Major accountabilities:

- Co-leads the clinical trial team with the CSL with per needed-basis oversight from the Study Director-community Lead (SD-CL) and support from the Clinical Operations Program Head (COPH), delivery of multiple medium to complex global studies and promotes learning, sharing, consistent performance, and operational excellence through an agile mindset, agile principles, and a team of teams' model
- Acts as the CTT product owner with duties and responsibilities for delivery of operational strategy per established ways of working
- Guides planning and decision making at the study level and delivers assigned clinical study/studies per the Operational Execution Plan (OEP) and clinical study protocol
- Fosters an agile culture within assigned studies to achieve sprint goals and cycles, maximizing collaboration and minimizing dependencies to achieve long-term business impact
- In collaboration with regulatory writing and clinical development, promotes operational excellence in the development of global clinical study protocol(s), by translating the approved study concept sheet(s) into efficient, high quality, executable clinical protocols, and study-related documents
- Create effective CTT dynamics and achieve on performance, prioritization, and communication in close collaboration with CTT sub-team leaders
- Proactive risk management and inspection readiness
- Responsible for developing clinical study timelines with per needed-basis oversight from the Study Director-community Lead (SD-CL) and support from the Clinical Operations Program Head (COPH), and overseeing assigned study budgets

Minimum Requirements:

- 4 years of recent involvement in clinical research or drug development in an academic or industry environment spanning clinical activities in Phases I through IV of standard to high complexity and priority
- 3 years of recent contribution to and accomplishment in all aspects of conducting clinical studies of standard to high complexity and priority (e.g., planning, executing, reporting and publishing) in a global/matrix environment in pharmaceutical industry or a contract research organization, including expert knowledge of international standards (GCP/ICH), health authorities (FDA/EMA), local/National Health Authorities regulations and Novartis standards
- Experience in managing people globally in a complex matrix environment preferred
- Management of virtual teams. Proven ability and strong experience leading teams and building capabilities
- Experience in developing effective working relationships with internal and external stakeholders
- Excellent communicator and presenter (oral and written); ability to communicate at all levels
- Strong negotiation and conflict resolution skills and enterprise mindset. Strong project management skills and demonstrated ability to meet timelines

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

Benefits and Rewards: Learn about all the ways we'll help you thrive personally and professionally.
Read our handbook (PDF 30 MB)

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Development
Business Unit
Development
Место
Индия
Сайт
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

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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