NOVARTIS

Senior Study Leader

Job ID
REQ-10020551
Sep 09, 2024
India

Resumen

The Senior Study Leader is responsible for the execution and delivery of the Global Clinical Operations (GCO), clinical studies in accordance with the Operational Execution Plan (OEP) and clinical study protocol. You will lead the cross-functional Clinical Trial Team (CTT) and guide the planning and management of assigned clinical study/studies end-to-end to achieve Global Program Team (GPT), Global Clinical Team (GCT) and GCO objectives.

About the Role

YOUR KEY RESPONSIBILITIES:

Your responsibilities include, but are not limited to:
• Lead the CTT delivery of multiple medium to complex global studies and promote learning, sharing, consistent performance, and operational excellence through an agile mindset, agile principles, and an agile team of teams model
• Act as the CTT product owner with duties and responsibilities per the agile ways of working
• In collaboration with regulatory writing and clinical development, promote 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
• Responsible for developing clinical study timelines and overseeing assigned study budgets
• Oversees study recruitment and responsible for activating mitigation strategies in collaboration with the Study & Site Operations (SSO) Clinical Project Manager Country representatives
• Ensures proper handling of all study close out activities including but not limited to site close out, final drug accountability and audit/inspection readiness of Trial Master File documentation
• Promotes operational excellence and contributes to the development of Clinical Study Reports, reporting of clinical trial results, and internal/external publications, when appropriate .

WHAT YOU'LL BRING TO THE ROLE:
• Advanced or Bachelor's degree in life sciences/healthcare or clinically relevant degree (or equivalent). 12- 15 years of Industrial experience in Clinical Research or Drug Development in any Phase.
• Significant recent experience in various aspects of clinical trial activity in a global/matrix environment in pharmaceutical industry or a Contract Research
Organization Including expert knowledge of international standards (ICH-GCP), health authorities (FDA/EMA)
• Experience of leading and/or working with a global team in a matrix environment, including the management of virtual teams and strong experience leading teams and building capabilities

• Experience in developing effective working relationships with internal and external stakeholders
• Strong negotiation and conflict resolution skills and enterprise mindset, demonstrated by ability to drive for aligned solutions for SSO and GCO
• Strong project management skills and demonstrated ability to meet timelines
• Proven track record in trial operations process improvement(s)

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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

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: https://www.novartis.com/careers/benefits-rewards

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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.

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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