Senior Study Leader (Associate Director)

Job ID
REQ-10020271

8月 29, 2024

Ireland

摘要

When we put our heads together, we can do brilliant work. And when we do brilliant work, we can achieve remarkable things for patients as we positively transform healthcare. We are looking for a Senior Study Leaders to join our global team.

The Senior Study Leader is responsible for the execution and delivery of the Global Clinical Operations (GCO) supported clinical studies per the Operational Execution Plan (OEP) and clinical study protocol.

You will lead the cross-functional clinical trial team (CTT), guides planning and management of the assigned clinical study/studies end-to-end to achieve Global Program Team (GPT), Global Clinical Team (GCT) and GCO objectives.

The Senior Study Lead will oversee budget and people allocation within assigned study/studies. Promotes operational excellence through process improvement and knowledge sharing across studies. Fosters an empowered, psychologically safe organization that can navigate a matrix environment, learns, and adjusts quickly to changing conditions and business needs. Accountable for resolution of study management operational issues and impediments within assigned study/studies.

This role can be based in our Dublin office in a hybrid model.

About the Role

Your responsibilities will include;

- Leads the clinical trial team delivery of multiple medium to complex global studies and promotes learning, sharing, consistent performance, and operational excellence through an agile mindset, agile principles, and an agile team of teams model
- Acts as the CTT product owner with duties and responsibilities per the agile 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 in order 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
- Fosters a close working relationship with SSO Clinical Project Managers (CPMs), VPG Vendor Program Managers (VPMs) and CDO Trial Data Scientist (TDS) to deliver on clinical study objectives and to strengthen the relationship between the global and local teams
- Oversees study recruitment and responsible for activating mitigation strategies in collaboration with the SSO Clinical Project Managers (CPMs)
- Ensures proper handling of all study close out activities including but not limited to site close out, final drug accountability and audit readiness of Trial Master File documentation
- Partners and collaborates with PSP/Clinical Operations Program Head (COPH) to deliver clinical studies in alignment with program strategy
- Achieves excellence in study operations and management through process improvement in collaboration with the Study Leadership Community Lead/Host and GCO Process, Training, and Compliance (PTC)

Minimum requirements

- Bachelor ' s degree in life sciences/healthcare (or clinically relevant degree) is required. Advanced degree is preferred.
- $\geq$ 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
- $\geq$ 3 years of recent contribution to and accomplishment in all aspects of conducting clinical studies (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
- 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, demonstrated by ability to drive for aligned solutions for SSO and GCO/GDD
- Strong project management skills and demonstrated ability to meet timelines
- Superior strategic thinking with strong analytical and problem-solving skills
- Knowledge of appropriate therapeutic area preferred

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You ' ll receive: You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook. https://www.novartis.com/careers/benefits-rewards 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.

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

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部门
Development

Business Unit
Innovative Medicines

地点
Ireland

站点
Dublin (Novartis Corporate Center (NOCC))

Company / Legal Entity
IE02 (FCRS = IE002) Novartis Ireland Ltd

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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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.

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