NOVARTIS

Study Leader

Job ID
REQ-10028306

11月 18, 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 Study Leader to join our global team.

The Study Leader is responsible, with appropriate oversight from the Study Director-Community Lead (SD-CL), for the execution and delivery of clinical studies of standard complexity and priority, per the Operational Execution Plan (OEP) and clinical study protocol.

The Study Leader is the leader of 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 Global Clinical Operations objectives. Accountable for proactive, iterative operational planning with effective contingencies and embedded risk management mindset in CTT. Oversee budget and people allocation within assigned study/studies.

The Study Leader will contribute in promoting 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.

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 global studies of standard complexity and priority and promotes learning, sharing, consistent performance, and operational excellence through an agile mindset, agile principles, and team of teams' model
- Acts as the CTT product owner with duties and responsibilities 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 trial 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 appropriate oversight from the Study Director-community Lead (SD-CL) and close support from the Clinical Operations Program Head, and overseeing assigned study budgets
- Ensures systems are maintained with up-to-date study status, risks, and issues.
- Fosters a close working relationship with SSO Clinical Project Managers, Trial Vendor Managers and CDO Trial Data Scientist to deliver on clinical study objectives and to strengthen the relationship between the global and local teams.
- Oversees study recruitment and responsible for activating mitigations strategies in collaboration with the SSO Clinical Program Managers.
- Ensures proper handling of all study close out activities, including, site close out, final drug accountability, and audit readiness of Trial Master File documentation, developing of Clinical Study Reports, reporting of clinical trial results and publications.
- Partners and collaborates with Clinical Operations Program Head to deliver clinical studies in alignment with program strategy
- Plays an important role in achieving excellence in study operations and management through process improvement in collaboration with the Study Leadership Community Lead/Host and GCO Process, Training, and Compliance.

Minimum requirements

- Bachelor's degree in life sciences/healthcare (or clinically relevant degree) is strongly preferred. Advanced degree is preferred.

- ≥ 2 years of recent involvement in clinical research or drug development in an academic or industry environment spanning clinical activities in Phases I through IV
- ≥ 1 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
- Good communicator and presenter (oral and written)
- Negotiation and conflict resolution skills and enterprise mindset, demonstrated by ability to drive for aligned solutions for Study & Site Operations and Global Clinical Operations.
- Project management skills and demonstrated ability to meet timelines
- Strategic thinking with analytical and problem-solving skills
- Knowledge of appropriate therapeutic area preferred

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

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

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

部门
Development

Business Unit
Innovative Medicines

地点
Ireland

站点
Dublin (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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