NOVARTIS

Study Leader

Job ID
REQ-10078606
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Ирландия

Сводка

Location: Dublin - Hybrid
#LI-Hybrid

Accountable, with appropriate oversight from the Study Director-community Lead (SD-CL), for the execution and delivery of GCO supported clinical studies of standard complexity and priority, per the Operational Execution Plan (OEP) and clinical study protocol.
The Study Leader co-leads together with the Clinical Science Lead (CSL) 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. 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. May 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.

About the Role

Accountabilities:

Co-Leader of the Clinical Trial Team

Co-leads the clinical trial team with the CSL with appropriate oversight from the Study Director-community Lead (SD-CL) and close support from the Clinical Operations Program Head (COPH), 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 co-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 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 (COPH), and overseeing assigned study budgets.

Requirements:

Education (minimum/desirable):

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

Languages:

- Fluent English, oral and written

Experience/Professional requirements:

- ≥ 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 of standard complexity and priority
- ≥ 1 year of recent contribution to and accomplishment in all aspects of conducting clinical studies of standard 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 experience leading
- Experience in developing effective working relationships with internal and external stakeholders
- Good communicator and presenter (oral and written)
- Good organization and prioritization
- Negotiation and conflict resolution skills and enterprise mindset
- 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: 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.
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