Study Director

Job ID
REQ-10040557

2月 21, 2025

United Kingdom

摘要

Responsible independently for the execution and delivery of the GCO supported Radioligand Therapy (RLT) clinical studies of medium to highly complexity and of high priority for novartis, per the Operational Execution Plan (OEP) and clinical study protocol.
The Study Director 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 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.

Identify area of improvements (process and trainings), 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.

This is a hybrid position with 12 days per month from the office in White City, London.

#LI-Hybrid

About the Role

Key responsibilities:

- Leads independently the clinical trial team in collaboration with the Clinical Operations Program Head (COPH), delivery of multiple complex global studies and promotes learning, sharing, consistent performance, and operational excellence through an agile mindset, agile principles, and a team of team ' s 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 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
- Responsible for developing clinical study timelines in collaboration with the Clinical Operations Program Head (COPH), and overseeing assigned study budgets
- Ensures systems are maintained with up-to-date study status, risks, and issues
- Fosters a close working relationship with the SSO Clinical Program Managers (CPMs) 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 Program Managers (CPMs)
- Fosters a close working relationship with the VPG Vendor Program Managers (VPMs) to strengthen the relationship between the vendors and CTT to deliver on clinical study objectives
- Fosters a close working relationship with the CDO Trial Data Scientist (TDS) to deliver on clinical study objectives
- 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
- Promotes operational excellence and contributes to the development of Clinical Study Reports; reporting of clinical study results, and internal/external publications, when appropriate
- 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 Head Study Leadership or the Study Leadership Community Lead/Host (as applicable) and GCO Process, Training, and Compliance (PTC)
- May deputize for the COPH as a leader and spokesperson for the CTT at Novartis internal meetings

Essential requirements:

- Bachelor's degree in life sciences/healthcare (or clinically relevant degree) is required. Advanced degree is preferred.
- ≥ 5 years' experience in Radioligand Therapy (RLT) technology
- ≥ 7 years of recent involvement in clinical research or drug development in an academic or industry environment spanning clinical activities in Phases I through IV studies of medium to highly complexity and of high priority
- ≥ 3-5 years of recent contribution to and accomplishment in all aspects of conducting clinical studies of medium to highly complexity and of high priority for novartis (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
- 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
- Outstanding organization and prioritization
- Excellent negotiation and conflict resolution skills and enterprise mindset
- Strong project management skills and demonstrated ability to meet timelines
- Proven track record in study operations process improvement(s)
- Superior strategic thinking with strong analytical and problem-solving skills
- Extensive knowledge of appropriate therapeutic area preferred

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部门
Development

Business Unit
Innovative Medicines

地点
United Kingdom

站点
London (The Westworks)

Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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