Study Director (Study & Site Operations)

Job ID
REQ-10049780

4月 25, 2025

USA

摘要

Accountable independently for the execution and delivery of the GCO supported 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 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.

About the Role

Key Responsibilities:

- Co-leads with the CSL 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
- 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
- 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. Ensures systems are maintained with up-to-date study status, risks, and issues
- Responsible for developing clinical study timelines in collaboration with the Clinical Operations Program Head (COPH), and overseeing assigned study budgets
- Oversees study recruitment and responsible for activating mitigation strategies in collaboration with the SSO Clinical Program 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
- Promotes operational excellence and contributes to the development of Clinical Study Reports; reporting of clinical study results, and internal/external publications, when appropriate
- Achieves excellence in study operations and management through process improvement in collaboration with the Study Leadership Community Lead and GCO Process, Training, and Compliance (PTC)

Essential Requirements:

- Education: Bachelor ' s degree in life sciences/healthcare (or clinically relevant degree) is required. Advanced degree is strongly preferred.
- $\geq$ 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
- $\geq$ 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
- Excellent negotiation and conflict resolution skills and enterprise mindset
- Strong project management skills and demonstrated ability to meet timeline
- Proven track record in study operations process improvement(s)

The pay range for this position at commencement of employment is expected to be between $185,500 and $344,500/year; however, while salary ranges are effective from 1/1/25 through 12/31/25, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an "at-will position" and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

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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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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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The Novartis Group of Companies are 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 application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

部门
Development

Business Unit
Innovative Medicines

地点
USA

状态
Distant Working Arrangement, US

站点
Distant Employee - Distant Working Arrangement (DWA) (USA)

Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Alternative Location 1
East Hanover, New Jersey, USA

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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