Clinical Sciences Associate Director

Job ID REQ-10022402 Sep 25, 2024 USA

Summary #LI-Hybrid

Location: Cambridge, MA or East Hanover, NJ

About the role: Study Leader for complex global early-phase oncology trials

About the Role

Key Responsibilities:

- Study Leader and/or Clinical Scientist for predominantly high complexity, global studies. May function as a Core Project Team member for assigned projects to drive the Research-Development-Commercial (RDC) continuum. May co-lead project clinical sub-team and reports study/project progress and issues with their resolution plan to project teams and stakeholders. Directs early stages of study design and operational plans.
- Lead a global cross functional Clinical Trial Team (CTT) to ensure all trial deliverables are met; sets stretch goals, promotes realistic planning and timelines, and presents actionable alternatives to accelerate timelines. Proactively lead risk mitigation discussions, risk management and implementation at the trial level. Responsible and accountable for forecasting and managing overall study budget(s) in collaboration with key partners.
- Lead development of strategic and scientific input into study concept, feasibility, and ability to execute; develops and implements study-level operational execution plan in partnership with key cross functional partners, if applicable. Independently lead the clinical protocol development process in collaboration with the Medical Lead and other line functions; responsible author for clinical protocols, amendments, etc.; contribute to the medical/scientific input given for the development of study-related documents and processes which resides in other line functions; contribute to the development of clinical sections of study-level regulatory documents. May provide clinical leadership and strategic input for all clinical deliverables across assigned indication/program or studies within Biomedical Research. May act as Focus/Disease/Platform Area Lead.
- Lead the ongoing medical/scientific review of clinical trial data across assigned studies in collaboration with the medical expert and key line functions, and partners on data analysis and data interpretation, including safety trend analysis, signal detection, development of first interpretable results, reporting clinical study results in Clinical Study Report (CSR), and internal/external publications
- Prepare and lead dose escalation meetings with investigators. Coordinate the real time availability of quality clinical trial data, to provide consolidated information for dose escalation meetings and Phase II data reviews with relevant stakeholders.
- Responsible for implementation of best practices and standards for trial management, including sharing lessons learned. Represent group on initiatives; may serve as Subject Matter Expert.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between \$174,400 - \$261,600/year. While salary ranges are effective from 1/1/24 through 12/31/24, 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.

Novartis EVP Manifesto.mp4

Essential Requirements:

- This position will be located at either the Cambridge, MA or the East Hanover, NJ site and will not have the ability to be located remotely. This position will require 0-5% travel as defined by the business (domestic and/ or international).
- Bachelors in life science/healthcare required; Advanced degree or equivalent education/degree in life sciences/ healthcare preferred (PhD/MD/ PharmD/ Masters).
- Approximately 8+ years' experience in clinical trials/development with 3+ years leading cross-functional teams. Ability to lead multiple complex clinical trials concurrently.
- Strong understanding of oncology/hematology and demonstrates high learning agility. Proficient in clinical trial methodology with an emphasis in early clinical development. Strong operational project and program management experience with an emphasis in early clinical development, including excellent planning, prioritization, problem solving and organizational skills. Demonstrated capability to interpret, discuss and represent trial level data.
- Demonstrated knowledge and ability to confidently drive complex collaborations through unpredictable circumstances and higher paced changes. Demonstrate strong tolerance for ambiguity, willingness to adapt, and willingness to speak-up and challenge. Proven track record of successfully interacting with and influencing with a wide range of people, building strong positive relationships.
- Embraces a culture of diversity, inclusion, quality, innovation, and integrity.
- · Maintain expert knowledge of ICH-GCP, external regulations and procedures, and supplements by training and practice of Novartis SOPs and internal policies.

Preferred Requirements:

· Radioligand therapy (RLT) experience preferred.

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

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?

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

EEO Statement:

The Novartis Group of Companies are Equal Opportunity Employers who are focused on building and advancing a culture of inclusion that values and celebrates individual differences, uniqueness, backgrounds and perspectives. We do not discriminate in recruitment, hiring, training, promotion or other employment practices for reasons of race, color, religion, sex, national origin, age, sexual orientation, gender identity or expression, marital or veteran status, disability, or any other legally protected status. We are committed to fostering a diverse and inclusive workplace that reflects the world around us and connects us to the patients, customers and communities we serve.

Accessibility & Reasonable Accommodations

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 <u>us.reasonableaccommodations@novartis.com</u> 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.

Division **Biomedical Research Business Unit** Pharma Research Location USA Site Cambridge (USA) Company / Legal Entity U175 (FCRS = US175) Novartis Institutes for BioMedical Research, Inc. Functional Area Research & Development Job Type Full time Employment Type Regular Shift Work No Apply to Job iframe{ width: 100%; margin-top: 3rem; } @media screen and (max-width: 767px){ iframe{ height: 30vh !important; } } @media screen and (min-width: 768px){ iframe{ height: 34vh !important; } } Job ID REQ-10022402

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