

Sr. Clinical Sciences Trial Leader (Multiple Positions)

Job ID
REQ-10014358
Jul 22, 2024
Estados Unidos

Resumen

#LI-Hybrid Location: Hybrid. Cambridge, MA. About the role: 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.

About the Role

Key Responsibilities:

- Responsible for financial and resource decisions within scope of assigned authority
- Study Leader and/or Clinical Scientist for predominantly medium to high complexity, global studies and may provide additional Clinical Sciences support to high priority, high complexity, global studies
- 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
- 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. Collaborate with key cross functional partners to identify and select strategic and high performing sites to ensure recruitment commitments are met
- Partner with line functions to gain input and alignment and manages internal and external stakeholder expectations
- 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 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
- 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
- Collaborate with key partners to set vendor strategy and timelines for assigned studies
- 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
- Contribute to talent and career development of staff. In collaboration with the relevant manager, contributes to hiring/interview/onboarding and mentoring process for new hires

The pay range for this position at commencement of employment is expected to be between \$136,800 and \$205,200 / year; however, 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.

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Essential Requirements:

- This position will be located at the Cambridge, MA site and will not have the ability to be located remotely. This position will require approximately 3-5% travel as defined by the business (domestic and/ or international).
- Bachelors in life science, healthcare and/or related field required; Advanced degree or equivalent education/degree in life sciences, healthcare and/or related field preferred (PhD/MD/ PharmD/ Masters)
- Minimum 5 years of experience in clinical trials development; Strong understanding of oncology/hematology and demonstrates high learning agility
- Demonstrated ability to confidently drive complex collaborations through unpredictable circumstances and higher paced changes; Demonstrates leadership and influence by creating a positive work environment by inspiring and encouraging mutual respect, instills innovation and accountability on a functional and trial level
- Demonstrates strong interpersonal skills with a proven track record of building strong positive relationships
- Demonstrates strong tolerance for ambiguity, willingness to adapt, and willingness to speak-up and challenge; Maintain extensive knowledge of ICH-GCP, external regulations and procedures, and supplements by training
- Embraces a culture of diversity, inclusion, quality, innovation and always driving forward with integrity

- Proficient in clinical trial methodology with a strong emphasis in early clinical development; Demonstrated capability to interpret, discuss and represent trial level data
- Strong operational project management experience including excellent planning, prioritization, problem solving and organizational skills
- Track record of successfully managing or leading multiple complex clinical trials concurrently. Used to managing multiple priorities. Working knowledge of clinical finance principles to manage efficient expenditure to minimize variance between actual and forecasted spend

Desirable Requirements:

- Radioligand therapy 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?

<https://www.novartis.com/about/strategy/people-and-culture>

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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 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.

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Functional Area
 Research & Development

Job Type
 Full time
 Employment Type
 Regular

Shift Work
 No

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