

Senior Clinical Sciences Trial Leader

Job ID
REQ-10074785
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Сводка

Study Leader and/or Clinical Scientist for predominantly low complexity, global studies and may provide additional Clinical Sciences support to high complexity, global studies

About the Role

Key responsibilities:

- Lead or support 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.
- Support 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.
- Lead or support a global cross functional CTT to ensure all trial deliverables are met; sets stretch goals, promotes realistic planning and timelines, and presents actionable alternatives to accelerate timelines.
- Partner with line functions to gain input and alignment and manages internal and external stakeholder expectations.
- Lead or support 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, lead or support 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 or support 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.

Essential requirements:

- Bachelors in life science/healthcare required; Advanced degree or equivalent education/degree in life sciences/ healthcare preferred (PhD/MD/PharmD/ Masters).
- Approximately 6+ years' experience in clinical trials/development
- Demonstrates high learning agility.
- Proficient in clinical trial methodology with an emphasis in early clinical development. Operational project management experience including excellent planning, prioritization, problem solving and organizational skills.
- Track record of successfully managing multiple clinical trials concurrently. Used to managing multiple priorities.
- Demonstrated capability to interpret, discuss and represent trial level data.
- Working knowledge of clinical finance principles to manage efficient expenditure to minimize variance between actual and forecasted spend.
- Maintain good knowledge of ICH-GCP, external regulations and procedures, and supplements by training and practice of Novartis SOPs and internal policies.
- Fluent oral and written English

Desirable requirements:

- Demonstrates strong interpersonal skills to build positive relationships.
- Demonstrated ability to drive collaborations through unpredictable circumstances and higher paced changes.
- Demonstrates leadership and influence by creating a positive work environment by inspiring and encouraging mutual respect.
- Demonstrates tolerance for ambiguity, willingness to adapt, and willingness to speak-up and challenge.
- Embraces a culture of diversity, inclusion, quality and always driving forward with integrity.

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.

[Read our handbook \(PDF 30 MB\)](#)

Дивизион
Biomedical Research
Business Unit
Research
Место
Китай

Сайт
Shanghai (Shanghai)
Company / Legal Entity
CN14 (FCRS = CN014) China Novartis Institutes for BioMedical Research Co., Ltd.
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Accessibility and accommodation

Novartis is 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 recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.china@novartis.com 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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