

Clinical Sciences Trial Leader

Job ID
REQ-10014919

7月 10, 2024

Japan

摘要

Study Leader of cross-functional, clinical trial team for assigned low complexity, global clinical trials in early clinical development. Accountable for all aspects of the scientific, clinical and operational planning and implementation, from study design to data analysis and reporting of studies and assigned program-level activities according to timelines, budget and quality standards.

About the Role

Major Accountabilities:

1. 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.

2.

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.

3.

Collaborate with key cross functional partners to identify and select strategic and high performing sites to ensure recruitment commitments are met.

4.

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.

5.

Partner with line functions to gain input and alignment and manages internal and external stakeholder expectations.

6.

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.

7.

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.

8.

Proactively lead or support risk mitigation discussions, risk management and implementation at the trial level.

9.

Responsible and accountable for forecasting and managing overall study budget(s) in collaboration with key partners.

10.

Collaborate with key partners to set vendor strategy and timelines for assigned studies.

11.

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.

12.

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.

For associates based in China and Japan, develop local early development strategy, lead local study activities throughout the study lifecycle, may serve as a regional BR liaison for scientific research activities, if required.

Education / Background:

•Bachelors in life science/healthcare required; Advanced degree or equivalent education/degree in life sciences/ healthcare preferred (PhD/MD/PharmD/ Masters).

Years of Experience:

•Approximately 2+ years ' experience in clinical trials/development

Languages:

Fluent English (oral and written). For Japan, Fluent Japanese (oral and written)

Key Competencies:

- Demonstrates high learning agility.
- 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 strong interpersonal skills to build positive relationships.
- 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.
- 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.
- 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.

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Japan

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部門
Biomedical Research

Business Unit
Pharma Research

地点
Japan

站点
Head Office (Japan) (Pharmaceuticals)

Company / Legal Entity
JP05 (FCRS = JP005) Novartis Pharma K.K.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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