Clinical Sciences Trial Leader

Job ID
REQ-10065230

10月 20, 2025

Japan

摘要

-Contributes, with appropriate oversight, to all relevant aspects of global clinical trial(s) activities to deliver study outcomes within schedule, budget, quality/compliance and performance standards. May lead specific aspects of global clinical trial(s). Core member of the Clinical Trial Team, Contributes to operational excellence through process improvement and knowledge sharing and/or provide inputs to clinical development process. -Applicable to Clinical Scientific Expert IIThe Clinical Scientific Expert II (CSE II) provides clinical and scientific support through all phases of a clinical study under the guidance of the (A)CD(M)D in compliance with Novartis processes, ICH GCP and regulatory requirements. This role applies the principles of clinical data review excellence and identifies clinical data insights to ensure data is scientifically plausible and to identify trends, signals and risks associated to trial endpoints and patient safety. The CSE II is a core member of the Clinical Trial Team (CTT). In addition, the CSE II supports/leads program level documents or activities as assigned.

About the Role

This is a newly created position regarding the establishment of a clinical translational research hub.
本募集はClinical Translational Research Hub設置に関して新設されるポジションです。

Major accountabilities:

- Contributes to all operational/clinical trial deliverables that are in scope of the specific JD, according to timelines, budget, operational procedures, quality /compliance and performance standards.
- Conduct/Contribute to study start-up activities such as overseeing protocol development, CRF development, Informed Consent Form development.
- Ensuring proper handling of all study conduct and close out activities including but not limited to site close out, final drug accountability and audit readiness of Trial Master File documentation (if in scope of the specific JD).
- Responsible for education, implementation and compliance to standards (SOPs) and best practices for clinical operations/clinical data review activities within assigned clinical trial(s) and within clinical program(s), including sharing lessons learned.
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt -Distribution of marketing samples (where applicable)

Key performance indicators:

- Timely, efficient and quality execution of assigned trials and trial related activities within budget, and in compliance with quality standards.
- Proactive operational planning with effective contingency and risk mitigation plans.
- Adherence to Novartis policy and guidelines and external regulations -Applicable for Clincial Scientific Expert II: -Performing clinical data review and insights consistently and accurately which meets the Novartis quality standards, timelines, and is inspection ready.
- High quality contributions to study/ program level and/or submission documents (e.g. IDP, protocol, ICF, clinical sections of CTA).
- Strong leadership skills to be able to support management in team competency building, lead/contribute to local/global initiatives and best practice sharing across programs and/or departments -Clearly demonstrates Novartis Values and Behaviors (i.e. Innovation, Quality, Collaboration, Performance, Courage and Integrity.

Minimum Requirements:
Work Experience:

- Financial Management.
- Collaborating across boundaries.
- Operations Management and Execution.
- Project Management.

Skills:

- Budget Management.
- Clinical Research.
- Clinical Trial Protocol.
- Clinical Trials.

- Coaching.
- Data Analysis.
- Data Integrity.
- Learning Design.
- Lifesciences.
- Risk Monitoring.
- Trends Analysis.

Languages :

- English.

Program/Project Responsibility

1.Study Leader and/or Clinical Scientist for predominantly low complexity, global studies and may provide additional Clinical Sciences support to high complexity, global studies.
2.Lead or support the clinical protocol development process incollaboration 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.
3.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.

4.Collaborate with key cross functional partners to identify and select strategic and high performing sites to ensure recruitment commitments are met.
5.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.
6.Partner with line functions to gain input and alignment and manages internal and external stakeholder expectations.
7.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.
8.Prepare, lead or support dose escalation meetings with investigators.Coordinate the real time availability of quality clinical trial data, toprovide consolidated information for dose escalation meetings andPhase II data reviews with relevant stakeholders.
9.Proactively lead or support risk mitigation discussions, riskmanagement and implementation at the trial level.
10.Responsible and accountable for forecasting and managing overallstudy budget(s) in collaboration with key partners.
11.Collaborate with key partners to set vendor strategy and timelines forassigned studies.
12.Responsible for implementation of best practices and standards fortrial management, including sharing lessons learned. Represent Groupon initiatives; may serve as Subject Matter Expert.
13.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.

Impact on the Organization

▪ Responsible for the availability of high quality, Biomedical Research data according to agreed timelines and budget to enable no delays in strategic decision making and drug registration. External impact: Novartis perceived as a credible, ethical and preferred business partner.

Minimum Requirements/Skills

▪ Bachelors in life science/healthcare required; Advanced degree or equivalent education/degree in life sciences/ healthcare preferred (PhD/MD/PharmD/ Masters).
▪ Approximately 2+ years' experience in clinical trials/development
▪ For TCO: Strong understanding of oncology/hematology and demonstrates high learning agility.
▪ For TM: Demonstrates high learning agility.
▪ Demonstrated ability to drive collaborations through unpredictable circumstances and higher paced changes.
▪ Demonstrates tolerance for ambiguity, willingness to adapt, and willingness to speak-up and challenge.
▪ 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.

Language:

Fluent Japanese and English (oral and written)

Benefits and Rewards:

You can find everything you need to know about our benefits and rewards in the Novartis Life Handbook.

novartis-life-handbook.pdf

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.

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 midcareer-r.japan@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Be aware of fake job advertisements and job offers

Novartis is aware of employment scams which make false use of our company name or leader ' s names to defraud job seekers. Novartis does not make job offers without interview and never asks candidates for money.

All our current job openings are displayed here. If you have encountered a job posting or been approached with a job offer that you suspect may be fraudulent, we strongly recommend you do not respond, send money or personal information.

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ノバルティスでは、当社名や幹部の名前を不正に使用して求職者をだます「採用詐欺」が発生していることを認識しています。

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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

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

部门
Biomedical Research

Business Unit
Universal Hierarchy Node

地点
Japan

站点
Tokyo (NPKK Sales)

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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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 midcareer-r.japan@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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