

Clinical Sciences Associate Director

Job ID
REQ-10047900

Apr 25, 2025

Japan

Summary

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。
Responsible for financial and resource decisions within scope of assigned authority.

About the Role

Program/Project Responsibility

1. May provide clinical leadership and strategic input for all clinical deliverables across assigned indication/program or studies within BR. May act as Focus/Disease/Platform Area Lead.
2. May function as a Core Project Team member for assigned projects to drive the R-D-C 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.

3. Study Leader and/or Clinical Scientist for predominantly high complexity, global studies and may provide additional Clinical Sciences support to high priority, high complexity, global studies.
4. 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.
5. 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.
6. Collaborate with key cross functional partners to identify and select strategic and high performing sites to ensure recruitment commitments are met.
7. Lead 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.
8. Partner with line functions to gain input and alignment and manages internal and external stakeholder expectations.
9. 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.
10. 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.
11. Proactively lead risk mitigation discussions, risk management and implementation at the trial level.
12. Responsible and accountable for forecasting and managing overall study budget(s) in collaboration with key partners.

Head of TCO Japan

13. Collaborate with key partners to set vendor strategy and timelines for assigned studies.
14. 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
15. 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.
16. Line management of assigned associates. Accountable for talent attraction and retention; supporting career growth and development.
17. May deputize for his/her manager upon request.

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 8+ years ' experience in clinical trials/development.
- For TCO: Strong understanding of oncology/hematology and demonstrates high learning agility.
- For TM: Demonstrates high learning agility in multiple therapeutic areas.
- Demonstrated knowledge and ability to confidently drive complex collaborations through unpredictable circumstances and higher paced changes.
- Demonstrates strong organizational awareness and stakeholder management skills.
- Demonstrate strong 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. Strong operational project and program management experience with an emphasis in early clinical development, including excellent planning, prioritization, problem solving and organizational skills.
- Track record of successfully leading multiple complex clinical trials concurrently. Used to managing multiple priorities.
- Demonstrated capability to interpret, discuss and represent trial level data.
- Good working knowledge of clinical finance principles to manage efficient expenditure to minimize variance between actual and forecasted spend.
- Maintain expert knowledge of ICH-GCP, external regulations and procedures, and supplements by training and practice of Novartis SOPs and internal policies.

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.

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>

部門

Biomedical Research

部門

Universal Hierarchy Node

国

Japan

勤務地

Toranomon (NPKK Head Office)

Company / Legal Entity

JP05 (FCRS = JP005) Novartis Pharma K.K.

Functional Area
Research & Development

職種
Full time

雇用形態
Regular

Shift Work
No

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