

Clinical Sciences Director

Job ID

REQ-10027026

nov 11, 2024

Royaume-Uni de Grande-Bretagne et d'Irl. du Nord

Résumé

Novartis BioMedical Research (BR) is the innovation engine of Novartis. We collaborate across scientific and organization boundaries, focusing on powerful new technologies that have the potential to help produce therapeutic breakthroughs from patients. Within BR, Translational Medicine (TM) is the clinical research arm and includes over 900 associates globally. TM plays a pivotal role in bringing innovative medicines to patients, by building on research advances to develop new therapies, and bridging drug discovery and clinical application.

The Clinical Sciences Director is the clinical leader for indication and/or program-level activities leading to clinical Proof of Concept or NDA registration, achieving BR/Translational Medicine (TM), Global Drug Development (GDD)/Global Project Team (GPT) and/or ECN objectives.

The Clinical Sciences Director is accountable for the clinical, scientific and operational strategy of all assigned global TM projects, including leading the planning, implementation and delivery of all aspects of TM studies.

About the Role

Major accountabilities:

- May lead highly scientific, complex BR studies end-to-end, directing all aspects of strategic planning, execution and study management. As independent leader of the global, crossfunctional, cross-divisional clinical study team deliver on BR and Development objectives.
- Core Project Team member for assigned projects to drive the R-D-C continuum. Co-lead project clinical sub-team and report study/project progress and issues with their resolution plan to project teams and stakeholders. Direct early stages of study design and operational plans.
- Drive development of strategic and scientific input into CDP, early phase study design, feasibility, and ability to execute; including development and management of study-specific patient recruitment strategies; develop and implement project level operational execution plan in partnership with key cross-functional partners.
- Demonstrate strategic and critical thinking through influence and leadership of project clinical sub-team and/or CTT to identify recruitment and clinical strategic risks and develop mitigation strategies to demonstrate team's agility to adapt in a dynamic and ambiguous environment.
- Oversee, mentor and coach Clinical Scientists assigned to the indication/project on the planning and implementation of studies within assigned BR projects.; Set stretch goals, promote realistic planning and timelines, and present actionable alternatives to accelerate timelines.
- Ensure continuity and consistency across all studies within a given project.
- Review and provide input on study protocols and operational plans within a project for consistency and

- quality and lead the development and standardization of project level documents.
- Partner with line functions to gain input and alignment and manages internal and external stakeholder expectations.
 - Collaborate with key cross functional partners to identify and select strategic and high performing sites to ensure recruitment commitments are met.
 - Lead the clinical protocol development and operational plan process in collaboration with the Medical Lead and other line functions; contributes to the medical/scientific input for the development of study related documents and processes which reside in other line functions; contributes to the development of clinical sections of project-level regulatory documents (if applicable).
 - Support strong relationships with investigators for insight on early trial design.
 - Collaborate with key partners to set vendor strategy and timelines for the assigned projects/studies.
 - Responsible and accountable for forecasting and managing overall study budget(s) in collaboration with key partner line functions.
 - Lead the ongoing medical/scientific review of clinical trial data across assigned projects/studies, in collaboration with the medical expert and key LFs, and coordinates 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.
 - 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 as appropriate. Contribute to talent and career development of staff. In collaboration with the relevant manager, contribute to hiring/interview/onboarding and mentoring process for new hires.
 - Line management of assigned associates. Accountable for talent attraction and retention; supporting career growth and development.
 - May deputize for his/her manager upon request

Minimum Requirements:

Education (minimum/desirable):

Advanced degree (or equivalent education) in life sciences/healthcare required. PhD/PharmD strongly preferred

Experience/Professional Requirement:

- Approximately 10+ years in clinical trials with significant early phase drug development experience.
- Expert knowledge of Good Clinical Practice. Proven experience across multiple clinical indications or therapeutic areas.
- Track record of successfully managing multiple complex global Phase I and IIa clinical trials concurrently, supported by experience of Phase IIb/III clinical trials. Superior leadership and problem-solving skills.
- Excellent operational project and program management experience including excellent planning, prioritization, problem solving and organizational skills. Used to managing multiple priorities.
- Demonstrated operational excellence and scientific contribution to both clinical and preclinical projects.
- Strategic thinking: create major innovations, ability to network with and influence opinion leaders, clear and logical presentation of complex strategic issues.
- Clear written and verbal expression of ideas, an active/proactive communicator. Excellent interpersonal skills, with a proven track record of successfully interacting with and influencing with a wide range of people, building strong positive relationships.
- High level of customer orientation awareness and focus. Excels working independently and in a team environment, being flexible and adapting in a changing environment.

Languages :

- English.

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>

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>

Division

Biomedical Research

Business Unit

Innovative Medicines

Emplacement

Royaume-Uni de Grande-Bretagne et d'Irl. du Nord

Site

London (The Westworks)

Company / Legal Entity

GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Functional Area

Recherche & Développement

Job Type

Full time

Employment Type

Regular

Shift Work

No

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