

Medical Director, Clinical Pharmacology

Job ID
REQ-10030751

12月 09, 2024

United Kingdom

摘要

Novartis Biomedical Research (BR) is the innovation engine of Novartis, focusing on powerful new technologies that have the potential to help produce therapeutic breakthroughs for patients. Translational Medicine (TM) is the clinical research arm of BR and includes about 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. TM Clinical Pharmacology is a cross-functional team, which is specialized on the design, clinical execution and reporting of First-in-Human (FiH) and Clinical Pharmacology studies across all TM therapeutic areas. The operating model is built upon a strategic outsourcing partnership with qualified and specialized CROs, in which the Novartis team maintains sponsor oversight and retains the strategic elements of the studies (e.g. study design, regulatory interactions, project timelines). As part of TM Clinical Pharmacology, you will help to develop therapies for patients, by providing medical and scientific leadership and expertise to support both early and late-stage global programs across all BR therapeutic areas in a role that significantly affects the entire Novartis drug development pipeline.

About the Role

The Medical Director, Clinical Pharmacology (MD CP) will be the primary point of contact for the cross-functional Clinical Pharmacology (CP) Trial Team and for our qualified CROs used in the Clinical Pharmacology Partnership Model for any safety-related, medical and clinical pharmacology-related questions.

The MD CP will liaise with the project level Translational Medicine Expert to familiarize with the compound background and program strategy to ensure adequate medical supervision and execution of the study in the best interest of the program and the safety of study participants.

The MD CP will also support the project teams with Clinical Pharmacology advice to ensure study designs are optimal to serve the program strategy.

Clinical Pharmacology portfolio

Efficient and autonomous management and Medical and Clinical Pharmacology leadership for multiple, simultaneously conducted FiH and Clinical Pharmacology studies, including:

- Contribution and provision of Clinical Pharmacology expertise for the development of Study Concept Sheets and Protocols
- Review of Informed Consent Forms, Statistical Analysis Plans, Tables, Listings and Figure (TLF) shells and drafts, and results summaries
- Medical and Clinical Pharmacology coverage for Site Initiation Visits, during the clinical conduct of the trial, for safety reviews and safety reporting and for medical coding
- Development of the Clinical Study Report and contribution to publications of study results, including abstracts, posters, manuscripts, plain language trial summaries and technical results summaries.

Clinical Pharmacology strategy and initiatives

- Contribution to strategic initiatives and process optimization workstreams in TM Clinical Pharmacology
- Strengthening the collaboration with internal stakeholders in early and full development and external partners

Impact of this role

- This role has a significant impact on the entire Novartis pipeline, by supporting the efficient clinical execution of FiH and Clinical Pharmacology studies for early and full clinical development programs in accordance with the Clinical Development Plan and Clinical Pharmacology Plan, by enabling efficient and result-based decision-making and by delivering key study results to support regulatory submissions.
- As a recognized specialist in the field, your strong experience in early clinical development and Clinical Pharmacology will enrich the Medical Team's expertise and will help to build and grow Clinical Pharmacology as the Novartis Center of Excellence for FiH and Clinical Pharmacology studies across all therapeutic areas in the BR portfolio.

- The Medical Director, Clinical Pharmacology, will further help to strengthen our collaboration with our internal Novartis stakeholders in early and full development and to establish efficient partnerships with our qualified CROs.

Minimum Requirements

- Medical Degree combined with a PhD/post-doctoral degree, specialized training (board certification) or clinical research experience in Clinical Pharmacology.
- Previous relevant & significant clinical study experience, across the broad spectrum of Clinical Pharmacology and FIH studies, either in the biopharmaceutical industry leading early phase clinical trials, as a PI or sub-investigator in a CRO or relevant academic medical center.
- Track record of drug submissions / approval and / or high-quality publications in international scientific journals and advanced training or additional clinical development experience in one of the TM Therapeutic areas would be an upside.
- Full professional proficiency in English (written and spoken).

Why Novartis? Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: <https://www.novartis.com/about/strategy/people-and-culture>

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部门

Biomedical Research

Business Unit

Innovative Medicines

地点

United Kingdom

站点

London (The Westworks)

Company / Legal Entity

GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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