Global Program Clinical Head - Rheumatology/Gastroenterology

Job ID
REQ-10060922

9月 10, 2025

United Kingdom

摘要

Leads the strategic planning, execution, and delivery of all global clinical trials across all programs within the assigned TA. Complete oversight of budget and resource allocation within the therapeutic area - including enterprise review of resources across the TAs. Drives operational excellence through process improvement and knowledge sharing across the function. Develops an empowered organization which can navigate in a matrix environment and adjust quickly to business needs.

About the Role

This hybrid role can be based in London, Basel, Dublin or Barcelona.

Major accountabilities:

- Leads the GCT, represents Clinical Development on the Global Program Team (GPT)

- May serve as the Clinical Development Representative on Biomedical Research clinical/project teams to drive transition of pre-PoC (Proof of Concept) projects to Development Decision Point (DDP)
- May support Business Development & Licensing (BD&L) activities Post-DDP, leads the development and execution of the clinical strategy.
- Develops an endorsed Integrated Development Plan (IDP) in line with the Target Product Profile (TPP) which is designed for successful global regulatory approval/market access for one or multiple treatment indications and/or multiple programs
- Leads the creation of clinical components of key documents (e.g., Clinical Trial Protocols (CTPs), Investigator's Brochures, Clinical Study Reports (CSRs), regulatory documents including maintenance of product licenses, registration dossiers, value dossiers, pharmacoeconomic dossiers) with high quality and consistency with IDP and TPP.
- Supports registration, market access, commercialization, and maintenance of product licenses (e.g., Core Data Sheet, Periodic Safety Update Report, clinical benefit-risk assessment for license renewals) for the compound(s)
- Together with Patient Safety, ensures continuous evaluation of drug safety profile, including safety monitoring of clinical studies and signal detection from post-marketing surveillance. Serves as a core member of the Safety Management Team (SMT)
- As the medical expert, leads interactions with external stakeholders (e.g., regulatory authorities, key opinion leaders, data monitoring committees, advisory boards, patient advocacy groups), internal stakeholders (e.g., Research, Translational Medicine, Global Medical Affairs (GMA), Marketing, Health Economics & Outcomes Research), and internal decision boards.

Minimum requirements:

What you'll bring to the role:

- MD or equivalent (preferred) PhD, or PharmD degree required
- 6 years professional experience with (MD or equivalent) OR 10 years (PhD or PharmD) of involvement in clinical research or drug development in an industry environment spanning clinical activities in Phases I through III/IV, including submission dossiers required
- Immunology disease expertise, ideally experience with Rheumatology / Gastroenterology
- Advanced knowledge of assigned therapeutic area required, with the capability to innovate in clinical development study designs that provide relevant evidence to decision-makers, and to interpret, discuss and present clinical trial or section program level data
- Thorough knowledge of Good Clinical Practice, clinical trial design, statistics, and regulatory/clinical development process required
- Experience with submissions and health authorities required
- Demonstrated ability to establish strong scientific partnership with key stakeholders
- Demonstrated leadership and management skills with a documented track record of delivering high quality projects/submissions/trials in a global/matrix environment (including remote) in pharmaceutical or biotech industry

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#LI - hybrid

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部门
Development

Business Unit
Innovative Medicines

地点
United Kingdom

站点

London (The Westworks)

Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.

Alternative Location 1
Barcelona Gran V í a, Spain

Alternative Location 2
Basel (City), Switzerland

Alternative Location 3
Dublin (NOCC), Ireland

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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