

Associate Clinical Research Medical Director - Immunology, Rheumatology

Job ID
REQ-10005168
Mag 22, 2024
USA

Sommario

• Accountable for all country clinical/medical aspects associated with Development and prioritized Re-search programs/trials by providing clinical strategic and tactical leadership as the Country Clinical Development representative. May work across several countries. • Gathers, informs, and acts on clinical/medical/scientific insights for clinical trial concept sheets/protocols, Informed Consent Forms (ICFs) and other relevant clinical documents to optimize clinical trial implementation. • Drives the identification and involvement of qualified investigators with greatest recruitment potential, identifies clinical recruitment hurdles and drives clinical recruitment activities to overcome these hurdles. • Accountable for adherence to safety standards and clinical data quality in the country by providing general clinical/medical support for trial related safety findings. • In close collaboration with other country functions (e.g., clinical trial operations, Medical Affairs, Patient Engagement, and Patient Access) actively contributes to successful allocation, fast clinical trial start-up, timely recruitment, early identification of potential delays, and development and implementation of mitigation plans.

About the Role

Major accountabilities:

- Validates study designs, is accountable for, and makes the final decision on the clinical/medical trial and program feasibility of implementing a clinical trial protocol based on medical/clinical practice and analysis of the competitive environment in the country.
- Actively contributes to scientific/clinical/medical aspects of the start-up phase to ensure fast clinical trial site start-up.
- Provides clinical/medical expertise to clinical trial operations team members and clinical trial sites for Institutional Review Boards (IRB)/ Ethics Committee (EC) interactions.
- Decides on site/Country-specific scientific/clinical/medical content of the Informed Consent Form(ICF) as needed and ensures appropriateness of patient suitable language.
- Provides scientific/clinical/medical expertise during interactions with Country/Cluster external Experts(e.g., Regulatory Authorities, Medical Experts, Advisory Boards, Patient Advocacy Groups, etc.).
- Building disease area expertise, especially for new/rare indications.
- Provides robust indication, compound, and protocol training: To the clinical operations team in the country, especially to the Clinical Research Associates, and other country line functions as needed.

- Supports planning, implementation, and follow-up of scientific/clinical/medical components of Regulatory Authority inspections and internal audits.
- Reviews and resolves Country trial-related scientific/clinical/medical issues/questions. If necessary, initiates the discussion with the Global Clinical Development team.
- May be involved in reviewing the clinical/medical aspects of clinical trial Serious Adverse Events (SAEs) occurring in the Country and supports the patient safety team, and Global as needed to ensure high quality of clinical/medical information.
- Follows-up with the Investigator for additional clinical/medical information or clarifications for AEs and SAEs and provides clinical/medical expertise for safety amendments, Investigator Notifications (INs), Urgent Safety Measures (USM), etc. as needed.

Job Requirements:

- MD or equivalent medical degree is required, in addition to a proven track record of clinical experience in and scientific contributions to your field of expertise.
- Specialty training in Rheumatology is desired but not an absolute prerequisite.
- Ideally, 3 years of clinical development experience in the pharmaceutical industry or clinical practice
- Working knowledge in the area of Immunology and Inflammation with ability to interpret, discuss and present efficacy & safety data relating to clinical trials.
- Sound understanding of the overall clinical development process, and ICH/GCP principles.
- Ability to manage a study from the scientific/medical/clinical perspective, and a demonstrated capability to problem solve and mediate complex scientific/clinical/medical/operational issues.
- Applies a detailed understanding of the drug in question to provide medical context as it relates to disease processes, populations, and standards of care.
- Ability to assess the feasibility of implementing the protocol based on Country/Cluster medical practice and sound understanding of the overall Clinical Development Plan.
- Demonstrates an understanding of the protocol to evaluate compliance on the part of the Investigator/site staff/study participant and any patient safety issues.
- Demonstrates an understanding of Regulatory requirements and internal policies, procedures, and guidelines pertaining to clinical trials.

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>

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Posizione

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Remote Position (USA)

Company / Legal Entity

U014 (FCRS = US014) Novartis Pharmaceuticals Corporation

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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