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Associate Clinical Research Medical Director - Oncology

Job ID
REQ-10011666
Jun 17, 2024
USA

Summary

Job Description Summary • 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:

- Advanced degree (Doctorate) required, MD is preferred. Also open to PhD, PharmD, DO.
- Proven track record of clinical experience in and scientific contributions to your field of expertise.
- Specialty training in Oncology is highly desired but not an absolute prerequisite.
- Ideally, 3 years of clinical development experience in the pharmaceutical industry or clinical practice
- 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.
- Ability to lead effectively by communicating well, motivating a cross-functional team, and handling and delegating responsibilities.
- Demonstrates a knowledge of how to adequately review and read a protocol to understand specifics of study design and answer questions regarding the trial.
- Applies a detailed understanding of the drug in question to pro-vide 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 a high level of understanding of the protocol to train others, including site personnel.
- 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.
- Applies knowledge of Regulatory/industry requirements to work in a Country regulated environment.
- Provides clinical, medical, and scientific expertise to facilitate the safe use of product(s) in clinical trials.

- Applies safety expertise to answer clinical trial site safety questions and provides required information to Country/Global where appropriate.
- Applies clinical/medical expertise to provide prompt review and follow-up on all SAEs and other safety documents relevant for clinical trial sites.

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

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Business Unit
Innovative Medicines
Location
USA
Site
Remote Position (USA)
Company / Legal Entity
U014 (FCRS = US014) Novartis Pharmaceuticals Corporation
Functional Area
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Job Type
Full time
Employment Type
Regular
Shift Work
No
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