

Associate Clinical Research Medical Director - Oncology RLT

Job ID
REQ-10017934
Aug 29, 2024
USA

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.
- Specialty training in Oncology Radiation or Nuclear Medicine is required.
- Proven track record of clinical experience in and scientific contributions to your field of expertise.
- 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 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 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.

EEO Statement:

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<https://www.novartis.com/careers/careers-research/notice-all-applicants-us-job-openings>

Salary Range

\$222,400.00 - \$333,600.00

Skills Desired

Clinical Trials, Data Analysis, Data Monitoring, Drug Development, Drug Discovery, Medical Strategy, People Management

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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accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Division

Development

Business Unit

Innovative Medicines

Location

USA

Site

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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