NOVARTIS

Associate Clinical Research Medical Director - Oncology RLT (Remote)

Job ID
REQ-10028373
Nov 21, 2024
USA

About the Role

Key Responsibilities:

- 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.

Role 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 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.

Novartis Compensation and Benefit Summary: The pay range for this position at commencement of employment is expected to be between: (non-MD range) $174,400 and 261,600/year and (MD range) $222,440 and 333,600/year; however, while salary ranges are effective from 1/1/24 through 12/31/24, fluctuations in the job market may necessitate adjustments to pay ranges during this period. Further, final pay determinations will depend on various factors, including, but not limited to geographical location, experience level, knowledge, skills, and abilities. The total compensation package for this position may also include other elements, including a sign-on bonus, restricted stock units, and discretionary awards in addition to a full range of medical, financial, and/or other benefits (including 401(k) eligibility and various paid time off benefits, such as vacation, sick time, and parental leave), dependent on the position offered. Details of participation in these benefit plans will be provided if an employee receives an offer of employment. If hired, employee will be in an “at-will position” and the Company reserves the right to modify base salary (as well as any other discretionary payment or compensation program) at any time, including for reasons related to individual performance, Company or individual department/team performance, and market factors.

Role Requirements

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

Benefits and Rewards: Read our handbook to learn about all the ways we’ll help you thrive personally and professionally: https://www.novartis.com/careers/benefits-rewards

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
Apply to Job

Job ID
REQ-10028373

Associate Clinical Research Medical Director - Oncology RLT (Remote)

Apply to Job

Source URL: *https://prod1.jobapi.novartis.com/req-10028373-associate-clinical-research-medical-director-oncology-rlt-remote*

List of links present in page

1. https://prod1.jobapi.novartis.com/req-10028373-associate-clinical-research-medical-director-oncology-rlt-remote
2. https://www.novartis.com/about/strategy/people-and-culture
3. https://talentnetwork.novartis.com/network
4. https://www.novartis.com/careers/benefits-rewards
5. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Remote-Position-USA/Associate-Clinical-Research-Medical-Director---Oncology-RLT--Remote-_REQ-10028373-2
6. https://novartis.wd3.myworkdayjobs.com/en-US/Novartis_Careers/job/Remote-Position-USA/Associate-Clinical-Research-Medical-Director---Oncology-RLT--Remote-_REQ-10028373-2