

Clinical Research Medical Advisor

Job ID
REQ-10019244
Oct 29, 2024
Czech Republic

Summary

As a Clinical Research Medical Advisor, you will be responsible for overseeing all clinical and medical aspects of research programs and trials in a specific country or across multiple countries. You will provide strategic and tactical leadership as the Country Clinical Development representative, gathering and utilizing clinical, medical, and scientific insights to optimize the implementation of clinical trials. This includes ensuring that clinical trial concept sheets, protocols, and Informed Consent Forms (ICFs) are informed by the latest knowledge and research in the field. One of key responsibilities is to identify qualified investigators with the highest recruitment potential and address any recruitment hurdles that may arise. You will also have a crucial role in maintaining safety standards and ensuring the quality of clinical data in the country and provide general clinical and medical support for trial-related safety findings, further ensuring the integrity and validity of the research.

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.).
- Develops clinical/medical trial plans taking the broader ecosystem into account for assigned programs/trials to ensure successful trial implementation, which includes:
 - Proactively identifying early on clinical challenges to recruitment or clinical data quality and drives development of clinical/medical mitigation plans.
 - 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.
 - Externally as needed in the Country/Cluster at Investigator's Meetings or scientific venues to support recruitment and trial awareness.
- Leverages innovation in clinical trial planning and decides on clinical/medical recruitment strategy and

- implementation based upon physician interviews, analysis of competitive trials, and patient engagement.
- As the scientific/clinical/medical expert, supports and partners with internal Stakeholders (e.g., Clinical Trial Team, Regulatory Affairs, Medical Information, Medical Affairs, Marketing, Patient Access, HE&OR, clinical trial operations, etc.), and internal decision boards as needed regarding clinical trials.
 - Gathers, informs, and acts on insights from clinical trial Investigators/site staff, Medical Experts, patients, and payers, with internal Stakeholders at the Country/Cluster level with the goal to optimize clinical trial implementation.

Essential requirements:

- Scientific degree M.D., Ph.D., or Pharm.D. (M.D. highly desirable);
- 3 years of clinical development experience in the pharmaceutical industry or clinical practice;
- Good knowledge of the clinical development process, and ICH/GCP principles;
- Subspecialty training and/or RWE experience desirable;
- Fluent in Czech and English;
- 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;
- Agility to move quickly across different therapeutic areas and indications;
- Demonstrated problem-solving skills and comfort with complexity;
- Ability to prepare and deliver high quality presentations;
- Willingness to travel up to 50%, including Internationally, as needed.

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Division

Development

Business Unit

Innovative Medicines

Location

Czech Republic

Site

Prague

Company / Legal Entity

CZ02 (FCRS = CZ002) Novartis s.r.o

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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