NOVARTIS

Clinical Research Medical Advisor

Job ID
REQ-10058091

7月 16, 2025

Bulgaria

摘要

Accountable for all country clinical/medical aspects associated with Development and prioritized Research 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

From Strategy to Functional Excellence
Provides Clinical Development and indication expertise specific to Country/Cluster, and together with the clinical trial operations team, drives the execution of clinical trials with high quality and within planned time-lines:
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:
-Pro-actively 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.
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.
Accountable for adherence to safety standards, clinical data quality for the Country/Cluster and provides general scientific/clinical/medical support for safety issues:
Provides clinical/medical expertise to support pharmacovigilance activities.
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.
Supports the Global Clinical Development team as needed to address/clarify clinical/medical Protocol Deviations through follow-up with clinical trial sites.
May support innovative study designs by identifying and conducting quality assessments of Country datasets (e.g., Registries, Electronic Health Records, Payer data, Real World Data, etc.).
Drives all clinical/medical activities in adherence to GCP (Good Clinical Practices), and in line with ICH (International Conference on Harmonization) and Country regulations.
Provides scientific/clinical/medical input to the overall Product strategy at the Country level with an optimized cross-functional Country team.
May represent Clinical Development at internal and external meetings.
Provides a superior customer experience for Investigators/site study teams, significantly impacting the external visibility and reputation of Novartis.

Key performance indicators/Measures of success

Meets Country/Cluster-specific clinical trial operations Key Performance Index (KPI) targets, particularly those related to trial feasibility and recruitment.
Drives investigator site performance by providing high quality support to Investigators/Clinical trial site staff for Development and Biomedical Research studies, leading to a superior customer experience.
Prepares high quality Country clinical trial documents according to agreed timelines especially for IRB/EC/Regulatory Authorities, and Investigator queries as needed.
Timely management of local safety issues.
Quality of scientific/clinical/medical input to Country, and Global teams.
Support provided to Investigators and their level of engagement, and satisfaction.

Minimum Requirements:

Education:

- **Scientific degree M.D., Ph.D., or Pharm.D. (M.D. highly desirable, > 40 % of CRMA FTEs in a country if possible)**
- **Subspecialty training and/or RWE experience desirable, but not required.**

Languages:

- **Speaks and writes English.**
- **Speaks local language (if other than English).**

Skills:

- **Ability to manage a study from the scientific/medical/clinical perspec-tive, 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 indica-tions.**
- **Demonstrated problem-solving skills and comfort with complexity.**
- **Ability to prepare and deliver high quality presentations.**

Experience:

- **Ideally, 3 years of clinical development experience in the pharma-ceutical industry or clinical practice.**
- **Sound understanding of the overall clinical development process, and ICH/GCP principles.**

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

部门
Development

Business Unit
Innovative Medicines

地点
Bulgaria

站点
Bulgaria

Company / Legal Entity
BG03 (FCRS = BG003) NPHS Bulgaria

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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