Clinical Research Medical Advisor

Job ID
REQ-10043867

7月 02, 2025

Brazil

摘要

Supervisa la ejecuci ó n e interpretaci ó n de investigaciones de ensayos cl í nicos, actividades de recopilaci ó n de datos y operaciones cl í nicas. Establece y aprueba m é todos cient í ficos para el dise ñ o e implementaci ó n de protocolos cl í nicos, sistemas de recopilaci ó n de datos e informes finales. Ayuda en investigaciones cl í nicas nuevas y constantes y en ensayos cl í nicos y asegura la eficiencia y el oportuno procesamiento de acuerdos de confidencialidad y acuerdos cl í nicos. Superv. el cumplim. de los protoc. y determ. la terminaci ó n de los estudios. Gestiona archivos cl í nicos y reglamentarios y mantiene el inventario cl í nico previsto para la distribuci ó n a sitios de investigaci ó n. Puede interactuar con sitios de investigaci ó n, consultores cl í nicos, Organizaciones de Investigaci ó n de Contratos y otros proveedores. Selecciona, desarrolla y eval ú a personal para asegurar la operaci ó n eficiente de la funci ó n.

About the Role

Major Accountabilities

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 pro-

grams/trials to ensure successful trial implementation, which includes:

o Pro-actively identifying early on clinical challenges to recruitment or clinical data quality and

drives development of clinical/medical mitigation plans.

o Building disease area expertise, especially for new/rare indications.

Provides robust indication, compound, and protocol training:

o To the clinical operations team in the country, especially to the Clinical Research Associates, and other country line functions as needed. o 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 en-gagement. · As the scientific/clinical/medical expert, supports and partners with internal Stakeholders (e.g., Clin-ical 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, pa-tients, 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 Regu-latory 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 pro-vides general scientific/clinical/medical support for safety issues: o Provides clinical/medical expertise to support pharmacovigilance activities. o 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. o 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.

Ideal Background

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).

Experience/Professional

Requirement: 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: Our purpose is to reimagine medicine to improve and extend people ' s lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

You ' ll receive: Competitive salary, annual bonus, life insurance, home office policy (home office 2x a week), retirement and wellbeing plans, flexible working arrangements, birthday day-off, parental leave, subsidized dining facilities, health insurance, employee recognition platform, Gympass, employee resource groups and virtual self-development tools.

If you want to learn more about our benefits, you can access the Novartis Life Handbook: https://www.novartis.com/careers/benefits-rewards

Commitment to Diversity and Inclusion: Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Careers: https://www.novartis.com/careers

Novartis is unable to offer relocation support for this role: please only apply if this location is accessible for you.

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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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
Brazil

站点
Santo Amaro

Company / Legal Entity
BR03 (FCRS = BR003) NOVARTIS BIOCIENCIAS S.A

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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Clinical Research Medical Advisor

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List of links present in page

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3. https://www.novartis.com/careers
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