

## Clinical Research Medical Advisor

Job ID  
REQ-10043867

3月 27, 2025

Brazil

### 摘要

Supervisa la ejecución e interpretación de investigaciones de ensayos clínicos, actividades de recopilación de datos y operaciones clínicas. Establece y aprueba métodos científicos para el diseño e implementación de protocolos clínicos, sistemas de recopilación de datos e informes finales. Ayuda en investigaciones clínicas nuevas y constantes y en ensayos clínicos y asegura la eficiencia y el oportuno procesamiento de acuerdos de confidencialidad y acuerdos clínicos. Superv. el cumplimiento de los protoc. y determ. la terminación de los estudios. Gestiona archivos clínicos y reglamentarios y mantiene el inventario clínico previsto para la distribución a sitios de investigación. Puede interactuar con sitios de investigación, consultores clínicos, Organizaciones de Investigación de Contratos y otros proveedores. Selecciona, desarrolla y evalúa a personal para asegurar la operación eficiente de la función.

### 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 programs/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 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: 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 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.

Experience: - 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.

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.

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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>

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部门  
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Business Unit  
Innovative Medicines

地点  
Brazil

站点  
Santo Amaro

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

Functional Area  
Research & Development

Job Type  
Full time

Employment Type  
Regular

Shift Work  
No

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