U NOVARTIS

Clinical Research Medical Advisor

Job ID REQ-10021501 Sep 06, 2024 España

Resumen

En línea con la estrategia general del producto, el Asesor Médico es responsable de apoyar el diseño, la implementación y la ejecución de los planes de Asuntos Médicos para el Área de Terapia asignada, proporcionar información científica, ayudar a diseñar y organizar estudios clínicos, construir un diálogo educativo con los KOL y las partes interesadas reguladoras.

About the Role

From Strategy to Functional Excellence

The CRMA 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 timelines:

Major Accountabilities

- 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.
- 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.
- 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, Health Economics and Outcomes Research (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.

• Accountable for adherence to safety standards, clinical data quality for the Country/Cluster and provides general scientific/clinical/medical support for safety issues

Key performance indicators

- 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.

Essential Requirements:

- Scientific degree M.D., Ph.D., or Pharm.D. (M.D. is preferred) with 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.
- The ability to speak and writes 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.

Desirable Requirements

• Subspecialty training

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: You can find everything you need to know about our benefits and rewards in 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 Network here: https://talentnetwork.novartis.com/network

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: <u>https://www.novartis.com/careers/benefits-rewards</u>

División Development **Business Unit Innovative Medicines** Ubicación España Sitio Barcelona Gran Vía Company / Legal Entity ES06 (FCRS = ES006) Novartis Farmacéutica, S.A. **Functional Area Research & Development** Job Type Full time **Employment Type** Regular Shift Work No Apply to Job iframe{ width: 100%; margin-top: 3rem; } @media screen and (max-width: 767px){ iframe{ height: 30vh !important; } } @media screen and (min-width: 768px){ iframe{ height: 34vh !important; } } Job ID REQ-10021501

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