Clinical Research Medical Advisor

Job ID
REQ-10021501

9月 06, 2024

Spain

摘要

En l í nea con la estrategia general del producto, el Asesor M é dico es responsable de apoyar el dise ñ o, la implementaci ó n y la ejecuci ó n de los planes de Asuntos M é dicos para el Á rea de Terapia asignada, proporcionar informaci ó n cient í fica, ayudar a dise ñ ar y organizar estudios cl í nicos, construir un di á logo 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

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部门
Development

Business Unit
Innovative Medicines

地点
Spain

站点
Barcelona Gran V í a

Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmac é utica, S.A.

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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