

Country/ Cluster Head CRMA

Job ID
REQ-10016231

8月 15, 2024

Argentina

摘要

Supervisa la planificación, ejecución e interpretación de la investigación de ensayos clínicos, las actividades de recopilación de datos y las operaciones clínicas. Establece y aprueba métodos científicos para el diseño e implementación de protocolos clínicos, sistemas de recolección de datos e informes finales. Apoyar la investigación clínica y los ensayos clínicos nuevos y en curso y garantizar el procesamiento eficiente y oportuno de los acuerdos de confidencialidad y los acuerdos clínicos. Monitorea el cumplimiento de los protocolos y determina la finalización del estudio. Gestiona archivos clínicos y regulatorios y mantiene el inventario clínico destinado a su distribución a sitios de investigación

About the Role

Major Accountabilities

Functional Excellence

- Accountable for CRMAs to deliver high quality clinical/medical program and trial feasibility for GDD and NIBR PoC trials; drives country clinical/medical feasibility process and outcome improvement including identification of new investigators and medical experts.
- Accountable for co-ordinating cross-CPO/Cluster initiatives to support recruitment for GDD studies, liaising between the CRMAs and the global team.
- Leverages innovation in clinical trial planning and execution, including patient engagement as appropriate to deliver recruitment goals.
- Supports CD&A vision to develop innovative clinical development plans that change the world by sharing early insights from sites, regional/local guidelines, patients and payers in partnership with medical affairs and the local Trial Monitoring Organization.
- Provides Clinical Development leadership to develop and execute innovative, patient-friendly and competitive clinical trial concept sheets/protocols by supporting nomination of experienced CRMAs to GCTs and other global/regional working groups and ensures high quality feedback.
- Performs CRMA activities as needed to cover potential CRMA resource gaps and may represent the clinical/medical and scientific interests in internal and external forums to support GDD and NIBR trials
- In collaboration with the local Trial Monitoring organization accountable for adherence to safety standards, clinical data quality and regulatory legislation.
- Ensures Cluster delivery by identifying and developing new sites, builds competitive advantage to establish Novartis as a preferred clinical research partner.
- Is accountable to implement global clinical standards for CRMAs.
- May coach the development of local study protocols, implementation and analysis, especially for local studies requested by Has.
- Guide CRMAs on how to ensure a smooth transition and collaboration with Medical Affairs (e.g. transparency of activities, availability of new data etc.).

Stakeholder Management

- Drives trial site performance and providing superior customer experience for investigators / site study teams, significantly impacting the external visibility and reputation of Novartis.
- Uses advanced influencing skills to manage collaborations between Cluster/local GDD, Medical Affairs and Patient Access, balancing potentially diverging objectives to achieve superior results. Aligns Cluster with Regional objectives.

People

- Hires CRMAs in the Cluster in collaboration with the Regional CRMA Head, the CSO in the country the CRMA will be hired (or delegate) and the country Trial Monitoring Organization.
- Accountable to implement global clinical standards for CRMAs incl. details on Roles and Responsibilities and capabilities.
- Guides targets/objectives, provides development feedback and evaluates performance. Supports development and implements criteria for CRMA performance assessments.
- Identifies CRMA talents, and promotes further development incl. succession planning
- Promotes adherence/compliance to SOPs, the global training and on-boarding plans within the Cluster.
- May deputize for Regional Head CRMA.

Ideal Background

Education:

Scientific degree: MD, PhD or PharmD to allow diverse CRMA team

(MDs preferable, depending on countries needs and availability)

Languages:

- Speaks and writes English
- Speaks at least local language of one country (if other than English)

Experience:

Skills:

- Ability to manage a study from the medical/clinical perspective, and a demonstrated capability to problem solve and mediate complex clinical / medical / operational issues.
- Agility to move fast across different therapeutic areas and indications

Experience:

- At least 6 years experience in pharmaceutical industry with at least 3 years experience in clinical development or trial monitoring across different indications / Therapeutic areas.
- Demonstrated leadership skills e.g. in a matrix with the ability to inspire teams and external experts.
- Sound understanding of the overall clinical development and ICH/GCP.
- Track record of delivering complex global clinical projects in quality and time.
- Demonstrates a knowledge of how to adequately review and read a protocol to understand specifics of study design and answer questions regarding the trial
- Applies a detailed understanding of the drug in question to provide medical/clinical context as it relates to disease processes, populations, and standards of care
- Ability to assess the feasibility of a clinical trial protocol based on cluster medical practice and sound understanding of the overall clinical development plan
- Demonstrating an understanding of regulatory requirements and internal policies, procedures, and guidelines pertaining to clinical trials
- Providing medical/clinical expertise to facilitate the safe use of product(s) in clinical trials

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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部门

Development

Business Unit

Innovative Medicines

地点

Argentina

站点

Ramallo (Argentina)

Company / Legal Entity

AR01 (FCRS = AR001) Novartis Argentina S.A.

Functional Area

Research & Development

Job Type

Full time

Employment Type

Regular

Shift Work

No

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