Governance & Excellence Specialist

Job ID
REQ-10041379
Feb 27, 2025
Colombia

Resumen

Contribuye, con una supervisión adecuada, a todos los aspectos de los ensayos clínicos globales para ofrecer resultados de estudio dentro de los estándares de programación, presupuesto, calidad/cumplimiento y rendimiento. Puede liderar aspectos específicos del proceso de ensayo clínico global. Contribuye a la excelencia operativa a través de la mejora de procesos y el intercambio de conocimientos.

About the Role

Major accountabilities

Data Generation, Governance & Excellence

- Ensures that all processes, systems and operational elements comply with internal policy, industry standards, country regulations and compliance metrics for the conduction of projects in MA (GxP activities such as Interventional and NIS/RWE, IIT, MAP, RC and other relevant activities in MA).
- Provides oversight of vendors/third parties involved in the planning and execution of MA projects and programs.
- Act as a Subject Matter Expert in regulatory and clinical supply processes.
- Contributes, with appropriate oversight, to all aspects RWE Projects to deliver study outcomes within schedule, budget, quality/compliance and performance standards.
- Provides oversight of budgets across Evidence Generation and other MA projects, aligning business and scientific objectives with the company priorities.
- Proactively identify root cause and implement action to improve future audit/inspection
- Support to the Data Generation & Governance team in local audit & inspection readiness and execution.
- performance and track deviation and support implementation/resolution of local CAPA.
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- Monitor and report KPI/KQI using existing Global systems & tools.
- Reporting of technical complaints / adverse events / special case scenarios related to Novartis products within 24 hours of receipt.
- Ensure proper classification of medical activities, in collaboration with local ERC department, if needed.

Leadership & Culture:

- Ensure and drive cross-enterprise capability building in expertise.
- Effective evidence team building through enterprise mindset & cross-functional excellence.
- Effectively operates in cross-functional teams, including early launch, BEE (data & insights).

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- Role model for our culture, values & behaviors, consistently demonstrating the highest ethics and integrity-based standards.
- Demonstrate enterprise perspective and delivery of medical evidence to address priority business challenges.

Additional specifications

- Knowledge in requirements for interventional and non-interventional trials, including implementation of clinical research activities for all Phase IV clinical trials.
- Operations Management and Execution

KPIs

- Adherence to Novartis policies and guidelines, as well as external regulations.
- Compliance risks for assigned responsibilities are identified with well-defined processes and appropriate internal level of controls.
- Internal Audits without critical findings for assigned functions and accountabilities.
- Preventive action plans in place and implemented in an effective and timely manner.
- Oversight through established KPIs/KQIs on existing systems, including training compliance

Ideal Background

Scientific degree: Pharmacist, BSc, RN or professional in life sciences.

Languages

English

Experience

- Equal or more than 2 years of experience in CRO or in pharmaceutical industry.
- Knowledge and understanding of:
  - Both scientific and operational aspects of clinical drug development and Medical Affairs.
  - GCP, ICH, and respective R/C regulations.
- Knowledge and understanding of Novartis standard operating procedures.

Competencies

Continuous Learning (Dyn. Knowledge Development)

Digital & Technology Savvy

Interpersonal Savvy

Operational Excellence

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

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

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: https://www.novartis.com/careers/benefits-rewards

División
International
Business Unit
Innovative Medicines
Ubicación

Colombia
Sitio
Bogota (Pharmaceuticals / GDD / NTO / CTS)
Company / Legal Entity
CO01 (FCRS = CO001) Novartis de Colombia S.A
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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REQ-10041379

Governance & Excellence Specialist

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