NOVARTIS

Manager, Clinical Disclosure Office

Job ID
REQ-10003670
juin 20, 2024
Espagne

Résumé

Manager, Clinical Disclosure Office, Location: Barcelona, Spain or London, UK #LI-Hybrid

The Manager, Clinical Disclosure Office ensures quality and compliant protocol registrations and results postings as well as alignment with global registries (i.e.ClinicalTrials.gov, EudraCT, EUCTIS, Novartis Clinical Trial Results EMA-HMA Catalogue of non-interventional studies etc.) with oversight.
They are also accountable for protocol registry and results eligibility assessment and must demonstrate capability to interpret, discuss and ensure appropriate trial data is accurately represented in clinical registries.

About the Role

Key Responsibilities:

- Participate in client trainings within Biomedical Research and Novartis Pharmaceuticals to drive quality and compliance and organizational alignment to changing disclosure requirements.
- Responsible for staying current with global policies & regulations and operational application to ensure harmonization of Novartis transparency processes and standards
- Independently represent Novartis to internal stakeholders. Develop and maintain effective working relationships with global and country multidisciplinary leaders, such as Study Leads, M.D.s, Legal, and Business Development & Licensing.
- Participate in the maintenance of Standard Operating Procedures and preparations for external & internal audits.
- Apply a continuous improvement mind set ensuring best practices are shared continually driving to the most productive processes

Essential Requirements

- Bachelor’s degree in a scientific discipline preferred.
- Minimum 3 years pharmaceutical industry experience with knowledge in disclosure including registration, maintenance, and results disclosure. (Experience with ClinicalTrials.gov, EudraCT and the Citeline Disclose tool (also known as PharmaCM) advantageous)
- knowledge of drug development, experience in writing protocols, experience in multiple clinical indications and/or therapy areas desired
- Proven development skills in a responsible position within Clinical Research & Development, Data Management, Project Management, Medical Writing, Regulatory Affairs or related areas
- Ability to successfully work within complex cross divisional matrix; previous experience leading multidisciplinary teams in matrix environment
- Strong negotiation & conflict resolution skills; well organized, focused on results/compliance, strong

planning, tracking, problem solving and decision making skills
- Proficiency in Good Clinical Practice, Regulatory Processes and clinical trial designs
- Ability to adapt to changing external environment

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

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Division
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Business Unit
Innovative Medicines
Emplacement
Espagne
Site
Barcelona Gran Vía
Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.
Alternative Location 1
Home Worker, Royaume-Uni de Grande-Bretagne et d'Irl. du Nord
Functional Area
Recherche & Développement
Job Type
Full time
Employment Type
Regular

Shift Work
No
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