Medical Safety Lead

Job ID
REQ-10015485
nov 18, 2024
Inde

Résumé

In close collaboration with the Global Program Safety Lead (GPSL) provides robust safety evaluation expertise and medical innovation in order to improve patients' lives and impact on overall Novartis results. As a member of the Medical Safety organization, prioritizes the safety of patients, ensures optimal patient safety for assigned compounds and shares responsibility for the integration, analysis, and evaluation of internal and external safety information through product lifecycle management, and evaluation of internal and external safety information through product lifecycle management.

About the Role

Major accountabilities:

- Monitors the clinical safety of projects /products including activities such as literature review, evaluation of individual cases or signal detection, and responds to safety related questions appropriately .
- Performs medical assessment and related activities for cases whenever required, including collecting additional follow-up information as necessary, medical evaluation of product quality defects with adverse events, review of line listings of single cases, and preparation of investigator notifications and periodic medical assessments for ethics committees.
- Identifies safety signals based on the review of solicited or unsolicited single cases.
- Performs signal detection, monitoring and evaluation of all safety signals.
- Provides inputs into responses to inquiries from regulatory authorities or health care professionals on safety issues.
- Prepares safety data for Health Authority review boards.
- Provides inputs to responses for legal queries and Country Organization requests involving safety issues.
- Provides expert evaluation on the clinical context of adverse event reports, assessment of the medical conditions, and the implications on Novartis products.
- Collaborates productively on clinical safety tasks with colleagues from Clinical Development, Regulatory Affairs, Medical Affairs, Medical Information, Statistics, Safety Data Management, Epidemiology and other related departments.
- Provides safety inputs for clinical and regulatory deliverables including clinical study protocols, clinical study reports, and investigator brochure. Provides relevant inputs for Global Program/Brand Team (GPT/GBT), Global Clinical Team (GCT), and Clinical Trial Team (CTT) meetings as needed. Provides support as needed for licensing activities, regulatory authority inspections and for project/product recall activities.

Minimum Requirements:

- Medical Degree (MBBS or MD) required. Medical degree with specialization preferred. Medical degree is essential for associates performing medical review of single case reports whenever business needs require this activity.Relevant experience (e.g., clinical, postdoctoral) after graduation.
- At least 12 years in drug development in a major pharmaceutical company, including 6years in patient safety at an operational or medical position (or equivalent experience) is desirable.
- Experience in drug development, clinical trial methodology, regulatory requirements, scientific methodology, statistics and writing of publication.Proven ability to analyze, interpret, discuss, and present safety information both in writing and orally. • Experience in preparing or contributing to preparation of clinical safety. assessments and regulatory reports involving safety information • Experience with (safety or others) issue management.**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

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Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to

diversityandincl.india@novartis.com and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

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