Medical Safety Lead / Sr Medical Safety Lead (CRM)

Job ID
REQ-10038099
fév 04, 2025
Espagne

Résumé

Location: Barcelona, Spain

Working model: Hybrid working model (which requires 12 days per month in the office)

Note: Novartis is not able to offer relocation support for this role. Please only apply if this location is accessible for you.

About this role:
Our Medical Safety Lead within the Cardio Renal Metabolic (CRM) therapeutic area, is part of a team that gets important compounds to market safely, helping millions of patients with serious diseases.

This role will report to the Head Patient Safety CRM.

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.
- Contributes to the development of departmental goals and objectives.

Role Requirements:

Education & Experience:

- Medical Degree (Preferred) but PhD, PharmD also considered
- Sufficient experience in drug development in a major pharmaceutical company, including some years of experience in patient safety ideally in an operational or medical position.
- Experience in clinical trial methodology, regulatory requirements, scientific methodology, statistics and writing of publications.
- Proven ability to analyse, interpret, discuss, and present safety information both in writing and orally.
- Experience in preparing or contributing to the preparation of clinical safety assessments and regulatory reports/submissions involving safety information.
- Experience with (safety or other) issue management.

Languages :

- Fluent English (both spoken and written).
- Additional EU languages are an advantage.

Skills:

- Clinical Trials.
- Functional Teams.
- Literature Review.
- Management Skills.
- Medical Information.
- Medical Records.
- Medical Strategy.
- Pharmacovigilance.
- Regulatory Compliance.
- Risk Management.
- Safety Science.

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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Division
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Innovative Medicines
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Barcelona Gran Vía
Company / Legal Entity
ES06 (FCRS = ES006) Novartis Farmacéutica, S.A.
Functional Area
Recherche & Développement
Job Type
Full time
Employment Type
Regular
Shift Work
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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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