Medical Safety Lead - Neuroscience

Job ID
REQ-10041132
Feb 24, 2025
Reino Unido

Resumen

About this role:

Our Medical Safety Lead within the NeuroScience therapeutic area, is part of a team that gets important compounds to market safely, helping millions of patients with serious diseases. Not only will you be working on marketed drugs, but you will also work on early stage drugs for disease with unmet needs. This role will report to the Head Patient Safety NS.

About the Role

Primary Location: London, England

Secondary Location: Barcelona, Spain

Working model: Both locations have a 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.

Key Responsibilities:

- Monitoring the clinical safety of projects /products including activities such as literature review, evaluation of individual cases or signal detection, and respond to safety related questions effectively.
- Perform 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.
- Identify safety signals based on the review of solicited or unsolicited single cases. Performing signal detection, monitoring and evaluation of all safety signals.
- Contributing towards responses to inquiries from regulatory authorities or health care professionals on safety issues.
- Preparing safety data for Health Authority review boards. Providing inputs to responses for legal queries and Country Organization requests involving safety issues.
- Providing expert evaluation on the clinical context of adverse event reports, assessment of the medical conditions, and the implications on Novartis products.
- Collaborate efficiently on clinical safety tasks with colleagues from Clinical Development, Regulatory Affairs, Medical Affairs, Medical Information, Statistics, Safety Data Management, Epidemiology and other related departments.

- Contribute 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.
- Global experience is required.

Languages :

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

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
Development
Business Unit
Innovative Medicines
Ubicación
Reino Unido
Sitio
London (The Westworks)
Company / Legal Entity
GB16 (FCRS = GB016) Novartis Pharmaceuticals UK Ltd.
Alternative Location 1
Barcelona Gran Vía, España
Functional Area
Research & Development
Job Type
Full time
Employment Type

Regular
Shift Work
No
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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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