Patient Safety Specialist

Job ID
REQ-10048332

4月 29, 2025

Czech Republic

摘要

The role of Patient Safety Specialist is to support management of Patient Safety operational processes at Country Organization ensuring compliance with Novartis global and local procedures, national and international regulations/ standards/ guidelines for vigilance of both marketed and investigational products (incl. drugs, food supplements and medical devices) from Novartis Group.

About the Role

Key Responsibilities:

Your responsibilities include, but are not limited to:

- Manage the collection, processing, documentation, reporting and follow-up of all adverse event reports for all Novartis products from Clinical Trials, Non-interventional Studies, Patient Oriented

Program (POPs), Literature, Spontaneous Reports, and any other source of information

- Transcribe, translate, and enter data from source documents into safety systems accurately and consistently with focus quality and on timeliness. When case processing activities are externalized, liaise with the respective External Service Providers to ensure Novartis Procedures ' compliance.

- Manage reporting/submission/distribution of safety reports/updates/information (e.g., SAE, SR, IN/SUSAR, PSUR, Biannual SUSAR Listing, DSUR) to Local Health Authorities (LHA) and/or clinical operations in cooperation with other Country Organization Departments.

- Develop, update, and implement local procedures to ensure compliance with Patient Safety global procedures and national requirements

- Interact and collaborate with other departments (such as Medical Affairs, Marketing, Patient Engagement, etc.) to ensure that any projects/ initiatives that potentially involve safety data collection (POPs, DEAs, SM/SML, etc.) follow the Novartis vigilance requirements.

- Ensure compliance with the commitments disposed in the contracts/ agreements. Ensure the applicable local contracts/ agreements are tracked in the respective Pharmacovigilance Agreement SharePoint. Ensure any significant departure from the standard vigilance templates are communicated and endorsed by the global PS Alliance group.

- Perform reconciliation with other departments (e.g., Medical Information, Quality Assurance, and Third-party contractors, as applicable) for potential AEs resulting from medical inquiries, quality related complaints and other sources.

- Management and maintenance of all relevant local Patient Safety databases

Essential Requirements:

- Health Care Sciences Professional (e.g., Medical Doctor, Nurse, Pharmacist), life science degree or equivalent training and experience.

- Fluent in English and Czech/Slovak.

- Knowledge of national and international regulations for pharmacovigilance

- Great communication and skills

- Quality and Results oriented

You 'll receive:

Monthly pension contribution matching your individual contribution up to 3% of your gross monthly base salary; Risk Life Insurance (full cost covered by Novartis); 5-week holiday per year; (1 week above the Labour Law requirement) ; 4 paid sick days within one calendar year in case of absence due to sickness without a medical sickness report; Cafeteria employee benefit program - choice of

benefits from Benefit Plus Cafeteria in the amount of 17,500 CZK per year; Meal vouchers in amount of 105 CZK for each working day (full tax covered by company); Public Transportation allowance; MultiSport Card, Employee Share Purchase Plan. Find out more about Novartis Business Services: https://www.novartis.cz/

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

部门
Development

Business Unit
Innovative Medicines

地点
Czech Republic

站点
Prague

Company / Legal Entity
CZ02 (FCRS = CZ002) Novartis s.r.o

Functional Area
Research & Development

Job Type
Full time

Employment Type
Temporary (Fixed Term)

Shift Work
No

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Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to all individuals. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to receive more detailed information about the essential functions of a position, please send an e-mail to di.cz@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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