Patient Safety Specialist

Job ID
REQ-10011130
Jun 10, 2024
Turquía

Resumen

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

Major accountabilities:

- 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.
- Management and distribution of vigilance clauses to other departments (such as Legal, Procurement, etc.) to be included in local agreements if necessary
- Advice the owners of local contracts/ agreements with impact in the vigilance system, about the vigilance provisions to be included, as required per Novartis procedures and/or applicable regulations.
- 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
- Ensure that relevant local literature articles are screened as appropriate.

- Prepare and submit KPI reports on compliance in a timely manner including identification of root cause(s) for late reporting to LHA, development and implementation of corrective action(s) as needed.
- Develop and update training materials for vigilance and ensure training of Country Organization associates on relevant Patient Safety procedures for AE reporting, including field force and third-party contractors, as applicable.
- Ensure support to the internal audits, LHA inspections and implementation of the respective CAPA plan
- Other agreed tasks assigned by manager
- ***Data privacy:** Cooperate in ensuring that Novartis systems (Argus, etc) are properly configured to guarantee compliance with local data privacy legislation, as well as ensure that local pharmaco-device vigilance information is captured, collected and managed as per local data privacy legislation

Ideal Background

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

Languages:

Fluent in both written and spoken English

Experience/Professional Requirement:

Knowledge of national and international regulations for pharmacovigilance

- Knowledge of pharmacological and medical terminology
- Good communication and interpersonal skills
- Quality and results oriented
- Computer skills

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Company / Legal Entity
TR01 (FCRS = TR001) Novartis Sağlık, Gıda ve Tarım Ürünleri San. Ve Tic. A.Ş.
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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