Patient Safety Manager

Job ID
REQ-10046296

4月 15, 2025

Ivory Coast

摘要

To manage the Patient Safety operational processes at the Country Organization ensuring compliance with Novartis global and local procedures, national and international regulations/ standards/ guidelines for the vigilance of Novartis group approved, marketed and investigational products (incl. drugs, food supplements and medical devices). To support the CPSH West Africa in the implementation of PS strategy at country level.

The PSM has direct responsibility for Ivory Coast and supports the following countries in the WA cluster organization: Benin, Burkina Faso, Cameroon, Cape Verde, Central African Republic, Chad, Congo Democratic Republic, Gabon, Ghana, Guinea, Guinea-Bissau, Guinea Equatorial, Liberia, Mali, Mauritania, Niger, Nigeria, Senegal, Sierra Leone and Togo.

About the Role

- **Single point of contact**: Act as the Local Qualified Person for Pharmacovigilance/ Local PV Responsible Person in Novartis Country Organization, as defined by local regulation and applicable legislation in WA. **Local operational activities:**
- Set up, update, and implement local procedures to ensure compliance with PS global procedures and national requirements.
- Case Processing (triage/ documentation; translation; data-entry; follow-up activities and archive, as applicable).
- Expedite ICSR reporting and aggregate reporting (PSUR, DSUR, ASR) in relation to quality, accuracy, completeness and timelines, as applicable.
- Ensure local PS-related RMP commitments are executed and properly documented.
- Training of MAH personnel in relation to PV.
- Local Licensing agreements.
- Pre- and post-authorisation safety studies, with appropriate PS input as required.

- Act as a key partner who provides input, during the process of establishing local programs (ex. POPs, DEAs; SM/SML, etc.): comments on proposals for vigilance language, content, and establishment of necessary controls on collection and reporting of adverse event information.
- Provide scientific expertise during review of all Phase IV Clinical Trial and NIS protocols safety sections including Research Collaborations and if a Contract Research Organization (CRO) is conducting the trial or study, review safety relevant sections of the contract.
- Ensure that relevant local literature articles are screened as appropriate.
- Supervision of management and maintenance all relevant PS databases.
- Ensure timely preparation and submission of KPI reports on AE reporting or AE follow-up including identification of root cause(s), development and implementation of corrective and preventative action(s) as needed.
- Provide scientific expertise during review of all Phase IV Clinical Trial and NIS protocols safety sections including Research Collaborations and if a Contract Research Organization (CRO) is conducting the trial or study, review safety relevant sections of the contract.
- Supports on monitoring and assessment of performance of PV third parties and local partners in line, with the applicable regulations, agreements and standard operational/ working procedures in place. In collaboration with QA and Vendor Management functions, ensures corrective and/or preventive actions are implemented in case contractual commitments are not met, as applicable.
- Monitor national pharmacovigilance regulations and provide update to global PS organization.
- Supports in a promptly answer to any safety related requests from Local Health Authorities in the country.
- Ensure support for and close-out of audits, corrective action plan, investigation, self-assessment and Health Authority inspections.
- Mentors less experienced staff, maintaining a professional network of key contacts and role model Novartis values and behaviors.
- Supports on cluster tasks assigned by reporting manager

Minimum Requirements:
Work Experience:

- Minimum 3 years ' experience in drug-safety or pharmacovigilance (preferred) and/ or experience in pharmaceutical industry.

Skills:

- Good knowledge of local requirements relating to PV and RMPs
- Working knowledge of PV-processes, covering compliance databases, procedures, QA, training.
- Quality and focus oriented.
- Computer/IT systems literacy
- Experience and knowledge of safety and RMP processes
- Good communication, interpersonal, negotiation skills, organizational skills
- Ability to work in cross-functional teams and influence in a matrix organization
- Results driven, committed and accountable

Languages :

- Fluent in both written and spoken English
- Knowledge of other languages desirable (French)

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部门
Development

Business Unit
Innovative Medicines

地点
Ivory Coast

站点
Ivory Coast

Company / Legal Entity
CI02 (FCRS = CI002) NPHS AG Ivory Coast NTLE

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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