Sr Global Program Safety Team Lead - Global Health (Malaria Team)

Job ID
REQ-10030110
Dec 16, 2024
Switzerland

Summary

-Designs & develops safety surveillance strategy for products and approval. Responsible for the company's drug surveillance program including the necessary follow-up, risk assessment, and relatedness to product on adverse reaction reports, oversight of safety in clinical trials and post marketing programs. Participates in the resolution of any legal liability and complying with governmental regulations. Provides and contributes trending and safety signal detection and risk management assessment for the products' life cycle. Provides safety support to the clinical development teams.

About the Role

Primary Location: Basel, Switzerland (80-100%)

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

About this role:

Are you ready to lead the charge in improving patients' lives and driving impactful results at Novartis? As the **Senior Global Program Safety Team Lead** – **Global Health** (Malaria Team), you will be at the forefront of our Medical Safety organization, ensuring robust safety risk management and making a positive impact on our development programs.

In this strategic leadership role, you will leverage your expertise as a seasoned safety clinician to predict safety risks and assess scientific information. Your guidance will be instrumental in shaping strategic considerations and effective risk management for our teams.

Key Responsibilities:

- Manage an efficient and successful disease area within the TA/DU Medical Safety organization, which provides robust medical and science-driven contribution to Benefit-Risk evaluation throughout product lifecycle to enable Novartis to provide impactful medicines to patients worldwide.
- Enhance scientific and clinical experience of Medical Safety physicians / scientists through continuous training and coaching. Prepares safety objectives and evaluates and manages performance of the Medical Safety associates within the TA/DU.
- Lead the day-to-day safety activities and provides guidance to assigned Medical Safety team members and mentee(s), as well as to the direct reports. Prepares objectives and evaluates related performance for the assigned team members.
- Mentor junior CMO and Patient Safety personnel. Proactively engages in the development of

competencies across the Medical Safety Function.
- Provide expert safety input to the clinical development program, in particular for heavy weight/high profile projects/products; is an active member of the Global Program Team (GPT), Global Clinical Team (GCT) and Clinical Trial Team (CTT).
- Provide guidance and support to assigned Medical Safety team members.
- Responsible for safety issue management from formation of GPT through Life Cycle Management.
- Develop and be responsible for key internal Novartis safety documents, reviews these documents regularly and updates as required (e.g., when significant new information received).
- Responsible for initial development and ongoing maintenance of safety information in Core Data Sheet (core global labelling), including addressing safety issues optimally in all project/product labelling indications.

Role Requirements:

- Medical Degree or equivalent (preferred), PhD, PharmD or equivalent graduate level health care professional degree required.
- Useful additional degrees: Post-graduate degree in Pharmaceutical Medicine. Master of Public Health in Epidemiology (or equivalent), Certification in Infectious Disease Epidemiology, Certification in Knowledge of Clinical Tropical Medicine or Diploma in Tropical Medicine and Hygiene
- Board Certification is desirable
- 3-5 years clinical postdoctoral experience, ideally in Tropical Medicine or working at an NGO
- At least 7 years progressive experience in drug development in a major pharmaceutical company, including 3 years in safety at a medical position.
- Expertise in preparing or contributing to preparation of clinical safety assessments and regulatory reports/submissions involving safety information – to include NDA submission documents
- Strong experience in leading cross-functional, multi- cultural teams
- Strong experience with (safety or others) issue management
- Strong experience in drug development, clinical trial methodology, regulatory requirements, scientific methodology, statistics and writing of publications
- Strong leadership skills including coaching, motivating, and directing, and fostering teamwork
- Previous people management preferred

Skills:

- Clinical Research.
- Clinical Trials.
- Functional Teams.
- Leadership.
- Medical Strategy.
- Process Safety Management.
- Regulatory Compliance.
- Risk Management.
- Safety Science.

Languages :

- Fluent English (both spoken and written).

Why Novartis: Our purpose is to reimagine medicine to improve and extend people's lives and our vision is to become the most valued and trusted medicines company in the world. How can we achieve this? With our

people. It is our associates that drive us each day to reach our ambitions. Be a part of this mission and join us! Learn more here: https://www.novartis.com/about/strategy/people-and-culture

Commitment to Diversity and Inclusion:

Novartis is committed to building an outstanding, inclusive work environment and diverse teams' representative of the patients and communities we serve.

Join our Novartis Network: If this role is not suitable to your experience or career goals but you wish to stay connected to hear more about Novartis and our career opportunities, join the Novartis Network here: https://talentnetwork.novartis.com/network

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

Division
Development
Business Unit
Innovative Medicines
Location
Switzerland
Site
Basel (City)
Company / Legal Entity
C028 (FCRS = CH028) Novartis Pharma AG
Functional Area
Research & Development
Job Type
Full time
Employment Type
Regular
Shift Work
No
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