Coding and Dictionary Management Lead

Job ID
REQ-10062089

9月 24, 2025

India

摘要

The Coding and Dictionary Management Lead provides, effective leadership and guidance to the team members, creates a positive and collaborative work environment, and ensures the Patient Safety & Pharmacovigilance mission of proactive, thorough, accurate safety signal detection/MedDRA query management and compliance with regulatory requirements.
Guidance to safety physicians on the optimal use of MedDRA grouping terms (Case retrieval strategy) and on the consistent use of MedDRA query definitions across products to enable the identification of potential safety concerns which could impact clinical programs or marketed products.
May deputize for Global Head of Safety Signal Detection at MSRB Meetings and audits/inspections.

About the Role

Major accountabilities:

- Lead the Cross-Functional MedDRA Team (CMT) and thus, has a key role in developing and

updating Novartis MedDRA queries (NMQs), which are crucial for uniform risk definitions, within and across Therapeutic Areas, during the development and post-marketing phases.
- Participate in SMT (as and when required) to evaluate the product ' s risk Case Retrieval Strategy and make sure that the risk definitions are suitable, consistent and rational.
- Analyze how MedDRA queries are used in CRS (Case retrieval strategies) at regular intervals for product risk and find the safety topic that needs a new NMQ or can use an existing SMQ to make sure the risk definitions in the CRS are consistent for similar safety topics across products/projects.
- Lead and govern initiatives to ensure the standard working practices/process or best practices is implemented for the creation and maintenance of Novartis custom queries, case retrieval strategies and versioning of regulatory dictionaries.
- Provide guidance on regulatory requirements (GCP, GVP, etc.) related to Regulatory dictionaries including MedDRA, WHO drug, IMDRF, IDF-J, WHO drug SK, CRT etc, Licensing policy and/or data sharing with external partners or vendors and assists with audits and inspections. Lead and support the project and programs to ensure the compliance.
- Identify and report any issues associated with Regulatory dictionary (Including MedDRA, WHO drug, IMDRF, IDF-J, WHO drug SK, CRT etc) implementation in Novartis (PS&PV and other divisions within Development) that could impact the compliance and or quality of safety signal analysis and reporting.
- Provide guidance to stakeholders on the Novartis product configuration management in line with industry standards, setting up the expediting rules for case submission per regulatory requirements.
- As a representative of Novartis, liase with the MedDRA Maintenance Organization (MSSO), Uppsala Monitoring center (UMC) for change requests in MedDRA/WHO drug dictionary (Submit requests for new terms in MedDRA/WHO drug dictionary or modification of existing MedDRA/WHO drug terms, Creation or update of SMQs/SDGs).
- Develop the skills of relevant stakeholders in using Regulatory dictionaries by creating and providing training for users across Novartis, which may include MedDRA update training (Twice a year during version release), Other regulatory dictionary fundamentals, Training on data extraction and analysis using MedDRA/SMQ/WHO drug, SDG MedDRA Query creation (Custom query approach), MedDRA and other dictionary related tools and utilities.
- Oversee the activities involved in the regular Regulatory dictionary updates done twice in a year (e.g. impact assessment, update of term list, repointing of deactivated terms as appropriate).
- May deputize for Global Head of Safety Signal Detection and MQM at MSRB meetings.
- May deputize for Global Head of Safety Signal Detection and MQM in audits and inspections to provide Coding and Dictionary overview.
- Support Global Head of Safety signal detection and MQM, Staying abreast of the latest trends, advancements, and best practices in Controlled terminologies/MedDRA Query management. Providing support in implementing new tools, technologies, and methodologies to enhance signal detection, Controlled terminologies/ Query management (Including MedDRA, WHO drug, etc), and improve efficiency and accuracy.

- **Key Performance Indicators**

< >Team collaboration and communication: Collaboration within and cross-functional teams for collective success.Compliance and adherence to policies: Compliance with company policies and procedures related to performance management and employee relations. Audits and inspection: Results of internal or external audits and inspections with no critical findings.

MedDRA search definitions are up to date, consistent, used across programs, and represent the opinion of the Cross Functional MedDRA Team (CMT).

Job Dimensions

Ideal Background

Acceptance of safety analyses and interpretations by external bodies (e.g. health authorities, healthcare providers, legal system)**Education (minimum/desirable):** Bachelor/Master of Pharmacy / PharmD with expertise in the use of MedDRA (i.e. search strategies, coding, MedDRA hierarchies) including grouping definitions (SMQs), is required.**Languages:** Fluent in spoken and written English.**Experience/Professional requirement:**≥ 8 years of proven experience in drug development in a major pharmaceutical company, including atleast 4 years in patient safety/signal detection is preferable.In-depth knowledge of pharmacovigilance regulations and requirements.Strong analytical skills and ability to interpret scientific literature and safety data.Strong Expertise in MedDRA/WHO drug coding(Other equivalent controlled vocabularies)/ case retrieval strategies and in all MedDRA dictionary aspects including SMQs/Custom Query management. Effective communication skills, both verbal and written.Strong attention to detail and the ability to prioritize and manage multiple tasks.Familiarity with clinical/safety databases and signal detection tools.Ability to work effectively in cross-functional teams.

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

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部门
Development

Business Unit
Innovative Medicines

地点
India

站点
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Research & Development

Job Type
Full time

Employment Type
Regular

Shift Work
No

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Accessibility and accommodation

Novartis is committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the recruitment process, or in order to perform the essential functions of a position, please send an e-mail to diversityandincl.india@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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