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Review Article

THE MEDICAL DICTIONARY FOR REGULATORY ACTIVITIES- SCOPE AND STRUCTURE

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Abstract

MedDRA (Medical Dictionary for Regulatory Activities is a rich and highly specific standardized medical terminology developed by ICH (International Conference on Harmonization) to facilitate sharing of regulatory information internationally for medical products used by humans. It is used for registration, documentation and safety monitoring of medical products both before and after a product has been authorized for sale. Products covered by the scope of MedDRA include pharmaceuticals, vaccines and drug-device combination products. ICH recognized that the use of different terminologies at different stages in the course of developing medicines made it difficult to cross-reference and analyse data. Converting data from one terminology to another cost time, resources and resulted in the inevitable loss or distortion of data. In view of these challenges, ICH created the MedDRA to facilitate the exchange of information through standardization. Each MedDRA term assigned an 8-digit numeric code, the code is non-expressive, Codes can fulfill a data field in various electronic submission types (e.g., E2B), initially assigned alphabetically by term starting with 10000001, new terms are assigned sequentially, and supplemental terms are assigned codes. MedDRA is fully implemented in the WHO global safety database allowing entry and retrieval of information in either MedDRA or WHO-ART (Adverse Reaction Terminology). A mapping bridge is kept updated by WHO and ICH, to allow conversion of WHO-ART coded data into MedDRA, allowing users to readily convert their data and use MedDRA.

Key words: MeDRA, medical terminology, WHO safety database, safety coding

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Introduction

MedDRA as an ICH initiative…..

MedDRA (Medical Dictionary for Regulatory Activities is a rich and highly specific standardized medical terminology developed by ICH (International Conference on

Harmonisation) to facilitate sharing of regulatory information internationally for medical products used by humans.

It is used for registration, documentation and safety monitoring of medical products both before and after a product has been authorized for sale.

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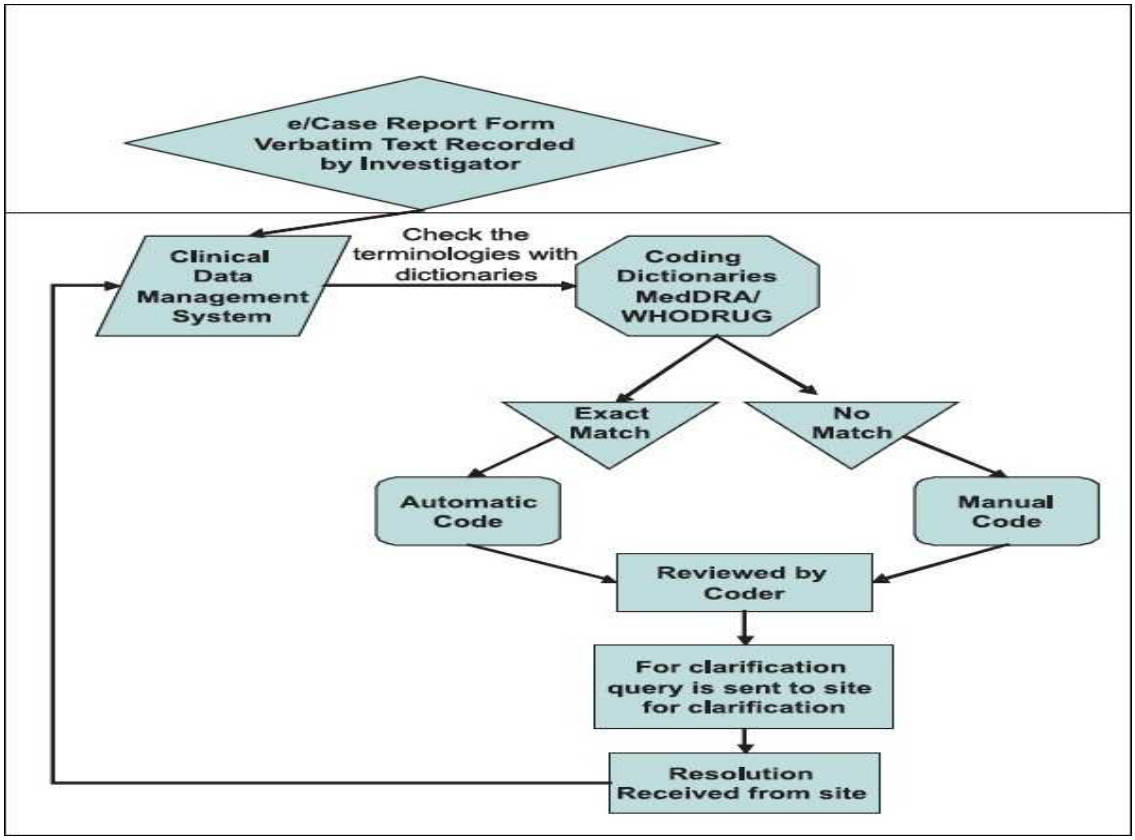
Converting data from one terminology to another cost time, resources and resulted in the inevitable loss or distortion of data. In view of these challenges, ICH created the MedDRA to facilitate the exchange of information through standardization.

Regulatory Status -

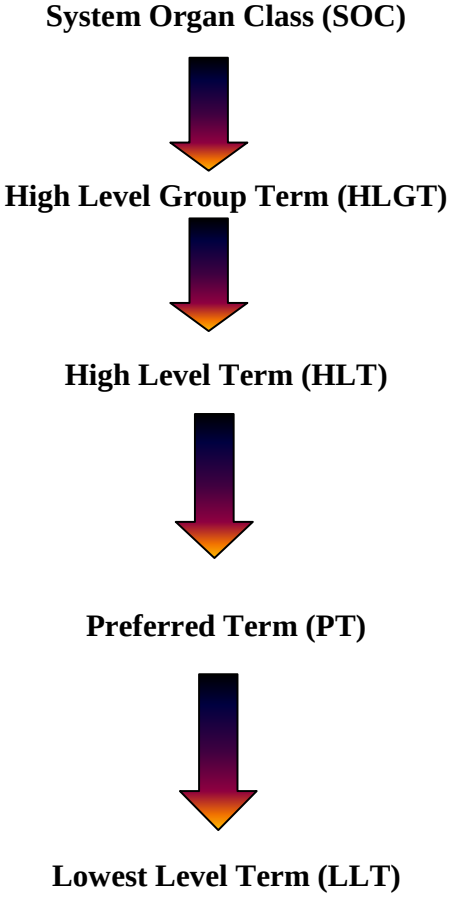
- ***US FDA***
  1. Used in FDA's adverse event database (AERS)
  2. Proposed Rule for Safety Reporting Requirements (2003): MedDRA for postmarketing safety reports
- **Japanese Ministry of Health, Labour and Welfare**
  1. Mandatory use for electronic reports
  2. Used in Periodic Infection and Safety Reports
  3. For medical devices with biological components,infections to be described with MedDRA terms
- **Canada**
  1. Reporting Adverse Reactions to Marketed Health Products (draft guidance)
  2. Product Monograph (labeling)



Materials-

Structure of MeDRA

MedDRA Structure



SOC

- Highest level of the terminology, and distinguished by anatomical or physiological system, etiology, or purpose

HLGT

- Subordinate to SOC, superordinate descriptor for one or more HLTs

HLT

- Subordinate to HLGT, superordinate descriptor for one or more PTs

PT

- Represents a single medical concept

LLT

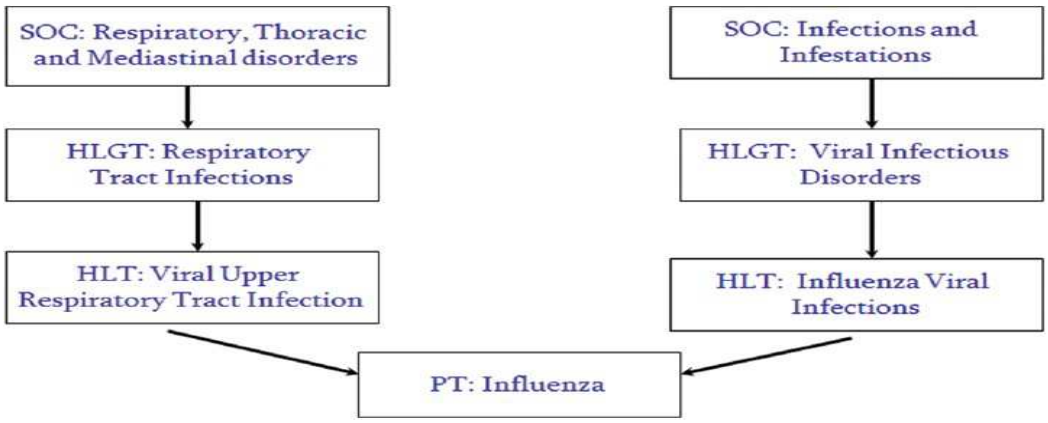
- Lowest level of the terminology, related to a single PT as a synonym, lexical variant, or quasi-synonym (Note: All PTs have an identical LLT)

Examples for System Organ Level…

Blood and lymphatic system disorders
Cardiac disorders
Congenital, familial and genetic disorders
Ear and labyrinth disorders
Endocrine disorders
Eye disorders
Gastrointestinal disorders
General disorders and administration site conditions
Hepatobiliary disorders
Immune system disorders Infections and infestations
Injury, poisoning and procedural complications
Investigations
Metabolism and nutrition disorders

Musculoskeletal and connective tissue disorders
Neoplasms benign, malignant and unspecified (include cysts and polyps)
Nervous system disorders
Pregnancy, puerperium and perinatal conditions
Psychiatric disorders
Renal and urinary disorders
Reproductive system and breast disorders
Respiratory, thoracic and mediastinal disorders

Examples of LTTs



MedDRA Codes…

Each MedDRA term assigned an 8-digit numeric code

- The code is non-expressive
- Codes can fulfill a data field in various electronic submission types (e.g., E2B)
- Initially assigned alphabetically by term starting with 10000001
- New terms are assigned sequentially
- Supplemental terms are assigned codes

Electronic submission

SCOPE of MeDRA

- Drug product terms
- Patient demographics
- Clinical trial terms
- Frequency qualifiers
- Numerical values for results
- Severity descriptors

Institutes offering MedDRA Training-

- CMC (Certified MeDRA Coder)-online fee-based webinar
- NOVUSLUNA Healthcare Management
- Asian Institute of Quality Management and etc.

Industries using and offering MedDRA Training in India-

- INDUS INFOCOM (I) PVT. LTD
- Helicon Infosystems
- Healthoffice India Pvt Ltd.Bangalore
- Divine Mercy Transcription
- Enter Technologies Pvt.Ltd.
- Giltedge Infotech Services Ltd.Mumbai

Results & Discussions-

1. MSSO (The Maintenance and Support Services Organization training: maintains and distributes the MedDRA and oversees training programs.Membership in the the MSSO is available through an annual subscription to regulators, researchers, nonprofit organizations and pharmaceutical companies. This subscription provides an organization with unlimited use of MedDRA data and also includes training. The all-day "Coding with MedDRA" course is the MSSO's basic training product, available free to members or on a fee basis to non-members. Other training courses focus on narrower aspects of the MedDRA program, such as safety-data analysis. Classes can be taken online, in formal seminars or by employees on site at their workplace. MedDRA training is counted as continuing education for some healthcare professions
2. **Certification:** The MSSO offers a Certified MedDRA Coder credential to pharmaceutical staffers or medical professionals. The test is available online to candidates with Internet access and a personal credit card. Exam questions describe the condition of hypothetical patients; aspiring coders answer with the most appropriate codes. Candidates are permitted to refer to their documentation or other resources as needed during the exam. Individuals take the exam on a two-year cycle to get re-certified.
3. **Career Consideration & conclusion:** The bureau projects 21 percent employment growth for this category by 2020, higher than the average for all occupations. In practice, the value of MedDRA training is hard to assess, because it's useful to such a broad range of pharmaceutical and healthcare professionals. Coding specialists, government regulators, laboratory administrators, MDs, and biotechnologists could benefit from MedDRA training, depending on their workplace and area of expertise.

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