Role of MedDRA® in Global Medical Product Safety

Harmonizing Terminology Across Nations and Languages
MedDRA was developed under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The activities of the MedDRA Maintenance and Support Services Organization (MSSO) are overseen by an ICH MedDRA Management Board, which is composed of the six ICH parties (EU, EFPIA, MHLW, JPMA, FDA, PhRMA), the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK, Health Canada, and the WHO (as Observer).
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Objectives of this Presentation

Role of MedDRA in global health:

- Background
- Users
- Examples of Use
Background
What is MedDRA?

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities

Supports public health by facilitating safety monitoring of medicinal products.
MedDRA is a clinically validated international medical terminology used by regulatory authorities and the regulated biopharmaceutical industry. The terminology is used through the entire regulatory process, from pre-marketing to post-marketing, and for data entry, retrieval, evaluation, and presentation.
MedDRA Features

- 70K terms arranged hierarchically
- Classification for a wide range of clinical data
- Available in 11 languages
- Rigorously maintained
- Required component for electronic reporting
Scope of MedDRA

- Medical conditions
- Indications
- Investigations (tests, results)
- Medical and surgical procedures
- Medical, social, family history
- Medication errors
- Product quality issues
- Device-related issues
- Pharmacogenetic terms
- Toxicologic issues
- Standardized queries
MedDRA Structure

- System Organ Classes: 26
- High Level Group Terms: > 330
- High Level Terms: > 1,700
- Preferred Terms: > 20,000
- Lowest Level Terms: > 70,000
MedDRA Structure (cont)

- SOC Ear and labyrinth disorders
  - HLGT Aural disorders NEC
  - HLGT Congenital ear disorders (excl deafness)
  - HLGT External ear disorders (excl congenital)
  - HLGT Hearing disorders
  - HLGT Inner ear and VIIIth cranial nerve disorders
    - HLTI Inner ear disorders NEC
    - HLTI Inner ear infections and inflammations
    - HLTI Inner ear signs and symptoms
      - PT Cogan's syndrome
      - PT Motion sickness
      - PT Tinnitus
      - PT Vertigo
        - LLTI Acute rotatory vertigo
        - LLTI Head revolving around
        - LLTI Head revolving round
        - LLTI Head spinning
        - LLTI Other and unspecified peripheral vertigo
        - LLTI Other peripheral vertigo
        - LLTI Peripheral vertigo, unspecified
        - LLTI Room going round
        - LLTI Rotatory vertigo
        - LLTI Spinning
Users
Regulatory Use

• True international standard for adverse event reporting and analysis
• US FDA
  – Not mandated but *de facto* standard in US
  – Used in several FDA databases
• Japanese Ministry of Health, Labour and Welfare
  – Mandatory use in electronic reporting
• European Union
  – Mandatory use in electronic reporting
  – EudraVigilance database
  – Good Pharmacovigilance Practices (GVP) specifically mention MedDRA
• Biopharmaceutical industry
Regulatory Use (cont)

- US FDA databases using MedDRA
  - Center for Drug Evaluation and Research (CDER)
    - FAERS (drugs and biologics)
  - Center for Biologics Evaluation and Research (CBER)
    - VAERS (vaccines)
  - Center for Food Safety and Applied Nutrition
    - CAERS (food, dietary supplements, cosmetics)
Who Else Uses MedDRA?

• Non-I CH regions
• WHO’s international drug monitoring center (Uppsala Monitoring Centre)
• Academic researchers
• Toxicologists
• Others

More than 3,700 subscribing organizations worldwide in more than 60 countries
Examples of Use
Where MedDRA is Used

- Individual Case Safety Reports and Safety Summaries
- Clinical Study Reports
- Investigators’ Brochures
- Core Company Safety Information
- Marketing Applications
- Publications
- Prescribing Information
- Advertising
How MedDRA is Used

...and by this SOC...

...by this HLGT...

...by this HLT...

All of these reports are represented by this PT...

Report 1: “My head felt like it was revolving on an axis”

Report 2: Patient diagnosed with rotary vertigo

Report 3: “Felt like the room was going around”
Codes and Languages

Cefaleia

Portuguese

Hoofdpijn

Dutch

Headache

English

Céphalée

French

Bolest hlavy

Czech

10019211

Kopfschmerz

German

Fejfájás

Hungarian

Cefalea

Italian

头痛

Chinese

Cefalea

Spanish

Electronic Submission
Electronic Transmission of Data

ICH E2B Expert Working Group

Implementation Guide for
Electronic Transmission of Individual Case Safety Reports (ICSRs)

E2B(R3) Data Elements and Message Specification

Version 5.01, 12 April 2013
Use of MedDRA at the FDA

Acknowledgement: Dr. Chuck Cooper, Office of Translational Sciences, CDER, FDA
Standardised MedDRA Queries (SMQs)

• Bring together MedDRA terms from multiple SOCs, all related to a condition of interest
• From a company perspective, these are pre-packaged queries that can be used for safety monitoring, responding to regulatory queries, etc.
• From a regulator perspective, allows a **standard terms list** for more efficient comparison of safety issues
SMQs in Production - Examples

As of Version 17.1, a total of 96 in production

- Agranulocytosis
- Anaphylactic reaction
- Cerebrovascular disorders
- Convulsions
- Depression and suicide/self-injury
- Hepatic disorders
- Hypersensitivity
- Ischaemic heart disease
- Lack of efficacy/effect
- Osteonecrosis
- Peripheral neuropathy
- Pregnancy and neonatal topics
- Pseudomembranous colitis
- Rhabdomyolysis/myopathy
- Severe cutaneous adverse reactions
- Systemic lupus erythematosus
How to “Run” an SMQ

Clinical Trial Database
Safety Database
Use of SMQs at FDA

Acknowledgement: Dr. Chuck Cooper, Office of Translational Sciences, CDER, FDA
Relationship Between MedDRA and Other Medical Terminologies

- Medical records, billing/insurance claims, morbidity & mortality
- SNOMED-CT
- ICD-9-CM
- ICD-10-CM – in 2015
- Adverse events in clinical trials and post-marketing
- WHO-ART
- CTCAE (National Cancer Institute)

Exploring mappings/interoperability
Subsets of MedDRA
Conclusion

MedDRA supports public health by providing:

• Support for safety monitoring of medicinal products
  – Facilitates the collection of data for analysis of potential safety signals
  – An international standard used by regulatory authorities, biopharmaceutical industry and others
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