



MedDRA

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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MedDRA

Objectives of this Presentation

Role of MedDRA in global health:

- Background
- Users
- Examples of Use





Background





MedDRA

What is MedDRA?

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities

Supports public health by facilitating safety monitoring of medicinal products.





MedDRA

MedDRA Definition

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

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



MedDRA

Scope of MedDRA

IN

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

MedDRA Structure





MedDRA Structure (cont)

- [-] SOC Ear and labyrinth disorders
 - [+] HL GT Aural disorders NEC
 - [+] HL GT Congenital ear disorders (excl deafness)
 - [+] HL GT External ear disorders (excl congenital)
 - [+] HL GT Hearing disorders
 - [-] HL GT Inner ear and VIIIth cranial nerve disorders
 - [+] HLT Inner ear disorders NEC
 - [+] HLT Inner ear infections and inflammations
 - [-] HLT Inner ear signs and symptoms
 - [+] PT Cogan's syndrome
 - [+] PT Motion sickness
 - [+] PT Tinnitus
 - [-] PT Vertigo
 - LLT Acute rotatory vertigo
 - LLT Head revolving around
 - LLT Head revolving round
 - LLT Head spinning
 - LLT Other and unspecified peripheral vertigo
 - LLT Other peripheral vertigo
 - LLT Peripheral vertigo, unspecified
 - LLT Room going round
 - LLT Rotatory vertigo
 - LLT Spinning





Users





MedDRA

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



MedDRA

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-ICH 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



MedDRA

Examples of Use





MedDRA

Where MedDRA is Used



Regulatory Authority and Industry Databases
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...

→ -SOC Ear and labyrinth disorders

- + HL GT Aural disorders NEC
- + HL GT Congenital ear disorders (excl deafness)
- + HL GT External ear disorders (excl congenital)
- + HL GT Hearing disorders

...by this HLG...

→ -HLG Inner ear and VIIIth cranial nerve disorders

- + HLT Inner ear disorders NEC
- + HLT Inner ear infections and inflammations

...by this HLT...

→ -HLT Inner ear signs and symptoms

- + PT Cogan's syndrome
- + PT Motion sickness
- + PT Tinnitus

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

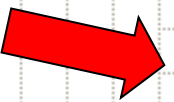
→ -PT Vertigo

- LLT Acute rotatory vertigo
- LLT Head revolving around
- LLT Head revolving round
- LLT Head spinning
- LLT Other and unspecified peripheral vertigo
- LLT Other peripheral vertigo
- LLT Peripheral vertigo, unspecified
- LLT Room going round
- LLT Rotatory vertigo
- LLT Spinning

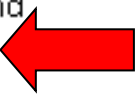
Report 1: "My head felt like it was revolving on an axis"



Report 3: "Felt like the room was going around"



Report 2: Patient diagnosed with rotary vertigo





MedDRA

Codes and Languages



Electronic Submission



MedDRA

Electronic Transmission of Data



**INTERNATIONAL CONFERENCE ON HARMONISATION OF
TECHNICAL REQUIREMENTS FOR REGISTRATION OF
PHARMACEUTICALS FOR HUMAN USE**

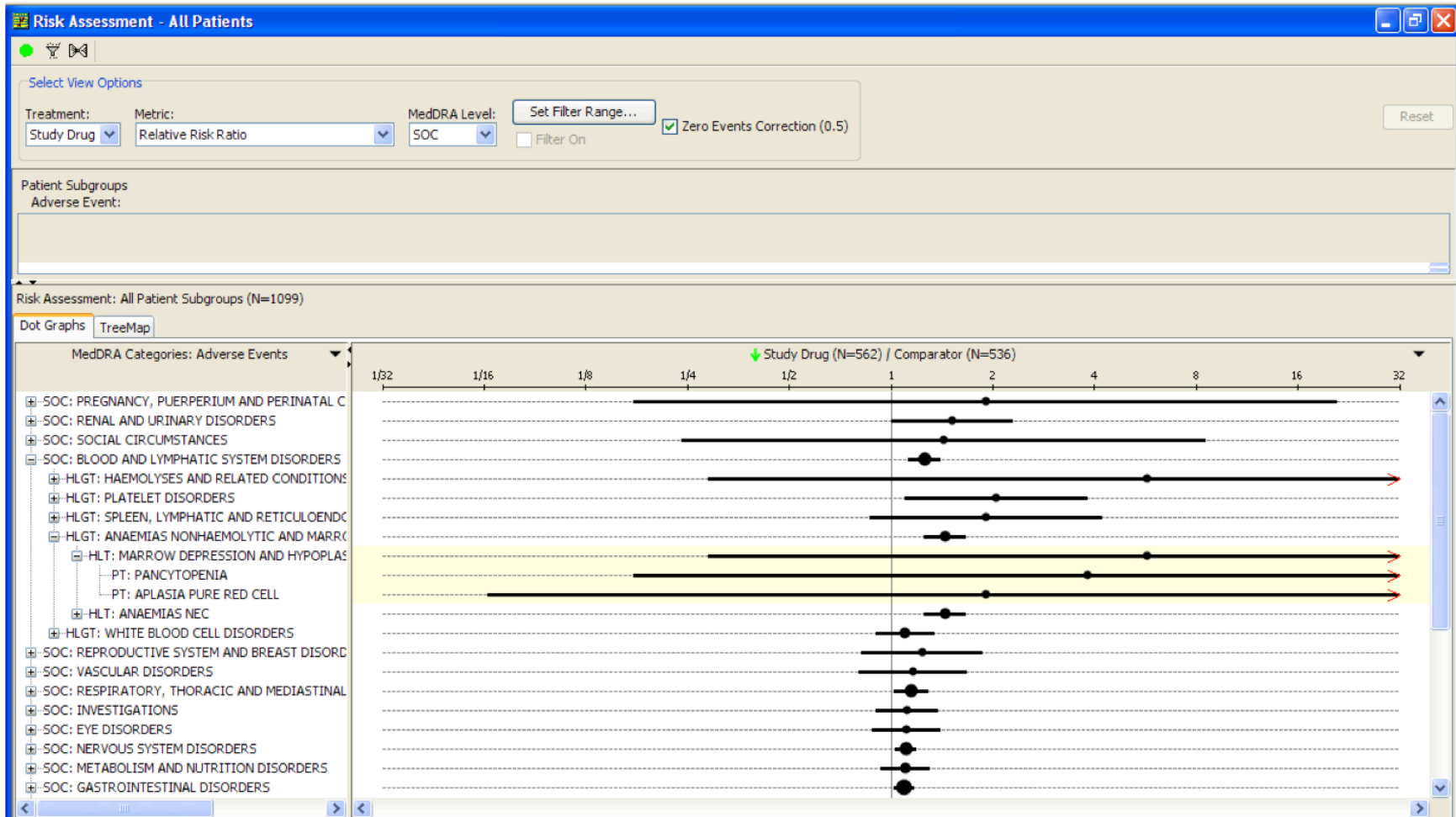
ICH E2B Expert Working Group

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

E2B(R3) Data Elements and Message Specification



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



MedDRA

SMQs in Production - Examples

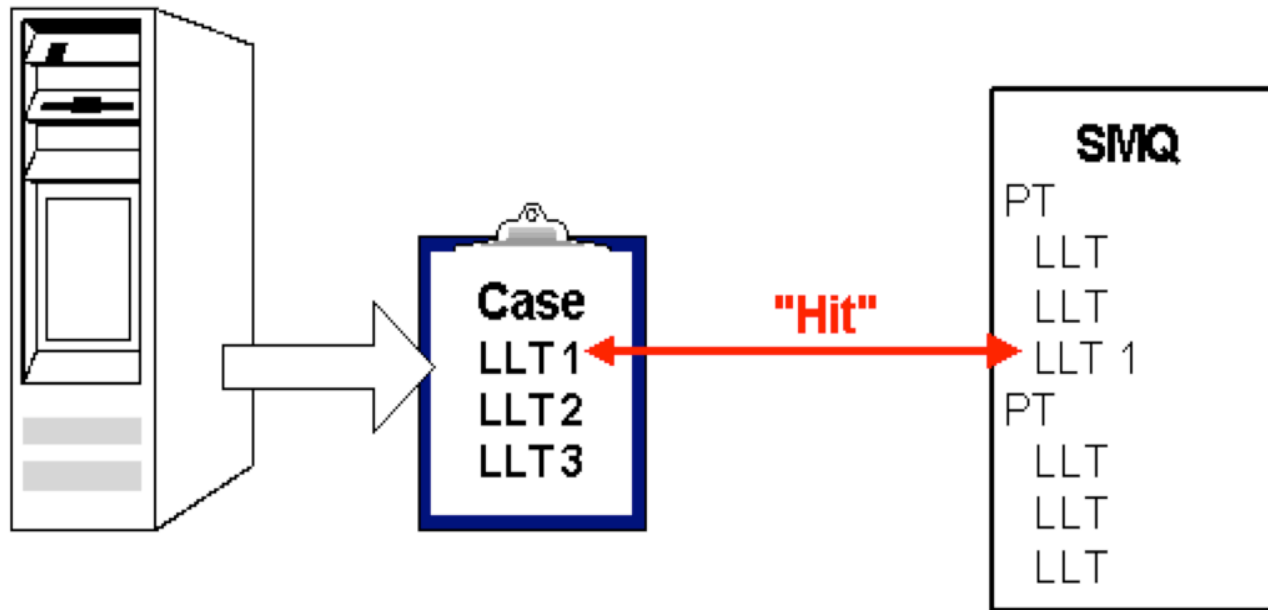
- As of Version 17.1, a total of 96 in production
 - Agranulocytosis
 - Anaphylactic reaction
 - Cerebrovascular disorders
 - Convulsions
 - Depression and suicide/self-injury
 - Hepatic disorders
 - Hypersensitivity
 - Ischaemic heart disease
 - Lack of efficacy/effect
 - Osteonecrosis
 - Peripheral neuropathy
 - Pregnancy and neonatal topics
 - Pseudomembranous colitis
 - Rhabdomyolysis/myopathy
 - Severe cutaneous adverse reactions
 - Systemic lupus erythematosus



MedDRA

How to "Run" an SMQ

Clinical Trial Database
Safety Database



Integrated Review - [CrossTab]

File Edit View Format Browse Tools Window Help

diff end

	A	B	C	D
1	SMQ name. Each SMQ carries 'SMQ' at t	CPI/r		Subjects
2	Dyslipidaemia (SMQ)	19 (4.44%)	48 (11.03%)	67 (7.74%)
3	Depression and suicide/self-injury (SMQ)	17 (3.97%)	22 (5.06%)	39 (4.50%)
4	Peripheral neuropathy (SMQ)	16 (3.74%)	19 (4.37%)	35 (4.04%)
5	Malignancies (SMQ)	11 (2.57%)	13 (2.99%)	24 (2.77%)
6	Malignant or unspecified tumours (SMQ)	11 (2.57%)	13 (2.99%)	24 (2.77%)
7	Haematopoietic cytopenias (SMQ)	12 (2.80%)	10 (2.30%)	22 (2.54%)
8	Leukopenia (SMQ)	11 (2.57%)	9 (2.07%)	20 (2.31%)
9	Asthma/bronchospasm (SMQ)	2 (0.47%)	6 (1.38%)	8 (0.92%)
10	Angioedema (SMQ)	2 (0.47%)	4 (0.92%)	6 (0.69%)
11	Acute pancreatitis (SMQ)	1 (0.23%)	4 (0.92%)	5 (0.58%)
12	Convulsions (SMQ)	3 (0.70%)	3 (0.69%)	6 (0.69%)
13	Ischaemic heart disease (SMQ)	0 (0.00%)	3 (0.69%)	3 (0.35%)
14	Acute renal failure (SMQ)	0 (0.00%)	2 (0.46%)	2 (0.23%)
15	Interstitial lung disease (SMQ)	0 (0.00%)	2 (0.46%)	2 (0.23%)
16	Embolic and thrombotic events, arterial (SMQ)	1 (0.23%)	2 (0.46%)	3 (0.35%)
17	Embolic and thrombotic events (SMQ)	3 (0.70%)	2 (0.46%)	5 (0.58%)

Studies

Patient Subsets All

- All patients
- Deaths
- Hemorrhage
- Hepatic
- Malignancies
- Resistance

Output Specifications All

- Endocrine
- Graphical Patient Profiles
- Hemorrhage
- Hepatic



Relationship Between MedDRA and Other Medical Terminologies



MedDRA

Medical records,
billing/insurance
claims, morbidity &
mortality

SNOMED-CT
ICD-9-CM
ICD-10-CM – in 2015



Exploring
mappings/interoperability



Subsets of
MedDRA

Adverse events in clinical
trials and post-marketing

WHO-ART
CTCAE (National Cancer
Institute)



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



MedDRA

Medical Dictionary
for Regulatory Activities

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