



MedDRA

Getting Started with MedDRA





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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Governance Structure for MedDRA

- ICH MedDRA Management Board appointed by the ICH Steering Committee to provide oversight of MedDRA related activities and the Maintenance and Support Services Organization (MSSO)





ICH MedDRA Management Board Members





MedDRA

MedDRA's Purpose

- Facilitate the exchange of clinical information through standardization
- Important tool for product evaluation, monitoring, communication, electronic records exchange, and oversight
- Supports coding (data entry) and retrieval and analysis of clinical information about human medical products including pharmaceuticals, biologics, vaccines, and drug-device combination products



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





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

Version 5.01, 12 April 2013



Regulatory Use in ICH Regions

- 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



Who Else Uses MedDRA?

- Countries beyond the ICH regions
- WHO's international drug monitoring center (Uppsala Monitoring Centre)
- Academic researchers
- Toxicologists
- Others

More than 3,700 organizations worldwide in more than 60 countries



MedDRA

What Is In MedDRA?

IN

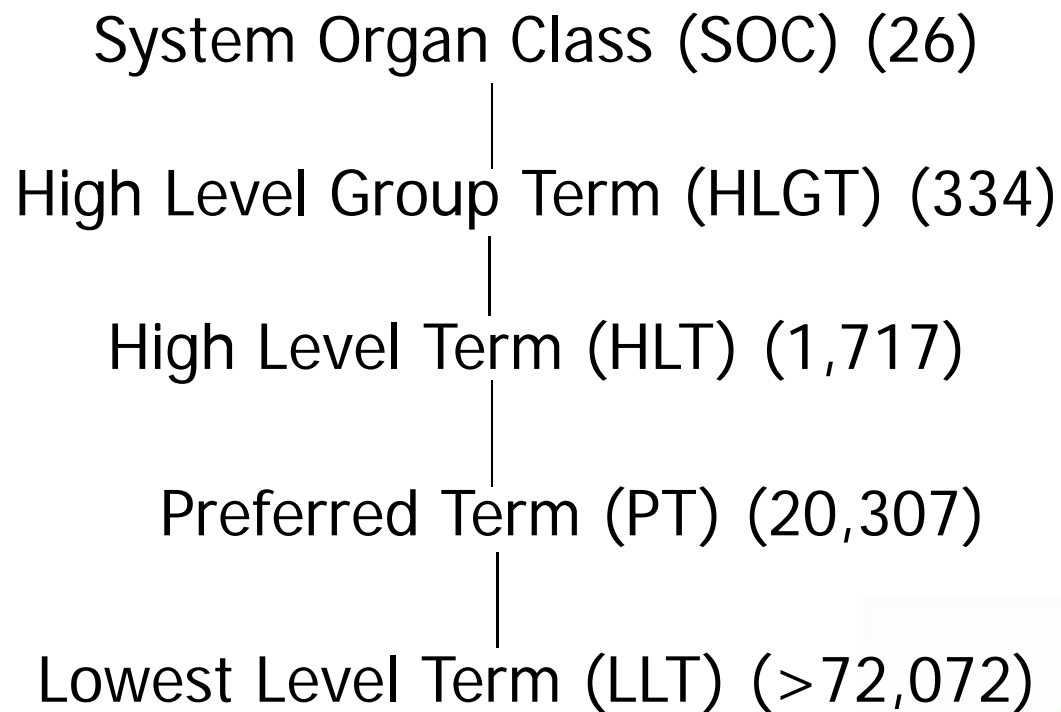
Medical conditions
Indications
Investigations (tests, results)
Medical and surgical procedures
Medical, social, family history
Medication errors
Product quality issues
Device-related issues
Pharmacogenetic terms
Toxicologic issues
Standardized queries





MedDRA

MedDRA Structure



MedDRA Version 16.1



MedDRA

How MedDRA is Used

...and by this SOC...→

- ⊖ soc Nervous system disorders
 - ⊕ HL GT Central nervous system infections and inflammations
 - ⊕ HL GT Central nervous system vascular disorders
 - ⊕ HL GT Congenital and peripartum neurological conditions
 - ⊕ HL GT Cranial nerve disorders (excl neoplasms)
 - ⊕ HL GT Demyelinating disorders
 - ⊕ HL GT Encephalopathies
 - ⊕ HL GT Headaches
 - ⊕ HL GT Increased intracranial pressure and hydrocephalus
 - ⊕ HL GT Mental impairment disorders
 - ⊕ HL GT Movement disorders (incl parkinsonism)
 - ⊕ HL GT Nervous system neoplasms benign
 - ⊕ HL GT Nervous system neoplasms malignant and unspecified NEC
 - ⊕ HL GT Neurological disorders NEC
 - ⊕ HL GT Neurological disorders of the eye
 - ⊕ HL GT Neuromuscular disorders
 - ⊕ HL GT Peripheral neuropathies
 - ⊕ HL GT Seizures (incl subtypes)

...by this HLT... →

- ⊖ HL GT Sleep disturbances (incl subtypes)
 - ⊕ HLT Abnormal sleep-related events
 - ⊖ HLT Disturbances in initiating and maintaining sleep

...by this HLT... →

- ⊕ PT Behavioural insomnia of childhood
- ⊕ PT Hyposomnia
- ⊖ PT Initial insomnia
 - ⋯ LLT Initial insomnia
 - ⋯ LLT Trouble falling asleep
- ⊕ PT Insomnia
- ⊕ PT Middle insomnia
- ⊕ PT Terminal insomnia

Both of these reports are represented by this PT... →

Report 1: Patient diagnosed with initial insomnia

Report 2: "I had problems falling asleep"



MedDRA

Codes and Languages





MedDRA

MedDRA Maintenance

- MSSO processes change requests from its subscriber organizations
- Rigorous medical review by MSSO physicians
- Twice yearly official updates
 - 1 March X.0 release
 - 1 September X.1 release





MedDRA

Implementing MedDRA

- No single method for all organizations
- Implementation approach depends on factors such as size of organization
- Topics to consider
 - Training
 - Coding and data retrieval conventions
 - Procedures documentation
 - Legacy data conversion
 - IT considerations





MedDRA

Training

- Free Face-to-Face training for users
 - Coding with MedDRA
 - MedDRA: Safety Data Analysis and SMQs
- Free webinars for users
 - Introduction to MedDRA
 - Coding Basics
 - Introduction to MedDRA Data Analysis and SMQs for Physicians
 - What's New with MedDRA
- Free videocasts on MedDRA website and YouTube



Coding and Data Retrieval Conventions

MedDRA® TERM SELECTION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users

Release 4.6
Based on MedDRA Version 16.1

1 October 2013

MedDRA® DATA RETRIEVAL AND PRESENTATION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users
on Data Output

Release 3.6
Based on MedDRA Version 16.1

1 October 2013

- ICH Working Group developed and maintains two guides for MedDRA users
- Recommended to be used as the basis for individual organizations' own guidelines



Procedures Documentation

- Documentation of procedures and processes is a best practice for all organizations
 - This includes the use of MedDRA
- Standard operating procedures and other relevant documents in an organization should address the use of MedDRA
 - Coding, dictionary management, MedDRA versioning, and analytical processes and tools (e.g., using MedDRA's hierarchy and Standardised MedDRA Queries)



MedDRA

Legacy Data Conversion

- Existing data may need to be converted to MedDRA
 - Options to consider
 - Convert from the original reported verbatims (if available)
 - Convert from the coded terms of the legacy terminology
 - WHO Uppsala Monitoring Centre and the MSSO maintain a WHO-ART to MedDRA bridge to support the conversion of WHO-ART coded data to MedDRA



MedDRA

IT Considerations

- Many software tools available to support the use of MedDRA
 - Several are provided free with the MedDRA subscription
 - Two browsers (desktop and web-based)
 - MedDRA Version Analysis Tool (MVAT)
 - Need for software tools should be driven by the volume of data to be supported
 - With small amounts of data users can use simple software tools (e.g., free MSSO browsers, spreadsheets)
 - Larger implementations should consider commercial data management software products
 - List of third-party software tools on MedDRA website



MedDRA

MedDRA Version Analysis Tool

The screenshot displays the MedDRA Version Analysis Tool (MVAT) interface. At the top left, there is a logo for MedDRA MSSO and the text 'MVAT MedDRA Version Analysis Tool'. At the top right, the user ID 'TM/90001' and the date/time '9 May 2013 16:24' are shown, along with links for 'End User License Statement', 'MedDRA MSSO Privacy Policy', and 'Statement'. A blue header bar contains the text 'Data Impact Report Result'. Below this, the 'Selected MedDRA' section shows 'Starting Version: MedDRA 11.0 English' and 'Ending Version: MedDRA 16.0 English', with an 'Export Selections to Spreadsheet' button. The 'Data Statistics' section provides the following information: 'The total number of rows uploaded: 431', 'The number of valid rows processed: 431', and 'Percentage of valid records impacted by the version update: 3.71%'. On the right side, there is a vertical menu with buttons for 'MVAT Home', 'Search Term Change', 'Data Impact Report', and 'Logout'.



Resources for MedDRA Users

- MedDRA website
 - Help Desk
 - Subscriptions
 - News and Events
 - Points to Consider documents
 - Terminology downloads
 - Training
 - Tools
 - MedDRA publications
 - User group meetings
 - Expert meetings





MedDRA

How to Subscribe

- MedDRA is available as a subscription
 - Free to Regulatory Authorities and Non-profit / Non-commercial organizations
 - Commercial organizations pay an annual fee from a sliding scale based on annual revenue (turnover)
 - MedDRA Management Board reviews and approves rates annually
- See MedDRA website for details





MedDRA

Medical Dictionary
for Regulatory Activities

MedDRA website: www.meddra.org
Email: mssohelp@meddra.org

