Getting Started with MedDRA

A Face-to-Face Course

MedDRA was developed under the auspices of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). The activities of the MedDRA Maintenance and Support Services Organization (MSSO) are overseen by an ICH MedDRA Management Committee, 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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Course Overview

- Describe MedDRA governance
- Discuss MedDRA's scope, structure, and characteristics
- Discuss MedDRA implementation topics
- Describe need for procedures documentation and conventions
- Describe Standardised MedDRA Queries (SMQs)
- Highlight MedDRA tools and training
- Appendix Slides: Downloading and Installing MedDRA
MedDRA Governance

Governance Structure for MedDRA

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

• ICH MedDRA Management Committee
  – Owns MedDRA
    • Contracts with MSSO to maintain it
  – Has oversight of all operations of the MSSO
    • Meets regularly with MSSO
    • Sets subscription rates
    • Approves developmental plans and services
  – Membership includes ICH regulatory authorities and industry associations

ICH MedDRA Management Committee Members

• ICH
• EC, Europe
• FDA, US
• MHLW/PMDA, Japan
• MHRA, UK
• EFPIA
• JPMA
• PhRMA
• Health Canada
• WHO (as Observer)
MedDRA Scope, Structure, and Characteristics

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’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

**Where MedDRA is Used**

- Preclinical Testing
- Clinical Phase I
- Clinical Phase II
- Clinical Phase III
- Clinical Phase IV
- Marketed Product
- Approval
- 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

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

• FDA, US
  – Electronic submission required for study data and postmarketing reports (uses ICH standards)
  – Used in several FDA databases (i.e., drugs, biologics, vaccines, food, dietary supplements, cosmetics)

• MHLW/PMDA, Japan
  – Mandatory use in electronic reporting

• EC, Europe
  – Mandatory use in electronic reporting
  – Used in EudraVigilance database
  – Good Pharmacovigilance Practices (GVP) specifically mention MedDRA
Regulatory Use in ICH Regions (cont)

- Health Canada, Canada
  - Used in Canada Vigilance database
  - Electronic reporting via Gateway

- CFDA, China
  - Implementing ICH standards for clinical trial/post-marketing safety reporting beginning in 2018

- 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 5,200 organizations worldwide in more than 115 countries
**Scope of MedDRA**

- Medical conditions
- Indications
- Medical and surgical procedures
- Medical, social, family history
- Medication errors
- Product quality issues
- Device-related issues
- Product use issues
- Pharmacogenetic terms
- Toxicologic issues
- Standardized queries

**MedDRA Structure**

- System Organ Class (SOC) (27)
- High Level Group Term (HLGT) (337)
- High Level Term (HLT) (1,737)
- Preferred Term (PT) (23,088)
- Lowest Level Term (LLT) (78,808)
System Organ Classes

- 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 (incl cysts and polyps)
- Nervous system disorders
- Pregnancy, puerperium and perinatal conditions
- Product issues
- Psychiatric disorders
- Renal and urinary disorders
- Reproductive system and breast disorders
- Respiratory, thoracic and mediastinal disorders
- Skin and subcutaneous tissue disorders
- Social circumstances
- Surgical and medical procedures
- Vascular disorders

Lowest Level Term

Synonyms, lexical variants, sub-elements

SOC = Cardiac disorders

HLGT = Cardiac arrhythmias

HLT = Rate and rhythm disorders NEC

PT = Arrhythmia

LLT = Arrhythmia

LLT (Non-current) Other specified cardiac dysrhythmias

Not all LLTs shown
Non-Current Terms

- Flagged at the LLT level in MedDRA
- Not recommended for continued use
- Retained to preserve historical data for retrieval and analysis
- Terms that are vague, ambiguous, outdated, truncated, or misspelled
- Terms derived from other terminologies that do not fit MedDRA rules

MedDRA Codes

- Each MedDRA term assigned an 8-digit numeric code starting with “1”
- The code is non-expressive
- Codes can fulfill a data field in various electronic submission types (e.g., E2B)
- New terms are assigned sequentially
A Multi-Axial Terminology

- Multi-axial = the representation of a medical concept in multiple SOCs
  - Allows grouping by different classifications
  - Allows retrieval and presentation via different data sets
- All PTs assigned a primary SOC
  - Determines which SOC will represent a PT during cumulative data outputs
  - Prevents “double counting”
  - Supports standardized data presentation
  - Pre-defined allocations should not be changed by users
A Multi-Axial Terminology (cont)

SOC = Respiratory, thoracic and mediastinal disorders (Secondary SOC)

HGT = Respiratory tract infections

HLT = Viral upper respiratory tract infections

PT = Influenza

SOC = Infections and infestations (Primary SOC)

HGT = Viral infectious disorders

HLT = Influenza viral infections

MedDRA Browser Demonstration SOC View
MedDRA Implementation Topics

Implementing MedDRA

- No single method for all organizations
- Implementation approach depends on factors such as size of organization
MedDRA | Downloading and Installing MedDRA

- Step-by-step instructions in Appendix slides
  - Downloading the latest release of MedDRA
  - Installing the MedDRA Desktop Browser
  - Loading MedDRA into the Desktop Browser

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
Reasons to Update to a New MedDRA Version

- Take advantage of new terms and other improvements
- Use the same new version to summarize data from different sources that had used older versions
  - “Pooling” clinical trials for analysis
  - Post-marketing safety summaries, etc.
- Use of recent versions of MedDRA may be required or preferred by regulatory authorities

Reasons to Update to a New MedDRA Version (cont)

- Stay current with development partners and contract research organizations
- Harmonize use of MedDRA to optimize communication of data
Resources for Version Updates

- MedDRA “Best Practice” documents
- Appendix 4.1 Versioning in the MedDRA Term Selection: Points to Consider document
- MSSO videocast – MedDRA Version Updates
- What’s New document
- MSSO “What’s New” webinars
- MedDRA Version Reports
- MedDRA Version Analysis Tool (MVAT)

Version Report

- List of various types of changes in MedDRA
MedDRA Version Analysis Tool

Note: The starting MedDRA version must be older than the ending MedDRA version.

Procedures Documentation and Conventions
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)

Need for Conventions

- Conventions are written guides and sets of principles for using MedDRA
- MedDRA may appear complicated but its structure is logical, and several guides are available to optimize its use
- Conventions help users achieve consistency in data entry (coding) and data retrieval
- Harmonizes exchange of MedDRA coded data worldwide
MedDRA® TERM SELECTION:
POINTS TO CONSIDER
ICH-Endorsed Guide for MedDRA Users

Release 4.15
Based on MedDRA Version 21.0

1 March 2018

MedDRA Term Selection: Points to Consider (MTS:PTC)

- Provides term selection advice for industry and regulatory purposes
- Objective is to promote accurate and consistent term selection to facilitate a common understanding of shared data
- Recommended to be used as basis for individual organization’s own coding conventions

MedDRA Term Selection: PTC (cont)

- Developed by a working group of the ICH Management Committee
- Updated twice yearly with each MedDRA release
- Available on MedDRA and JMO websites
  - English and Japanese
  - Word ("clean" and "redlined"), PDF, HTML formats
  - "Redlined" document identifies changes made from previous to current release of document
ICH M1 Points to Consider Working Group (PtC WG)

- Regulators and industry from EU, US, and Japan
  - Health Canada
  - MSSO
  - JMO
  - WHO (Observer)

New members 2017/2018
- MFDS, Republic of Korea
- ANVISA, Brazil
- CFDA, China

Meeting 13-15 November 2017, Geneva, Switzerland

Quality of Source Data Quality Assurance

- Quality of original information impacts quality of output
- Obtain clarification of data
- Can be optimized by careful design of data collection forms and proper training of staff
- Organizations’ coding guidelines should be consistent with MTS:PTC
- Review of term selection by qualified individuals
- Human oversight of automated coding results
Always Select a Lowest Level Term
Select Only Current LLTs

- Lowest Level Term that most accurately reflects the reported verbatim information should be selected
- Degree of specificity may be challenging
  - Example: “Abscess on face” → select “Facial abscess,” not simply “Abscess”
- Select current LLTs only
  - Non-current terms for legacy conversion/historical purposes

Coding: Translating into MedDRA

<table>
<thead>
<tr>
<th>Reported Information</th>
<th>LLT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Throbbing above temple</td>
<td>Headache</td>
</tr>
<tr>
<td>Aching all over head</td>
<td></td>
</tr>
<tr>
<td>Pulsing pain in head</td>
<td></td>
</tr>
<tr>
<td>Really bad headache</td>
<td></td>
</tr>
<tr>
<td>Headache</td>
<td></td>
</tr>
<tr>
<td>Infection in lungs</td>
<td>Lung infection</td>
</tr>
<tr>
<td>Patient took Drug A instead of Drug B and experienced hypertension</td>
<td>Wrong drug administered Hypertension</td>
</tr>
</tbody>
</table>
Exercise: Coding with MedDRA

MedDRA® DATA RETRIEVAL AND PRESENTATION: POINTS TO CONSIDER
ICH-Endorsed Guide for MedDRA Users on Data Output

Release 3.15
Based on MedDRA Version 21.0

1 March 2018

MedDRA® trademark is registered by IFFMin on behalf of ICH

- Provides data retrieval and presentation options for industry or regulatory purposes
- Most effective when used in conjunction with MedDRA Term Selection: PTC document
- Recommended to be used as basis for individual organization’s own data retrieval conventions
Data Retrieval PTC

Points Addressed

• General Principles
  – Quality of Source Data
  – Documentation of Data Retrieval and Presentation Practices
  – Do Not Alter MedDRA
  – Organisation-Specific Data Characteristics
  – Characteristics of MedDRA that Impact Data Retrieval and Analysis
  – MedDRA Versioning
• General Queries and Retrieval
• Standardised MedDRA Queries
• Customised Searches

Quality of Source Data

• High quality data output is dependent on maintaining quality of original information reported by using consistent and appropriate term selection (Refer to MedDRA Term Selection: Points to Consider document)
• Method of conversion of data into MedDRA might impact retrieval and presentation - legacy data conversion using verbatims or coded terms
Legacy Data Conversion

- Method 1 - Data converted from legacy terminology terms to MedDRA

<table>
<thead>
<tr>
<th>Reported</th>
<th>Legacy Term</th>
<th>MedDRA Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal ischaemia</td>
<td>Gastrointestinal disorder</td>
<td>Gastrointestinal disorder</td>
</tr>
</tbody>
</table>

- Results reflect specificity of legacy terminology
- Benefits of greater specificity of MedDRA not attained

Legacy Data Conversion (cont)

- 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
Legacy Data Conversion (cont)

- Method 2 - Data converted from original reported terms (verbatim terms) to MedDRA

<table>
<thead>
<tr>
<th>Reported</th>
<th>Legacy Term</th>
<th>MedDRA Term</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal ischaemia</td>
<td>Gastrointestinal disorder</td>
<td>Gastrointestinal ischaemia</td>
</tr>
</tbody>
</table>

-Specificity of reported term reflected by MedDRA term

Do Not Alter MedDRA

- MedDRA is a standardized terminology with a pre-defined term hierarchy
- Users must not make *ad hoc* structural alterations, including changing the primary SOC allocation
- If terms are incorrectly placed, submit a change request to the MSSO
Impact of MedDRA’s Characteristics
– Grouping Terms

• HLGTs and HLTs provide clinically relevant groupings
  – HLGT *Cardiac arrhythmias*
    • HLT *Cardiac conduction disorders*
    • HLT *Rate and rhythm disorders NEC*
    • HLT *Supraventricular arrhythmias*
    • HLT *Ventricular arrhythmias and cardiac arrest*

<table>
<thead>
<tr>
<th>Other Terminology Preferred Terms</th>
<th>No. of Events</th>
<th>MedDRA Version 19.0 Preferred Terms</th>
<th>No. of Events</th>
</tr>
</thead>
<tbody>
<tr>
<td>INFECTION</td>
<td>15</td>
<td>Upper respiratory tract infection</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Nasopharyngitis</td>
<td>2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Infection</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lower respiratory tract infection</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Skin infection</td>
<td>1</td>
</tr>
</tbody>
</table>
Multi-Axiality

- Primary SOC allocation rules affect the way data are distributed across the terminology
- Impact on frequencies of medical condition of interest should be considered
- Example: for hepatic abnormality search in SOC *Hepatobiliary disorders*, SOC *Investigations* (laboratory test terms), SOC *Surgical and medical procedures* (e.g., PT *Liver transplant*)

Introduction to Standardised MedDRA Queries (SMQs)
Standardised MedDRA Queries (SMQs)

- Collaboration between CIOMS (Council for International Organizations of Medical Sciences) and ICH (MSSO)
- Groupings of terms from one or more MedDRA SOCs related to medical condition or area of interest
- Terms relate to signs/symptoms, diagnoses, syndromes, physical findings, laboratory and other test data, etc.
- Intended to aid in case identification

SMQs in Production - Examples

- As of Version 21.0, a total of 103 level 1 SMQs in production

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

• Benefits
  – Application across multiple therapeutic areas
  – Validated reusable search logic
  – Standardized communication of safety information
  – Consistent data retrieval
  – Maintenance by MSSO/JMO

• Limitations
  – Do not cover all medical topics or safety issues
  – Will evolve and undergo further refinement even though they have been tested during development

SMQ Applications

• Clinical trials
  – Where safety profile is not fully established, use multiple SMQs on routine basis as screening tool
  – Selected SMQs to evaluate previously identified issue (pre-clinical data or class effect)

• Post-marketing
  – Selected SMQs to retrieve cases for suspected or known safety issue
  – Signal detection (multiple SMQs employed)
  – Single case alerts
  – Periodic reporting (aggregate cases for safety and other issues, e.g., lack of efficacy)
Narrow and Broad Searches

• “Narrow” scope – specificity (cases highly likely to be condition of interest)
• “Broad” scope – sensitivity (all possible cases)
• “Broad search” = All broad + all narrow terms

Narrow Terms

Broad Terms

Narrow Search

Broad Search

Narrow vs. Broad Example

SMQ Lactic acidosis

Definition
Lactic acidosis is a form of high anion gap metabolic acidosis - intrinsic cardiac contractility may be depressed, but inotropic function can be normal because of catecholamine release - Peripheral arterial vasodilation and central vasoconstriction can be present - Central nervous system function is depressed, with headache, lethargy, stupor, and, in some cases, even coma - Glucose intolerance may occur - Characterized by an increase in plasma L-lactate - Acidosis is seldom significant unless blood lactate exceeds 5 mmol - Clinical presentation in type B: Lactic acidosis. Symptoms: Hyperventilation or dyspnea, stupor or coma, vomiting, drowsiness, and abdominal pain. Onset of symptoms and signs is usually rapid accompanied by deterioration in the level of consciousness.

Source

Note
Testing in two regulatory databases confirmed that the term is adequate, in one regulatory database, the term “acidosis” identified cases, but this may be a phenomenon of the database characteristics (coding of variables to terms of an older terminology or other coding conventions).
How to “Run” SMQs (cont)
Exercise: Using an SMQ

MedDRA Tools and Training
IT Considerations

• Software tools support the use of MedDRA
  – Several are free with MedDRA subscription
    • Two browsers (Desktop and Web-Based)
    • MedDRA Version Analysis Tool (MVAT)
  – Software tools need driven by the volume of data
    • With small amounts, users can use simple software tools (e.g., free MSSO browsers, spreadsheets)
    • Larger implementations may need commercial data management products
    • List of third-party software tools on MedDRA website

MSSO’s MedDRA Browsers

• MedDRA Desktop Browser (MDB)
  – Download MDB and release files from MedDRA website

• MedDRA Web-Based Browser (WBB)
  – https://tools.meddra.org/wbb/

• Features
  – Both require MedDRA ID and password
  – View/search MedDRA and SMQs
  – Support for all MedDRA languages
  – Language specific interface
  – Ability to export search results and Research Bin to local file system
MedDRA Training Opportunities
– Available for Users

• Free Face-to-Face (F2F) training
  – Coding with MedDRA
  – Safety Data Analysis and Standardised MedDRA Queries
  – Getting Started with MedDRA

• Free webinars
  – Getting Started with MedDRA
  – MedDRA Overview
  – MedDRA Coding Basics
  – Advanced MedDRA Coding
  – Data Analysis and Query Building with MedDRA
  – Standardised MedDRA Queries
  – What’s New with MedDRA (with each MedDRA release)

MedDRA Training Opportunities
– Available to All

• Free resources on MedDRA website
  – Slides for all F2F courses and webinars
  – Short videocasts on MedDRA-related topics
    • Available in several languages
    • Can be downloaded or viewed directly on website
    • Help trainees prepare for F2F courses

• Webinars and videocasts available on new MedDRA MSSO YouTube Channel
More Resources for MedDRA Users

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

Summary

In this course, we:
• Described MedDRA governance
• Discussed MedDRA’s scope, structure, and characteristics
• Discussed MedDRA implementation topics
• Described need for procedures documentation and conventions
• Described Standardised MedDRA Queries
• Highlighted MedDRA tools and training
MSSO Contacts

- Website  
  - [www.meddra.org](http://www.meddra.org)
- Email  
  - mssohelp@meddra.org
- Frequently Asked Questions  
  - [www.meddra.org/faq](http://www.meddra.org/faq)

Question and Answer Session
Appendix: Downloading and Installing MedDRA

First Steps

- You just received your subscription letter from the MSSO, what’s next?
  - Download the latest release
- Identify the components and distribute accordingly
  - Install the MedDRA Desktop Browser
  - Load MedDRA into the Desktop Browser
Download the Latest Release

Click on Downloads

Download the Latest Release (cont)

- Enter Subscriber ID and password
Download the Latest Release (cont)

- Select the version and language(s)
  - Password protected zip file
- Save the zip file to your computer

Extract the Release Files

- Zip file structure and contents
  - Select a file to extract
  - Enter Unzip password from Welcome letter
**What’s in the Zip File?**

- Full Release of MedDRA Data and relationships files
- Changes in this release
- Description of contents of zip file
- Narrative discussion of changes in this release
- MedDRA Introductory Guide
- SMQ Spreadsheet
- SMQ Introductory Guide
- Spreadsheet with lists of new and modified terms
- Details of implemented changes
- File Format Descriptions

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**What to do with the Contents of the Zip File?**

<table>
<thead>
<tr>
<th>Item</th>
<th>Who should receive it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>MedAscii Directory</td>
<td>IT staff to load MedDRA</td>
</tr>
<tr>
<td>SEQAscii Directory</td>
<td>IT staff to review changes</td>
</tr>
<tr>
<td>Readme</td>
<td>All users</td>
</tr>
<tr>
<td>SMQ Spreadsheet</td>
<td>Those using SMQs</td>
</tr>
<tr>
<td>SMQ Introductory Guide</td>
<td>Those using SMQs</td>
</tr>
<tr>
<td>Version Report</td>
<td>Those interested in version changes</td>
</tr>
<tr>
<td>What’s New</td>
<td>All users</td>
</tr>
<tr>
<td>Detail Report</td>
<td>Those interested in version changes</td>
</tr>
<tr>
<td>Distribution File Format</td>
<td>IT staff to load MedDRA</td>
</tr>
<tr>
<td>MedDRA Introductory Guide</td>
<td>All users</td>
</tr>
</tbody>
</table>
Contents of MedASCII Directory

- MedDRA term and relationship files
- ASCII File format

Download and Install MedDRA Desktop Browser

1) Click on Downloads page from Home page
2) Log in (if not already)
3) Click on Desktop Browsers
Download and Install MedDRA Desktop Browser (cont)

- Download installation zip file
- Download installation instructions

Install MedDRA Desktop Browser

- Create a directory on your computer
- Unzip the contents of the zip file downloaded to this directory
- Double click the file MedDRABrowserWIN.exe to start the browser

- For future use, right click the MedDRABrowserWIN.exe file and choose “Send to” and then “Desktop” and an icon will be placed on your desktop

Load MedDRA into Desktop Browser
Load MedDRA into Desktop Browser (cont)

- Use the browse button to identify the directory where the MedDRA ASCII files are stored

- Click Import

Load MedDRA into Desktop Browser (cont)

- The load process will display a progress bar and then the load process will complete
- At the top of MedDRA Desktop Browser screen, select the version of MedDRA to display
Load MedDRA into Desktop Browser (cont)

- MedDRA Desktop Browser is loaded and ready for use