Resources and Tools for MedDRA Users

2019 GBC Workshop by MFDS
Seoul, Republic of Korea
27 June 2019
Dr. David Richardson
MedDRA MSSO
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• Resources available to MedDRA users
  - Educational offerings
  - Documents
  - Other resources
• Software tools available to MedDRA users
Educational Offerings
MSSO Free Training Program

• Formats
  – Face-to-face sessions, webinars, videocasts, YouTube Channel

• Languages
  – English, French, German, Spanish, Mandarin Chinese, Korean

• Locations
  – Worldwide and “virtual”
Face to Face Training
Session Titles

• Coding with MedDRA
• Safety Data Analysis and Standardised MedDRA Queries (SMQs)
• Getting Started with MedDRA
• MedDRA Overview
• Getting Started with MedDRA
• MedDRA Coding Basics
• Advanced MedDRA Coding
• Data Analysis and Query Building with MedDRA
• Standardised MedDRA Queries (SMQs)
• What’s New with MedDRA and the MSSO
### MedDRA Training

<table>
<thead>
<tr>
<th>Date</th>
<th>Event Description</th>
<th>Location</th>
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<td>Face-to-Face Training - MedDRA: Safety Data Analysis and SMQs</td>
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<td>MAY 22/2019</td>
<td>Face-to-Face Training - Coding with MedDRA</td>
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<td>JUN 05/2019</td>
<td>Face-to-Face Training - MedDRA: Safety Data Analysis and SMQs</td>
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<td>Face-to-Face Training - Coding with MedDRA</td>
<td>Lyon, France</td>
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Webinar Training Tab

MedDRA Training

- **MAY 08/2019**
  - MedDRA Overview
  - 396 left
  - Webinar

- **JUN 12/2019**
  - Data Analysis and Query Building with MedDRA
  - 462 left
  - Webinar

- **JUN 05/2019**
  - MedDRA Coding Basics
  - 439 left
  - Webinar

- **JUL 09/2019**
  - Advanced MedDRA Coding
  - 453 left
  - Webinar

- **AUG 28/2019**
  - What's New with MedDRA Version 22.1 and the MSSO
  - 446 left
  - Webinar

- **AUG 29/2019**
  - What's New with MedDRA Version 22.1 and the MSSO
  - 444 left
  - Webinar

- **SEP 04/2019**
  - Getting Started with MedDRA
  - 461 left
  - Webinar

- **SEP 18/2019**
  - MedDRA Coding Basics
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  - Webinar
## Summary of 2018 Training

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<th>Attendees</th>
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<td>Face-to-Face Training</td>
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<td>Central and North America, Europe, Russia, Asia/Eurasia, Scandinavia</td>
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<td>Webinars</td>
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<td>27</td>
<td>Worldwide</td>
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</table>
MedDRA Documents for Users
Documents for MedDRA Users

- MedDRA “Best Practices” document
- Introductory Guide MedDRA
- Introductory Guide for Standardised MedDRA Queries (SMQs)
- What’s New document
- MedDRA Version Report
- Points to Consider documents
Location of Most Documents: meddra.org Website
Support Documentation

Essential supporting documentation is maintained with each release of MedDRA.

MedDRA Version 21.1 English September 2018

MedDRA Points to Consider (Available in English and Japanese)

- MedDRA Term Selection: Points to Consider Release 4.16 Based on MedDRA Version 21.1
- MedDRA Data Retrieval and Presentation: Points to Consider Release 3.16 Based on MedDRA Version 21.1
- Radar of Changes to MedDRA Data Retrieval and Presentation: Points to Consider Release 3.16 Based on MedDRA Version 21.1

Additional MedDRA Guides

- Introductory Guide MedDRA Version 21.1
- Introductory Guide for Standardised MedDRA Queries (SMQs) Version 21.1
- What’s New MedDRA Version 21.1

Related Documents:

- Acronyms and Abbreviations
- Related Links:
  - Patient-Friendly Term List
  - Unqualified Test Name Term List
  - Paediatric & Gender Adverse Event Term Lists

Transition Dates

- 5 November 2018 - Version 21.1
- 6 May 2019 - Version 22.0
- 4 November 2019 - Version 22.1

Easy reference - transition dates

Controlled Lists
Support Documentation (cont)

PtC Companion Document – English and Japanese only
• Condensed PtC documents available in all MedDRA languages except English and Japanese

• MedDRA Best Practices document available in all MedDRA languages

• Will also be in Korean
MedDRA Best Practices Document
MedDRA Best Practices Document

- Objective is to promote accurate and consistent use of MedDRA
- Users encouraged to develop own best practices consistent with this document
- Endorsed by MMC
• Primary System Organ Class (SOC) Allocation in MedDRA
  – Useful reference for primary SOC rules in training classes or Help Desk questions
• Single Case Reporting Using Semi-annual Version Control
  – Pre- and post-marketing single case reports and transition dates
• MedDRA Implementation and Versioning for Clinical Trials
  – Options for versioning aggregate data over course of clinical trials
• Versioning Methodology
  – Extent of versioning (recoding of old data)
• Recommendations for the Implementation of MedDRA Supplemental Terms
  – Need to be aware of regulatory authorities’ position on use of supplementals
Introductory Guides and What’s New Document
**Release Documentation**

**MedDRA Version Releases:**

<table>
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<tr>
<th>MedDRA Version 22.0 March 2019</th>
<th></th>
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<tbody>
<tr>
<td>Release package</td>
<td>Language</td>
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<tr>
<td>MedDRA 22.0 版 中文</td>
<td>Chinese</td>
</tr>
<tr>
<td>MedDRA verze 22.0 Čeština</td>
<td>Czech</td>
</tr>
<tr>
<td>MedDRA Versie 22.0 Nederlands</td>
<td>Dutch</td>
</tr>
<tr>
<td>MedDRA Version 22.0 English</td>
<td>English</td>
</tr>
<tr>
<td>MedDRA Version 22.0 Français</td>
<td>French</td>
</tr>
<tr>
<td>MedDRA Version 22.0 Deutsch</td>
<td>German</td>
</tr>
<tr>
<td>MedDRA 22.0 változat Magyar</td>
<td>Hungarian</td>
</tr>
<tr>
<td>MedDRA versione 22.0 Italian</td>
<td>Italian</td>
</tr>
<tr>
<td>日本語シニオンバージョン22.0対応版</td>
<td>Japanese</td>
</tr>
<tr>
<td>MedDRA バージョン 22.0 日本語</td>
<td>Japanese</td>
</tr>
<tr>
<td>MedDRA Versão 22.0 Português</td>
<td>Portuguese</td>
</tr>
<tr>
<td>MedDRA Версия 22.0 Русский Март 2019 г.</td>
<td>Russian</td>
</tr>
<tr>
<td>Versión 22.0 de MedDRA Español</td>
<td>Spanish</td>
</tr>
</tbody>
</table>

**MedDRA Version 21.1 September 2018**

- Password needed to unzip release package
- Available from Self-Service Application
• Reference for MSSO and external MedDRA users
• Updated with each release
  – Terms cited are checked
  – Any new conventions, concept descriptions are added
• Topics
  – Background of MedDRA
  – Scope
    • Inclusions and Exclusions
  – Structure
    • Hierarchy and SMQs
  – Rules and conventions
    • Includes spelling, abbreviations, word usage, etc.
  – Explanatory notes on all 27 SOCs
    • Structure and basis for classification
• Appendix B Concept Descriptions
SMQ Introductory Guide

• Reference for MSSO and external MedDRA users
• Updated with each release
  – Terms cited are checked
  – New SMQ summaries are added

• Topics
  – Background and development
  – Design of SMQs
    • Narrow/broad, hierarchical, and algorithmic
  – SMQ implementation
  – Summaries of all SMQs in production
    • Definition
    • Inclusion/exclusion criteria
    • Relevant notes for use
    • Implementation and/or expectation of query results
    • References
Downloads

The MSSO download page provides access to the following types of information:

MedDRA Release packages – this includes all of the MedDRA data files and supporting documentation for all versions and supported MedDRA languages for the past six years. Please contact the MSSO Help Desk for any release packages earlier than what is provided above.

MedDRA Desktop Browsers – the MSSO Desktop Browser and the JMO’s Desktop Browser are available for download.

MedDRA supplemental releases (in weekly and comprehensive versions) are available for download.

• Full original documentation from testers for all SMQs in production
• Anonymized
  – Test databases and products not identified
• MSSO produces a summary (1-2 pages) for SMQ Introductory Guide and ASCII files
• Not part of release package; updated when new SMQ goes into production
What’s New Document

• Provides information on changes between new release and the previous one

• Topics
  – Summary of Change Requests for new version
  – New developments
    • SMQs
    • Proactivity requests
    • IT tools

• Basis for “What’s New with MedDRA and the MSSO” webinar for each release
MedDRA Version Report
Version Report

- List of various types of changes in MedDRA

<table>
<thead>
<tr>
<th>Report Title</th>
<th>Total Changes between selected versions</th>
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<tbody>
<tr>
<td>New LLTs including New PTs</td>
<td>755</td>
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<tr>
<td>New PTs</td>
<td>327</td>
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<tr>
<td>Promotions</td>
<td>42</td>
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<td>Demotions</td>
<td>50</td>
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<tr>
<td>LLTs under different PTs</td>
<td>288</td>
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<tr>
<td>LLT (excl PT) Primary SOC Chg</td>
<td>22</td>
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<td>PT Primary SOC Changes</td>
<td>4</td>
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<tr>
<td>MedDRA Term Name Changes</td>
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<td>MedDRA Code Switches</td>
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<tr>
<td>Currency Changes</td>
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<tr>
<td>Complex Changes</td>
<td>16</td>
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<td>SMQ Changes</td>
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<td>PT Changes in SMQs</td>
<td>421</td>
</tr>
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</table>
Points to Consider (PtC) Documents
ICH M1 Points to Consider Working Group (PtC WG)

- Regulators and industry from EU, US, and Japan
- Health Canada, Canada
- MFDS, Republic of Korea
- ANVISA, Brazil
- NMPA, China
- MSSO
- JMO
- WHO (Observer)

November 2017, Geneva, Switzerland
<table>
<thead>
<tr>
<th>PtC Category</th>
<th>PtC Document</th>
<th>Purpose</th>
<th>Languages</th>
<th>Release Cycle</th>
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<tr>
<td>Term Selection</td>
<td>MedDRA Term Selection: Points to Consider</td>
<td>Promote accurate and consistent coding with MedDRA</td>
<td>English and Japanese</td>
<td>Updated with each MedDRA release</td>
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<tr>
<td></td>
<td>MedDRA Term Selection: Points to Consider Condensed Version</td>
<td>Shorter version focusing on general coding principles to promote accurate and consistent use of MedDRA worldwide</td>
<td>All MedDRA languages (except English and Japanese)</td>
<td>Update as needed</td>
</tr>
<tr>
<td>Data Retrieval and Presentation</td>
<td>MedDRA Data Retrieval and Presentation: Points to Consider</td>
<td>Demonstrate how data retrieval options impact the accuracy and consistency of data output</td>
<td>English and Japanese</td>
<td>Updated with each MedDRA release</td>
</tr>
<tr>
<td></td>
<td>MedDRA Data Retrieval and Presentation: Points to Consider Condensed Version</td>
<td>Shorter version focusing on general retrieval and analysis principles to promote accurate and consistent use of MedDRA worldwide</td>
<td>All MedDRA languages (except English and Japanese)</td>
<td>Update as needed</td>
</tr>
<tr>
<td>General</td>
<td>MedDRA Points to Consider Companion Document</td>
<td>More detailed information, examples, and guidance on specific topics of regulatory importance. Intended as a &quot;living&quot; document with frequent updates based on users' needs. First edition covers data quality and medication errors.</td>
<td>English and Japanese</td>
<td>Updated as needed</td>
</tr>
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</table>
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
MedDRA® TERM SELECTION:
POINTS TO CONSIDER
ICH-Endorsed Guide for MedDRA Users

Release 4.17
Based on MedDRA Version 22.0

1 March 2019

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- 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
Other Resources
Additional Resources

- meddra.org website
- MedDRA Help Desk
- Change Request portal (WebCR)
- User Group Meetings
MedDRA Help Desk

mssohelp@meddra.org
Change Requests (CRs)

- Users can send change requests (CRs) to MSSO for consideration
  - Organizations allowed 100 CRs/month
  - For simple changes (PT and LLT levels), response within 7-10 working days
  - Complex changes (above PT level) posted for comments mid-year
• Web-based tool for Change Requests (CR)
  – URL: https://mssotools.com/webcr/
  – Via the Change Request Information page
• Ability to submit CRs online
  – Requests must be in English
• Immediate confirmation
• Review unsubmitted CRs online
• Ability to query CR history back to v5.1
• Online change request submission tool
• Guides the user to enter all needed information
Submitting Changes (cont)

- Sample entry for a new PT in WebCR
- Justification and supporting documentation is important to help MSSO understand the need
US MedDRA User Group Meeting

- Date: Thursday, 27 June 2019
- Time: 12:30 pm – 16:30 pm
- Where:
  San Diego Convention Center
  111 W Harbor Drive, Room 6E
  San Diego, California 92101
- Open to all MedDRA users
- Registration form and agenda posted to User Group page on MedDRA website
MedDRA Software Tools
• MSSO provides a set of free software tools to all MedDRA subscribers
  – Desktop Browser
  – Web-Based Browser
  – MedDRA Mobile Browser
  – MedDRA Version Analysis Tool
  – Self Service Application
  – New Data Analysis Tools (browser-based SMQ Analysis and Hierarchy Analysis Tools)
MedDRA Browsers

• MedDRA Desktop Browser and Web-based Browser
  – Useful for training and used to support coding and analysis
  – Search for terms
  – View terms in their hierarchy
  – View Standardised MedDRA Queries (SMQs)
• User interface available in all MedDRA languages
MedDRA Version Analysis Tool (MVAT)

- Web-based (https://tools.meddra.org/mvat)
- Free to all users
- Features
  - Version Report Generator (produces exportable report comparing any two versions)
  - Data Impact Report (identifies changes to a specific set of MedDRA terms or codes uploaded to MVAT)
  - Search Term Change (identifies changes to a single MedDRA term or code)
- User interface and report output available in all MedDRA languages
### MedDRA Version Analysis Tool (MVAT)

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<td>产品的各种质量问题（不分分类）</td>
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Self Service Application

- Provides User ID, Passwords, POC, Subscription status, Training certificates
- This is how users access new passwords
MedDRA browsers (both the Desktop and Web-Based versions) have new SMQ Analysis and Hierarchy tools

These tools will be discussed during the data analysis sessions
MSSO Contacts

• Website
  – www.meddra.org

• Email
  – mssohelp@meddra.org

• Frequently Asked Questions
  – www.meddra.org/faq
Questions?