MedDRA
Medical Dictionary for Regulatory Activities

Getting Started with MedDRA

ICH harmonisation for better health

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MedDRA

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 Steering Committee. The MedDRA SC is composed of the EC, Europe; EFPIA; FDA, United States; Health Canada, Canada; JPMA; MHLW/PMDA, Japan; MHRA UK; PhRMA; and WHO (as Observer). In addition, since May 2025, the following representatives have been appointed by the ICH MC to join the MedDRA SC and will serve until the next appointment in 2028: NMPA, China; SFDA, Saudi Arabia; and IFPMA (as Observer).

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Course Overview

- Describe what MedDRA is and who uses it
- Describe the process for subscribing to MedDRA
- Discuss development of a MedDRA implementation strategy within your organization
- Provide an overview of tools, services, and training offered as part of a MedDRA subscription
- Discuss the importance of a versioning strategy
- Conclude with a question and answer session

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MedDRA

MedDRA Description

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MedDRA

What is MedDRA?

Med = Medical

D = Dictionary for

R = Regulatory

A = Activities

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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.

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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

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MedDRA and the MSSO

MSSO
International support and development of terminology
"Custodians", not owners, of the terminology

Governance
Governed by a Steering Committee (industry, regulators, multi-national, other interested parties)

Educational offerings
Foster use of MedDRA through communications and educational offerings

JMO
Partner organization for Japanese-language MedDRA

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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

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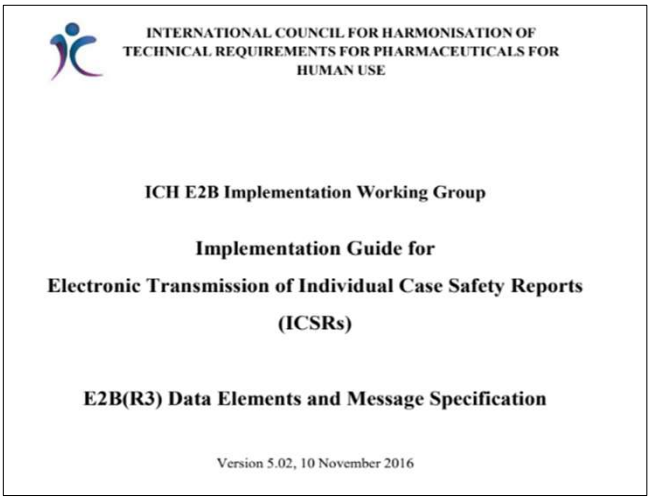
Electronic Transmission of Data



INTERNATIONAL COUNCIL FOR HARMONISATION OF TECHNICAL REQUIREMENTS FOR PHARMACEUTICALS FOR HUMAN USE

ICH E2B Implementation Working Group

Implementation Guide for

Electronic Transmission of Individual Case Safety Reports (ICSRs)

E2B(R3) Data Elements and Message Specification

Version 5.02, 10 November 2016

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Global Growth of MedDRA

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MedDRA

Global View

MedDRA is in over 140 countries

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MedDRA

Subscribing to MedDRA

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MedDRA Subscriptions

- To use MedDRA, you must obtain a subscription
- MedDRA subscriptions are enterprise subscriptions
  - All parts of the organization can use the same subscription
  - No limit to the number of users within an organization
- Subscription grants access to MedDRA for one year
- There are four types of MedDRA subscriptions
  - Regulatory
  - Non-Profit/Non-Commercial
  - Commercial
  - System Developers

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Types of MedDRA Subscriptions

- Regulatory Authority
  - Eligible to receive MedDRA at no charge
- Non-Profit/Non-Commercial
  - Eligible to receive MedDRA at no charge
  - Non-profit medical libraries, educational institutions, and direct patient care providers (i.e., hospitals for educational use)
  - In general, any organization conducting non-commercial work
- Commercial
  - Commercial organizations (e.g., pharmaceutical companies, CROs)
  - Rates vary based on the annual revenue (turnover) of the organization
- System Developers
  - Reserved for organizations that develop software products that use MedDRA
  - Use is limited to software development and MedDRA testing, not for providing MedDRA support services (e.g., coding, analysis, transmission of MedDRA coded data)

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What Do I Get with a MedDRA Subscription?

- Access to MedDRA release files
- Full features of MedDRA website
- Submit requests for changes to MedDRA
- Free training
- Help Desk
  - Global support via phone, email, online chat, social media
- Software tools
- MedDRA User Group participation

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MedDRA 2025 Subscription Rates

MedDRA Subscription Types	Annual Subscription Rates
Regulatory Authority	$0 USD
Non-Commercial / Non-Profit	$0 USD
Commercial (Parent Company Annual Revenue or Turnover)	
Level 0 (Annual Revenue < $1 Million)	$139 USD
Level 1 (Annual Revenue $1-$10 Million)	$589 USD
Level 2 (Annual Revenue $10-$100 Million)	$2,246 USD
Level 3 (Annual Revenue $100-$500 Million)	$4,254 USD
Level 4 (Annual Revenue $500 Million-$1 Billion)	$8,926 USD
Level 5 (Annual Revenue $1-$5 Billion)	$37,035 USD
Level 6 (Annual Revenue $5-$20 Billion)	$48,901 USD
Level 7 (Annual Revenue > $20 Billion)	$63,800 USD
System Developer	$2,300 USD

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Submitting an Online MedDRA Subscription

- There is an instructional video (in multiple languages) describing how to submit an online subscription to MedDRA on the MedDRA website (www.meddra.org)

https://www.meddra.org/instructional-videos

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Payment Methods

- For commercial users, payment is required before access is provided to MedDRA.
- For Commercial or Developer subscription types, users can pay by bank transfer or credit card

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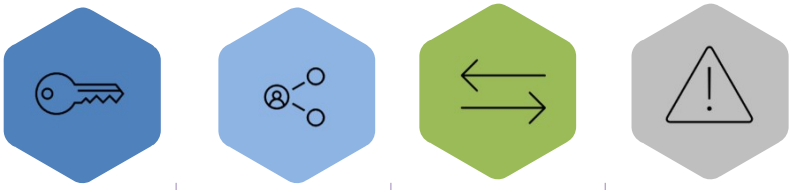
MedDRA Data Sharing



Access

Subscription grants access to MedDRA for one year

3rd Party Distribution

Subscriber cannot grant any sublicense, publish or otherwise distribute MedDRA to a third party

Free Exchange

Data may be freely exchanged between current MedDRA subscribers

Violation

Sharing MedDRA with a non-subscribing organization is a violation of the MedDRA license

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MedDRA Data Sharing (cont)

- For details, see the Statement on MedDRA Data Sharing:

  https://admin.meddra.org/sites/default/files/page/documents/000198%20Statement%20on%20MedDRA%20Data%20Sharing.pdf

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MedDRA

MedDRA Implementation Strategy

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MedDRA

Next Steps

Once you have subscribed to MedDRA, what's next?

- ✓ Develop your organizational implementation strategy
  - No single method
  - Depends on factors such as size of organization
  - MSSO provides many tools and resources to assist implementation
- ✓ Download the latest MedDRA release
- ✓ Use the MedDRA browser tools to begin coding and data analysis activities
- ✓ Consider the need for legacy data conversion to MedDRA

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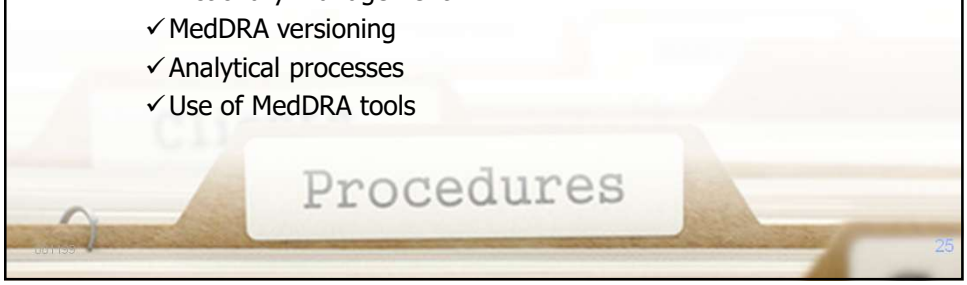
Procedures Documentation

- Documentation of procedures and processes is a best practice for all organizations
- Standard operating procedures and other relevant documents should address the use of MedDRA
  - ✓Coding
  - ✓Dictionary management
  - ✓MedDRA versioning
  - ✓Analytical processes
  - ✓Use of MedDRA tools



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Downloading MedDRA Release Files

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Downloading MedDRA Release Files

- There is an instructional video (in multiple languages) describing the process for downloading MedDRA release files on the MedDRA website (www.meddra.org)

https://www.meddra.org/instructional-videos

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Accessing the MedDRA Browsers

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MSSO's MedDRA Browsers

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

MedDRA Web-Based Browsers (WBB)

New WBB:
https://wbb.meddra.org

Legacy WBB:
https://tools.meddra.org/wbb/

Mobile MedDRA Browser
https://mmb.meddra.org

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MSSO's MedDRA Browsers (cont)

- Features
  - Each 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 (MDB and WBB only)

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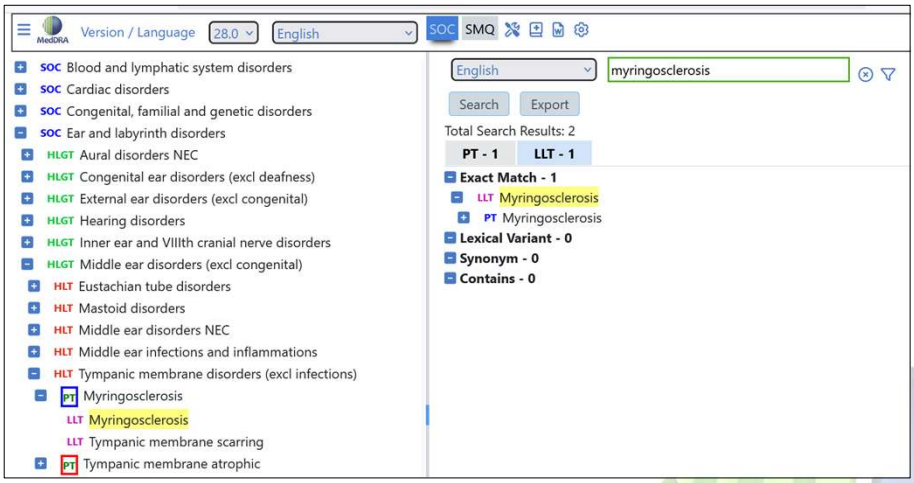
New WBB Screenshot



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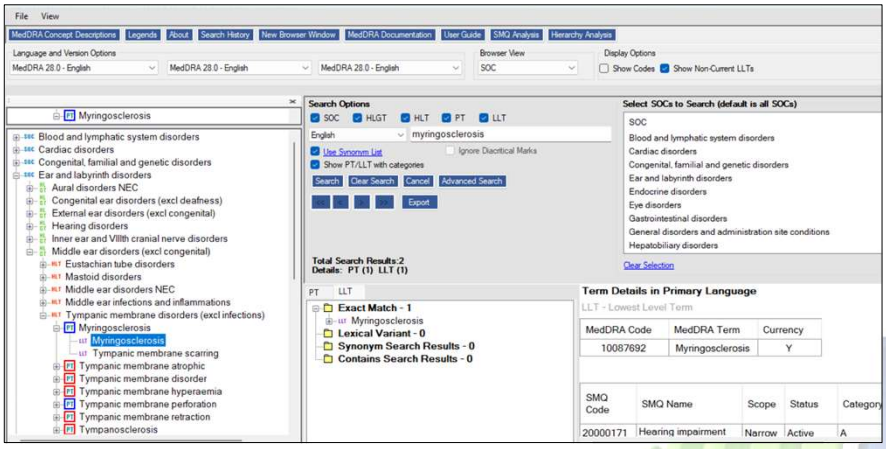
MDB Screenshot



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Installing the MedDRA Desktop Browser

- There is an instructional video (in multiple languages) describing how to download the MedDRA Desktop Browser (MDB) on the MedDRA website (www.meddra.org)

https://www.meddra.org/instructional-videos

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Overview of MedDRA Tools and Services

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Information Technology Resources

Looking for software tools to support the use of MedDRA?

- Free with MedDRA subscription
  - MedDRA browsers
  - MedDRA Version Analysis Tool (MVAT)

- Software tools need is <u>driven by the volume of data</u>
  - 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

Resources at www.meddra.org

- Help Desk
- Subscriptions
- News and Events
- MedDRA user documentation
- MedDRA Best Practices document
- Points to Consider documents
- Terminology downloads
- Training
- Tools
- MedDRA publications
- User Group meetings
- Expert meetings

Need for Conventions When Using MedDRA

- Conventions are written guides and sets of principles for using MedDRA that help users achieve consistency in coding and data retrieval
- Conventions also harmonize exchange of MedDRA coded data worldwide
- MedDRA may appear complicated but its structure is logical
- Several guides (Points to Consider documents) are provided to optimize your use of MedDRA

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PtC Documents

PtC Category	PtC Document	Purpose	Languages	Release Cycle
Term Selection	MedDRA Term Selection: Points to Consider	Promote accurate and consistent coding with MedDRA	English, Japanese, Chinese, Russian, Korean, and Spanish	Updated annually with the March release of MedDRA
	MedDRA Term Selection: Points to Consider Condensed Version	Shorter version focusing on general coding principles to promote accurate and consistent use of MedDRA worldwide	All MedDRA languages (except English, Japanese, other languages with an available translation of the full MTS:PTC document, and EEA languages*)	Update as needed
Data Retrieval and Presentation	MedDRA Data Retrieval and Presentation: Points to Consider	Demonstrate how data retrieval options impact the accuracy and consistency of data output	English, Japanese, Chinese, Russian, Korean, and Spanish	Updated annually with the March release of MedDRA
	MedDRA Data Retrieval and Presentation: Points to Consider Condensed Version	Shorter version focusing on general retrieval and analysis principles to promote accurate and consistent use of MedDRA worldwide	All MedDRA languages (except English, Japanese, other languages with an available translation of the full DRP:PTC document, and EEA languages*)	Update as needed

*The following European Economic Area (EEA) languages in MedDRA do not have translations of user documentation, including PtC documents: Bulgarian, Croatian, Danish, Estonian, Finnish, Greek, Icelandic, Latvian, Lithuanian, Maltese, Norwegian, Polish, Romanian, Slovak, Slovenian, Swedish

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PtC Documents (cont)

PtC Category	PtC Document	Purpose	Languages	Release Cycle
General	MedDRA Points to Consider Companion Document	More detailed information, examples, and guidance on specific topics of regulatory importance. Intended as a "living" document with updates based on users' needs. First edition covered data quality and medication errors. Updated in July 2020 (Release 1.1). Release 2.0 in October 2020 included a section on product quality issues. Release 3.0 in September 2024 included updates to the existing sections, as well as the addition of a new section (i.e., Section 5) which addresses Manufacturing and Quality System Issues.	English and Japanese	Updated as needed

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MedDRA Training

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MedDRA Training Opportunities 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
- What is MedDRA and How is It Used?
- MedDRA Coding Basics
- Advanced MedDRA Coding

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MedDRA Training Opportunities for Users (cont)

- Free webinars
  - Data Analysis and Query Building with MedDRA
  - Standardised MedDRA Queries
  - Let's Code Together
  - MVAT Demonstration
  - SMQ Analysis Tool Demonstration
  - Requesting Changes to MedDRA
  - What's New with MedDRA (with each MedDRA release)
  - MedDRA Coding of Medication Errors
  - Ask the MSSO

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MedDRA Training Opportunities for Users (cont)

- MedDRA Learning Management System (LMS)
  - MedDRA LMS is an e-Learning platform hosting MedDRA training videos
  - Since the launch of MedDRA LMS on 7 January 2025, users can earn training completion certificates on the e-Learning platform as well as in traditional in-person training classes and webinars
  - MedDRA LMS is designed for new users and experienced users
    - Training videos are "interactive" with self assessment quizzes in several languages

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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 MedDRA MSSO YouTube Channel

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MedDRA

MedDRA Versioning

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MedDRA

A Question You Might Be Asking

"I already have an old version of MedDRA.

Why do I need to keep subscribing every year?"

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Reasons to Update to a New MedDRA Version

- MedDRA is updated twice a year

- Take advantage of new terms and other improvements
- Use the same new version to summarize data coded with different versions
  - "Pooling" clinical trials for analysis
  - Post-marketing safety summaries, etc.
- May be required by regulatory authorities
- Stay current with business partners
- Harmonize to optimize communication of data

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Resources for Version Updates

- MedDRA Best Practices document
- What's New document and webinars
- MedDRA Version Reports
- MedDRA Version Analysis Tool (MVAT)

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Summary

- ✓Described MedDRA and who uses it
- ✓Described the process for subscribing to MedDRA
- ✓Discussed MedDRA implementation topics
- ✓Described tools, services, and training offered with a MedDRA subscription
- ✓Discussed the reasons for a MedDRA versioning strategy

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MSSO Contacts

- Website
  - www.meddra.org
- Email
  - mssohelp@meddra.org
- Frequently Asked Questions
  - www.meddra.org/faq
- MedDRA Browsers

Desktop - https://www.meddra.org/meddra-desktop-browsers

Web-Based

New WBB: https://wbb.meddra.org

Legacy WBB: https://tools.meddra.org/wbb/

Mobile

https://mmb.meddra.org

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MSSO Contacts (cont)

- Change Request Submission
  - https://www.meddra.org/how-to-use/change-requests
- Training Schedule
  - https://www.meddra.org/training/schedule
- MedDRA Support Documentation
  - https://www.meddra.org/how-to-use/support-documentation

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Question and Answer Session

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