



MedDRA

Medical Dictionary
for Regulatory Activities

Getting Started with MedDRA



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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 Management Committee, which is composed of the ICH parties, 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 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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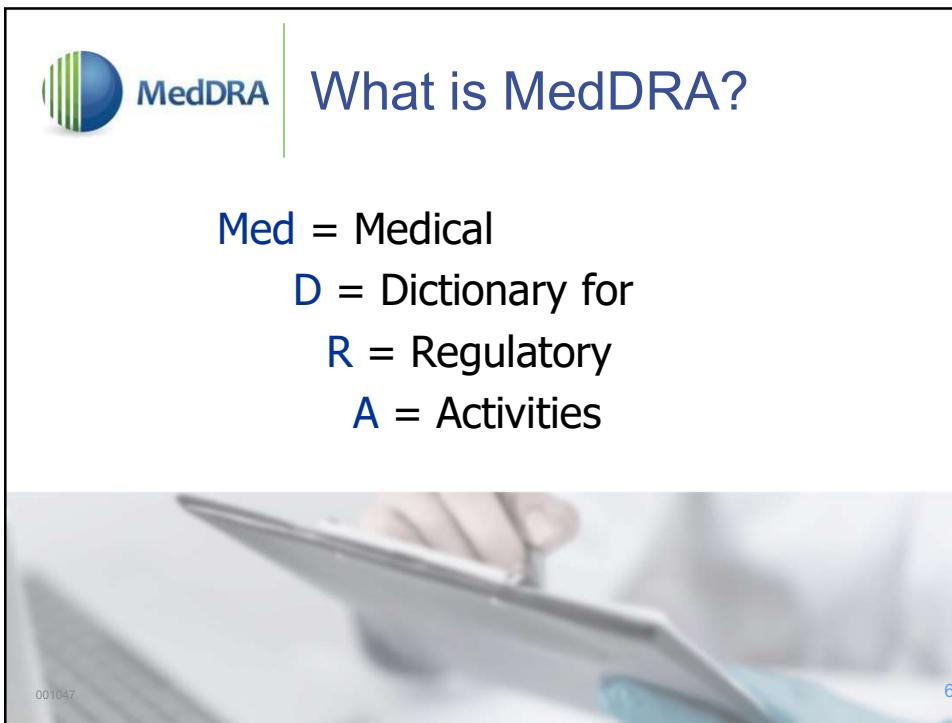
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MedDRA Description

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What is MedDRA?

Med = Medical
D = Dictionary for
R = Regulatory
A = Activities

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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.

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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

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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 Management 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



Preclinical Testing



Clinical Phase I → Clinical Phase II → Clinical Phase III → APPROVAL → Marketed Product Phase IV



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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MedDRA

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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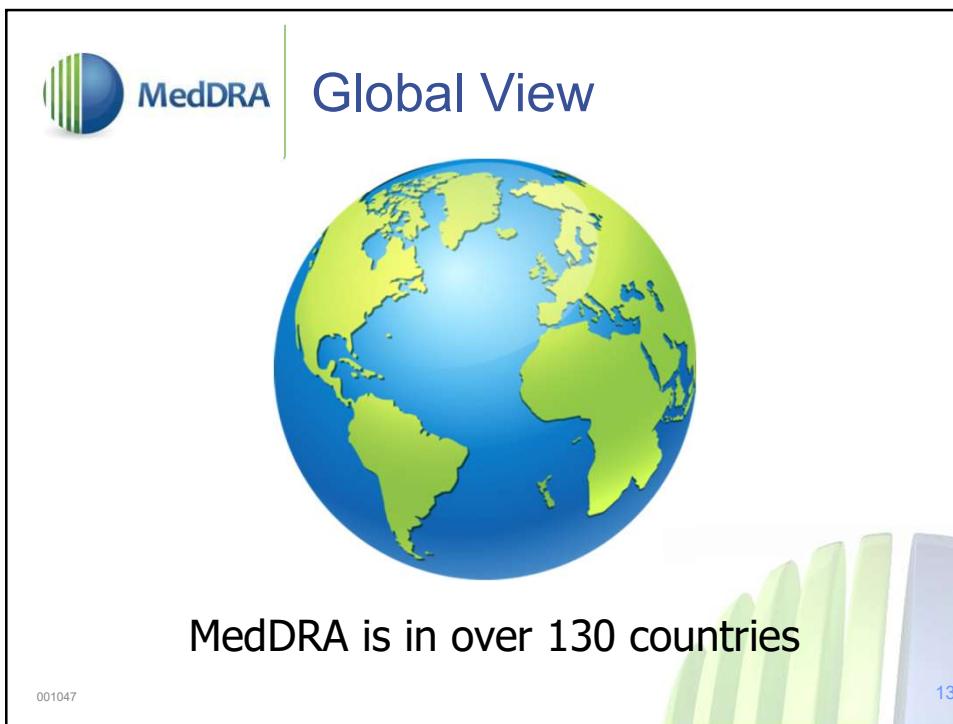
Global Growth of MedDRA



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MedDRA Global View

MedDRA is in over 130 countries

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A slide titled "MedDRA Global View" featuring a globe graphic and the text "MedDRA is in over 130 countries". The slide is identified by the code "001047" and the number "13".

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MedDRA

Subscribing to MedDRA

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A slide titled "Subscribing to MedDRA" featuring the MedDRA logo and the text "Subscribing to MedDRA". The slide is identified by the code "001047" and the number "14".

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MedDRA

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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MedDRA

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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MedDRA

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

MedDRA 2024 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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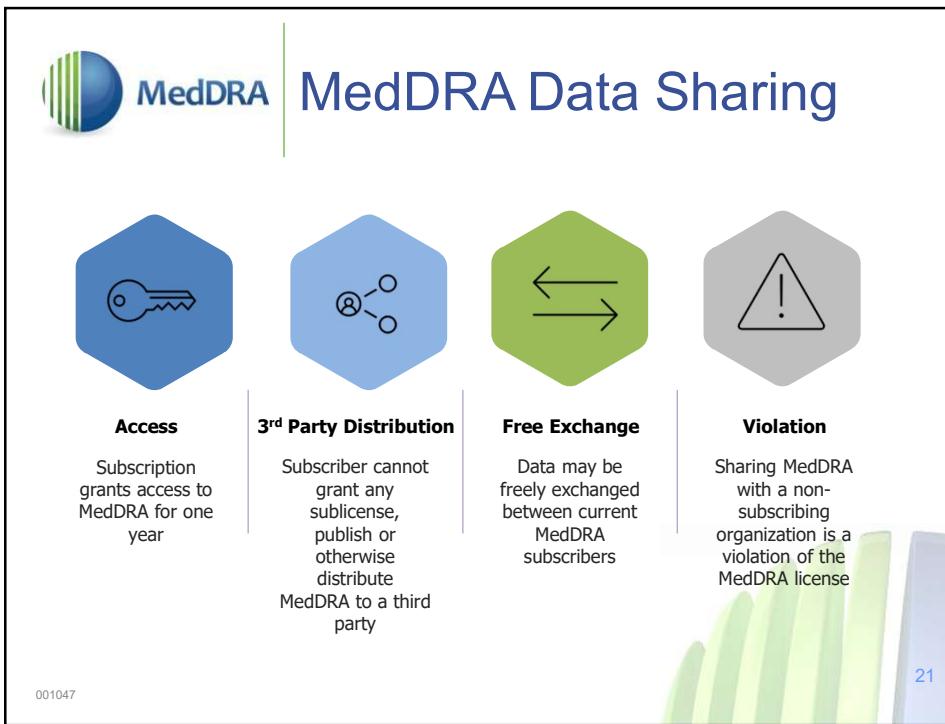
Payment Methods

- 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

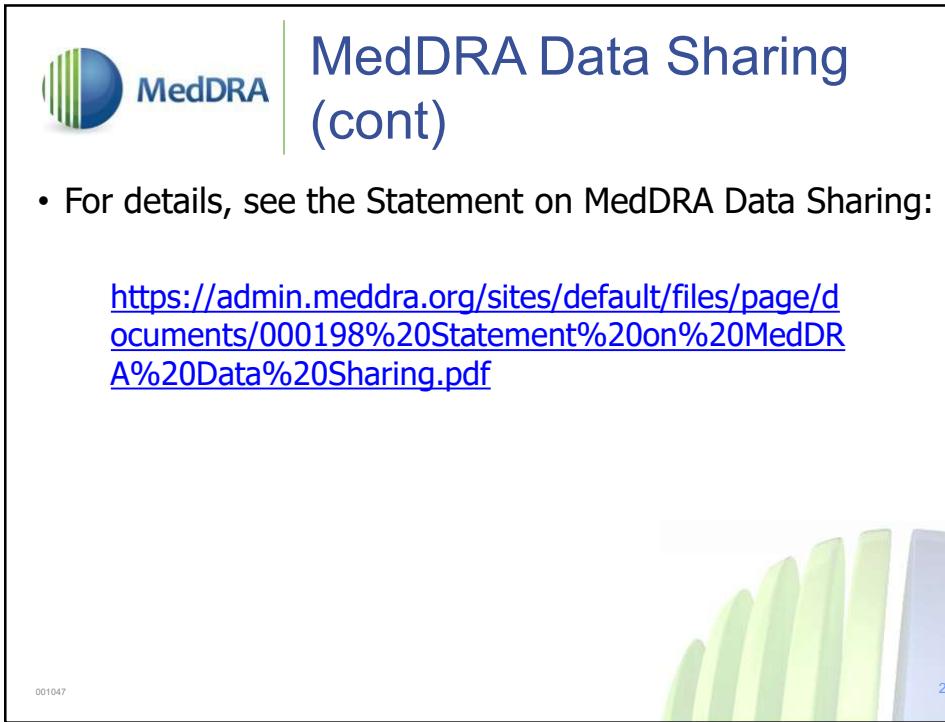


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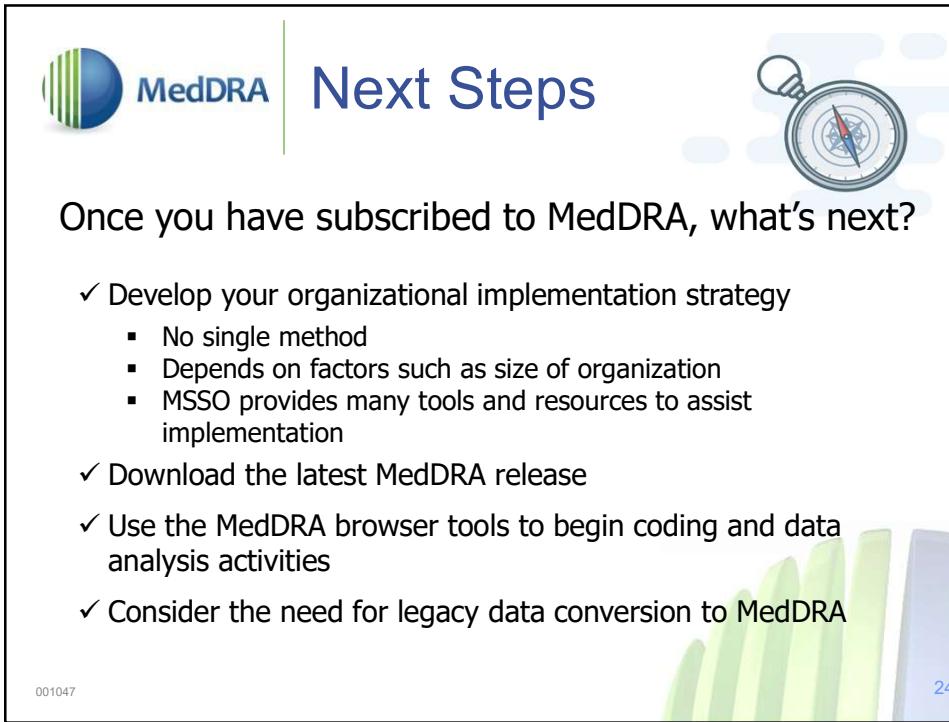


MedDRA Implementation Strategy

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This slide is titled 'MedDRA Implementation Strategy'. It features the MedDRA logo in the top left corner. The background is white with a decorative graphic of green and blue overlapping bars in the bottom right corner. The slide number '23' is in the bottom right corner.



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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This slide is titled 'Next Steps'. It features the MedDRA logo in the top left corner and a compass icon with a magnifying glass in the top right corner. The slide lists four steps for the implementation process. The slide number '24' is in the bottom right corner.



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

Procedures

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Downloading MedDRA Release Files

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MedDRA

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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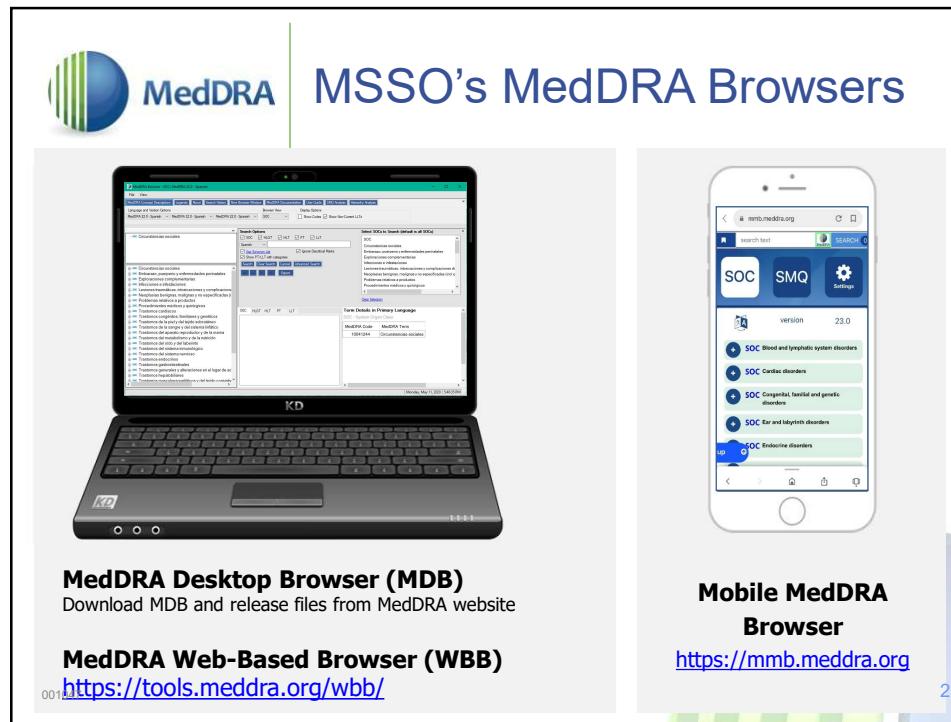
MedDRA

Accessing the MedDRA Browsers



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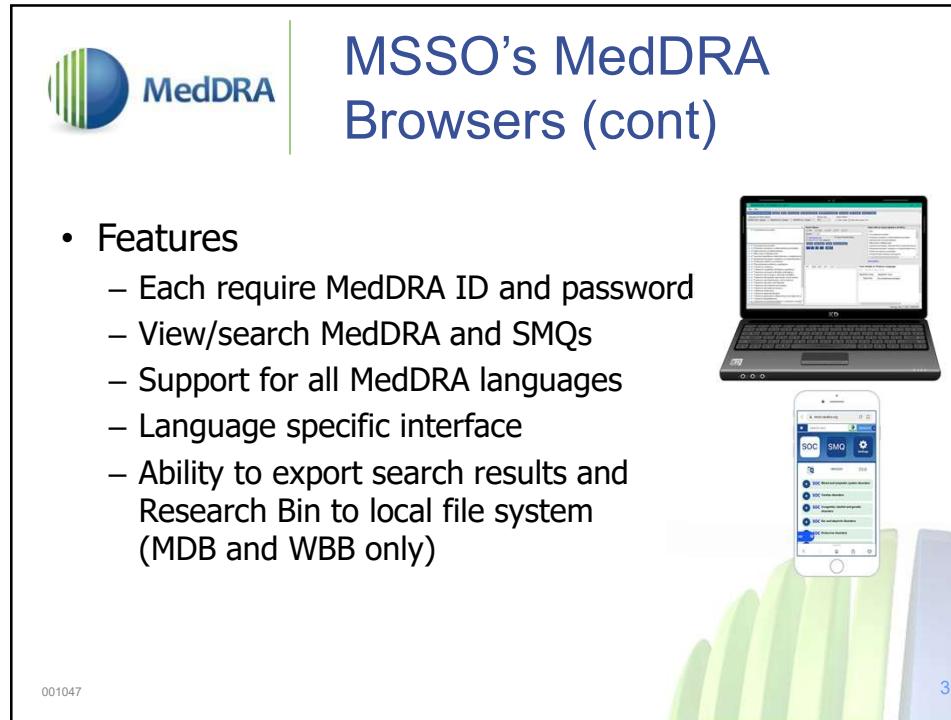
MedDRA | **MSSO's MedDRA Browsers**

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

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

Mobile MedDRA Browser
<https://mmbr.meddra.org>

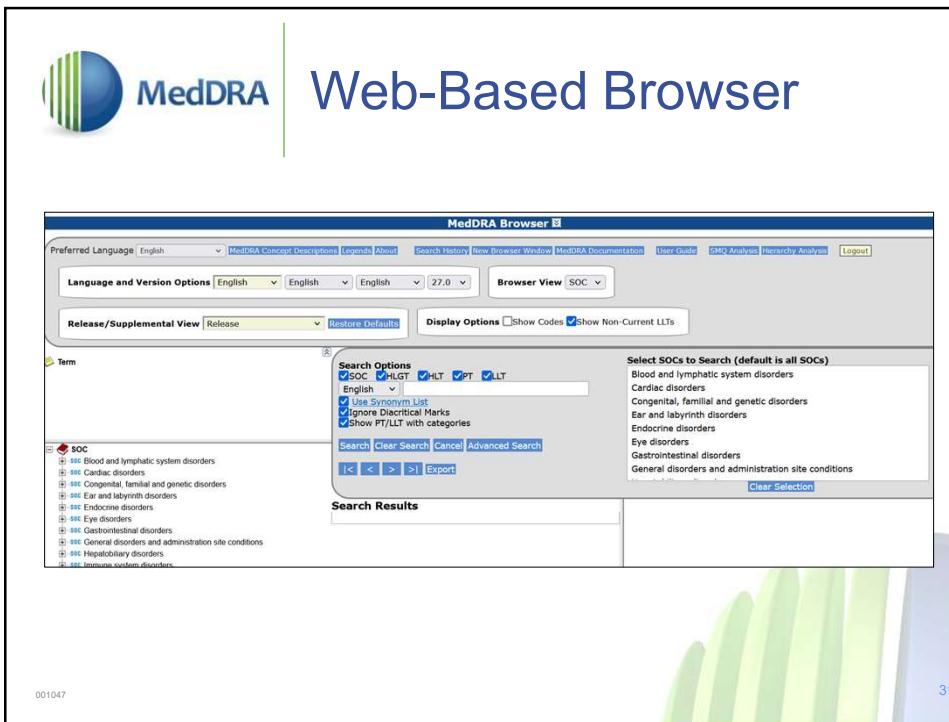
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MedDRA | **MSSO's MedDRA Browsers (cont)**

- **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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The image shows the MedDRA Web-Based Browser interface. The top navigation bar includes links for Preferred Language (English), MedDRA Concept Descriptions, Legends, About, Search History, New Browser Window, MedDRA Documentation, User Guide, SMQ2 Analysis, Hierarchy Analysis, and Logout. Below the navigation is a search bar with Language and Version Options (English, English, English, 27.0) and a Browser View dropdown set to SOC. The main content area shows a search results page for the term 'Blood and lymphatic system disorders'. The search options include SOC, VHLST, MHLT, PT, LLT, Use Synonym List, Ignore Diacritical Marks, and Show PT/LLT with categories. The search results list includes: Blood and lymphatic system disorders, Cardiac disorders, Congenital, familial and genetic disorders, Ear and labyrinth disorders, Endocrine disorders, Eye disorders, Gastrointestinal disorders, and General disorders and administration site conditions. A sidebar on the right lists these categories. At the bottom of the search results page are buttons for Search, Clear Search, Cancel, Advanced Search, and Export. The page number 001047 is at the bottom left, and 31 is at the bottom right.

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The image shows a guide for installing the MedDRA Desktop Browser. It features the MedDRA logo and the title 'Installing the MedDRA Desktop Browser'. Below the title is a blue icon of a laptop with a checkmark. The main content is a bulleted list: 'There is an instructional video (in multiple languages) describing how to download the MedDRA Desktop Browser (MDB) on the MedDRA website (www.meddra.org)'. Below the list is a blue link: <https://www.meddra.org/instructional-videos>. The page number 001047 is at the bottom left, and 32 is at the bottom right.

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MedDRA

Overview of MedDRA Tools and Services

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MedDRA

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 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

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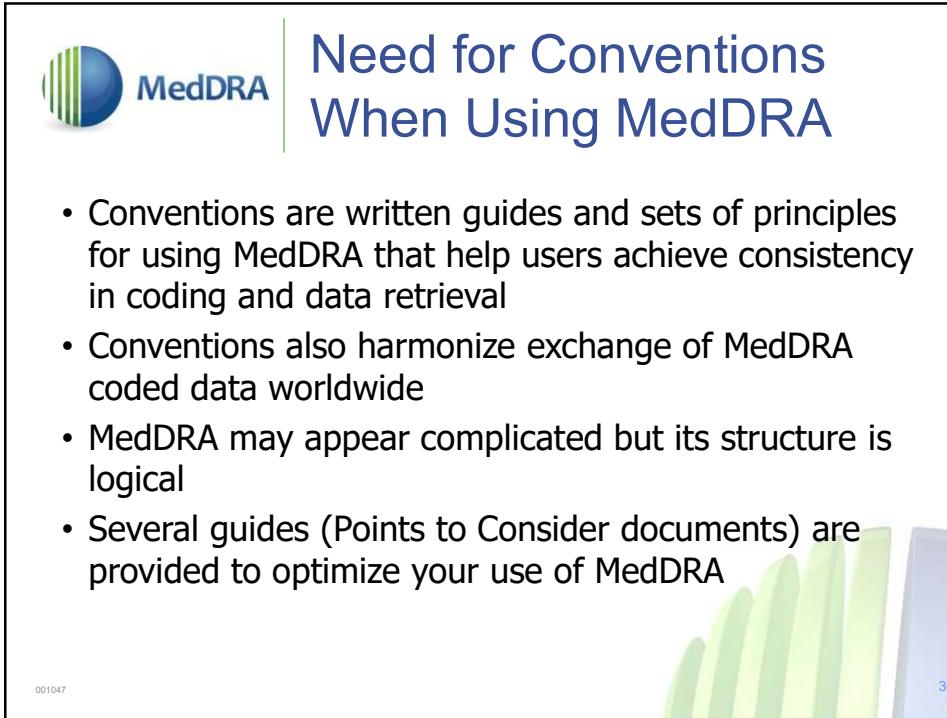
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Resources at www.meddra.org

- 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

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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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 **MedDRA** 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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 **MedDRA** 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. Additional section on Manufacturing and Quality System Issues is in development with expected release during 2024.	English and Japanese	Updated as needed

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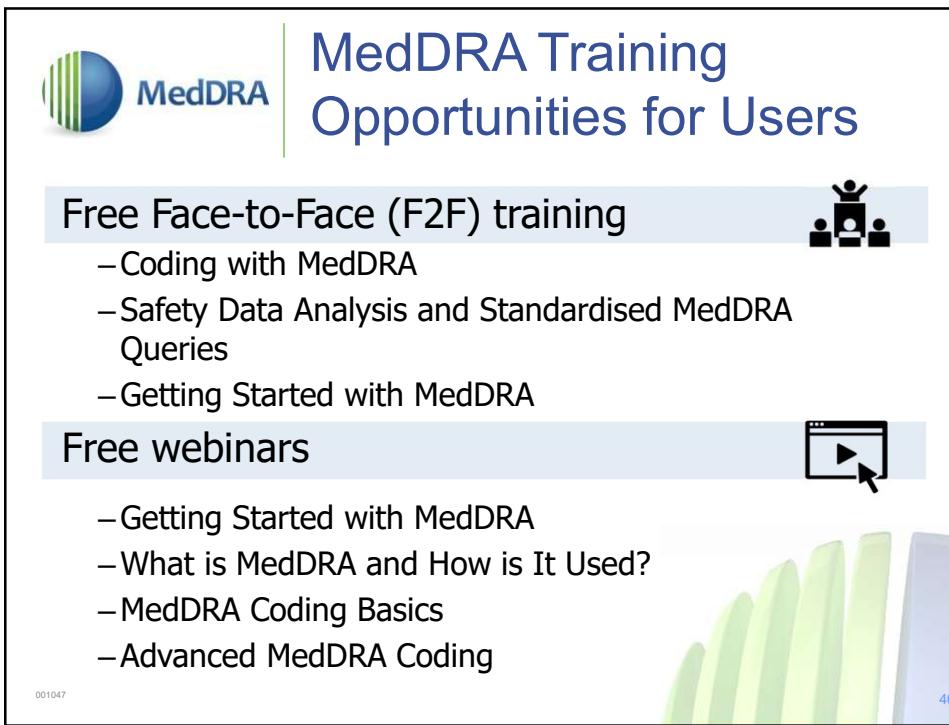
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MedDRA Training

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This slide features the MedDRA logo in the top left corner. The main title 'MedDRA Training' is centered in green text. In the bottom right corner, there is a small graphic of a bar chart with three bars: a green bar, a grey bar, and a blue bar, with the number '39' next to the blue bar. The slide has a light blue background with a vertical green bar on the right side.



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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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This slide is titled 'MedDRA Training Opportunities for Users' in blue text. It contains two main sections: 'Free Face-to-Face (F2F) training' and 'Free webinars', each with a list of topics. To the right of the 'Free Face-to-Face' section is a small icon of three people. To the right of the 'Free webinars' section is a small icon of a computer monitor with a play button. The slide has a light blue background with a vertical green bar on the right side.

 **MedDRA**

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**

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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A slide showing the MedDRA logo and the title "MedDRA Versioning". The slide features a decorative graphic of overlapping green and blue bars in the bottom right corner. The number "43" is visible in the bottom right corner of the slide area.



A Question You Might Be Asking

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A slide showing the MedDRA logo and the title "A Question You Might Be Asking". The slide features a large yellow question mark icon on the left and a hand holding a small white circular object. To the right, text reads: "I already have an old version of MedDRA. Why do I need to keep subscribing every year?" The slide features a decorative graphic of overlapping green and blue bars in the bottom right corner. The number "44" is visible in the bottom right corner of the slide area.



MedDRA

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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MedDRA

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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MedDRA

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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MedDRA

MSSO Contacts

- Website
 - www.meddra.org
- Email
 - mssohelp@meddra.org
- Frequently Asked Questions
 - www.meddra.org/faq
- MedDRA Browsers
 - <https://www.meddra.org/meddra-desktop-browsers> (Desktop Browser)
 - <https://tools.meddra.org/wbb/> (Web-Based Browser)
 - <https://mmb.meddra.org> (Mobile Browser)

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MedDRA

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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MedDRA

Question and Answer Session

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