



Getting Started with 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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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

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

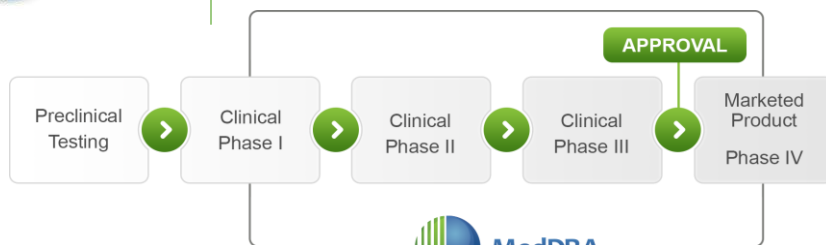
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MedDRA

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

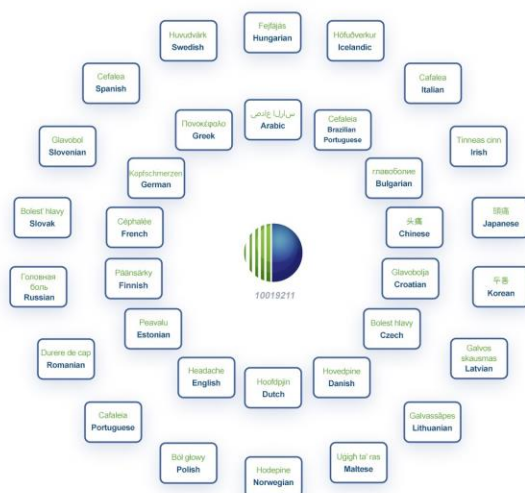
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MedDRA

Current and Planned MedDRA Translations



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MedDRA

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

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Who Uses MedDRA?

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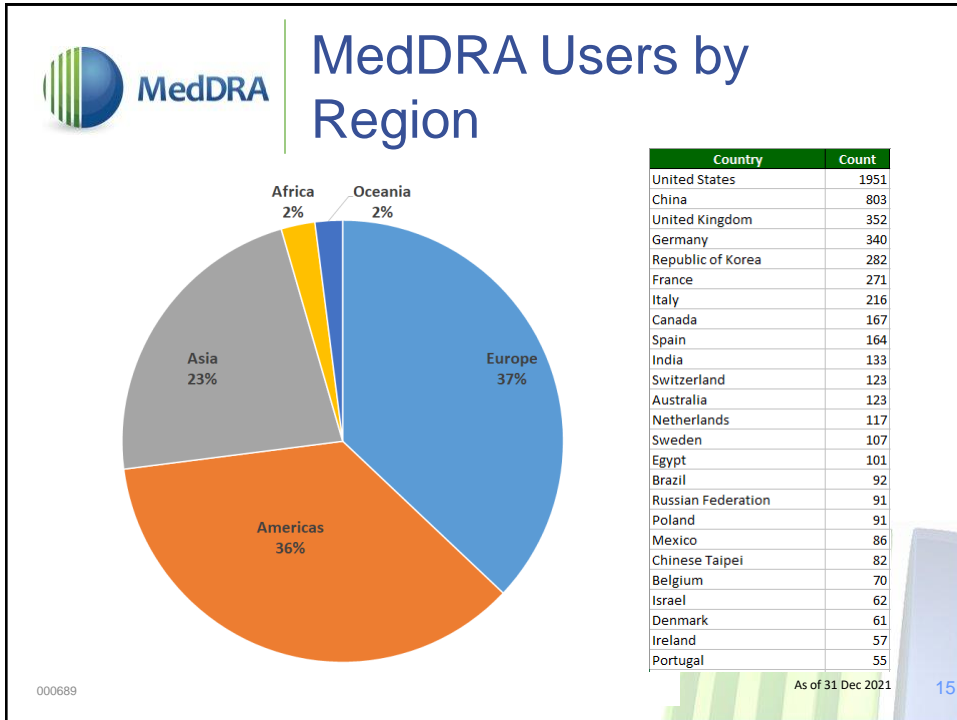
Global View



MedDRA is in 130 countries

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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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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 2022 Subscription Rates

MedDRA Subscription Types	2022 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)	\$154 USD
Level 1 (Annual Revenue \$1-\$10 Million)	\$654 USD
Level 2 (Annual Revenue \$10-\$20 Million)	\$2,496 USD
Level 3 (Annual Revenue \$20-\$500 Million)	\$4,727 USD
Level 4 (Annual Revenue \$500 Million-\$1 Billion)	\$9,918 USD
Level 5 (Annual Revenue \$1-\$5 Billion)	\$41,150 USD
Level 6 (Annual Revenue \$5-\$20 Billion)	\$54,334 USD
Level 7 (Annual Revenue > \$20 Billion)	\$70,889 USD
System Developer	\$2,556 USD

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Subscription Process

1. Go to MedDRA website (www.meddra.org)
2. Under Subscription, click on Online Subscription



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Subscription Process (cont)

3. Enter Organization Name
4. Select Organization Type
5. Select Subscription Type

The screenshot shows the 'Online Subscription' form on the MedDRA website. The form has three main sections: 'Organisation', 'Subscription Types', and 'Organisation Type'. The 'Organisation' section has a text field for 'Organisation Name' (containing 'MYPHARMA') and dropdowns for 'Street No.', 'City', and 'Country'. The 'Subscription Types' section has three radio buttons: 'Regulatory Authority', 'Non-Profit / Non-Commercial', and 'Commercial' (which is selected). The 'Organisation Type' section has a dropdown menu with options: 'Pharmaceutical', 'Academia', 'Biotechnology', 'Contract Research Organization', 'Government Non-Regulatory', 'Hospital', 'Individual', 'Medical Device', 'Non-Profit', 'Pharmaceutical', 'Regulator', 'Software Developer', and 'System Developer'. Blue arrows point to the 'Organisation Name' field, the 'Organisation Type' dropdown, and the 'Subscription Types' section.




MedDRA




Subscription Process (cont)

6. For all subscription types (except regulatory), MSSO requests documentation of organization type and annual revenue (if applicable)
 - User can attach a file or provide a web link for this information

Commercial ⓘ
Subscription for organisations that use MedDRA for commercial purposes. This includes biopharmaceutical companies and support service providers (e.g., CROs). Please provide a link to your company's financial information or attach a signed statement on your company's letterhead with your company's total revenue in PDF format.

No file selected  www.myfinancialinfo.com

Or paste a link to the appropriate web page

Add another   Add another link 

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MedDRA

Commercial License Financial Information

Letterhead

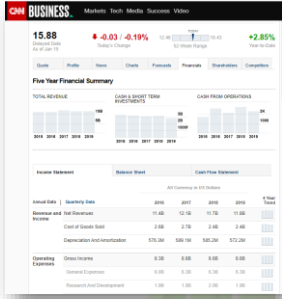
Or

English
USD

Signed

PDF

WWW





MedDRA

Subscription Process (cont)

7. Provide at least one Point of Contact (POC) for your organization
 - Many users have a primary POC and a billing POC (who receives MSSO invoices)

The screenshot shows a web form titled 'Contact Information'. It includes a 'Contact Type' dropdown menu with the text 'Select contact type'. Below this is a 'Contact details' section with fields for 'First Name', 'Last Name', 'Email', and 'Confirm Email'. There is a green '+' button labeled 'Add another Contact'. At the bottom, there is a 'Terms and Conditions' section with a link 'Read Terms & Conditions' and a checkbox 'I agree with Terms & Conditions'. The bottom of the form has a 'Submitting your Application Form' section with a blue 'Next' button.

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Subscription Process (cont)

8. All subscribers must review and agree to subscription Terms & Conditions (which protects MedDRA intellectual property)

The screenshot shows a web form titled 'Read Terms & Conditions'. It includes a checkbox 'I agree with Terms & Conditions' which is checked. Below this is a scrollable text area containing the following text: '1. This is a one year subscription, between Northrop Grumman International Trading Inc., incorporated in the State of Delaware, and the Subscriber, to MedDRA, continuing for twelve (12) calendar months following the enrollment date. The subscription will automatically renew for subsequent periods of one year each from the enrollment anniversary, unless either party gives the other notice of non-renewal at least sixty (60) calendar days before the end of any subsequent subscription term. Notwithstanding the foregoing, Northrop Grumman shall be entitled to give notice of non-renewal if renewal is prohibited by U.S. export law, subscriber is in breach of Subscription Agreement or for commercially reasonable reasons. The MedDRA subscription is available for use by the subscribing organization and any wholly-owned subsidiaries of the subscribing organization, provided the subscription can be made available to and used by such subscribing organization and wholly-owned subsidiaries in accordance with U.S. and any other applicable export control and/or sanctions laws and regulations. All prices shall remain unchanged during the initial subscription period. After the initial subscription period, Northrop Grumman will invoice the Subscriber at the then current applicable subscription fee. (to be...'. There is a 'Print' button at the bottom right.

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Subscription Process (cont)

9. MSSO reviews application and subscription level justification (e.g., commercial organizations may provide an annual report showing revenues)
10. Commercial or developer subscribers receive invoice

MSSO Invoice

MYPHARMA
Billing PoC

Service Date: 01 January 2021
Invoice #: 12345
Purchase Order:

Annual MedDRA Subscription Commercial Level 2

Subscription Rate	\$6,737.00
Sub Total	\$6,737.00
Service Total	\$6,737.00

Wire Payment Information
Please reference MedDRA Customer Order Number 220000012345 on payment.

Payment Terms: Due upon receipt.

Payment Method: Payments must be made in US Dollars. Checks and wire transfers are accepted forms of payment. If the wire transfer is coming through an international bank, please be aware that we may bank transfer fees with your payment.

SEND WIRE PAYMENTS TO:
MedDRA Customer International Trading, Inc.
MSSO
PO Box 2755
New York, NY 10007-7755
United States
Attention: MSSO MSSO
Bank: BSA & T (000001)
FIM: 00000000000000000000000000000000
Please reference order number 220000012345

FOR CHECK PAYMENTS:
MedDRA Customer International Trading, Inc.
PO Box 2755
New York, NY 10007-7755
United States
Attention: MSSO MSSO
Bank: BSA & T (000001)
FIM: 00000000000000000000000000000000
Please reference order number 220000012345

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Payment Methods

- For commercial users, payment is required before access is provided to MedDRA.
- For Commercial 0-2 and Developers, MSSO accepts credit card payments
- Organizations can also pay by bank transfer



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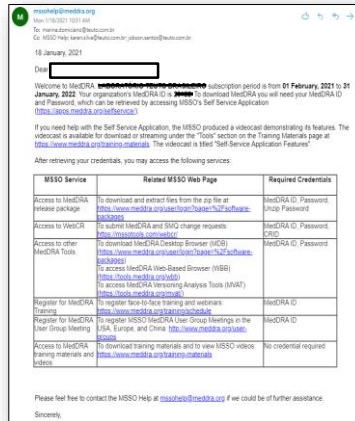
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Subscription Process (cont)

11. All new subscribers receive a Welcome Letter that provides MedDRA access instructions



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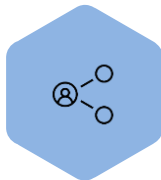
MedDRA

MedDRA Data Sharing



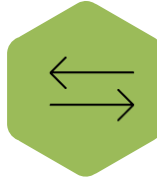
Access

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

The screenshot displays the MedDRA website's 'Subscription' page. The header includes the MedDRA logo and navigation links: Home, About MedDRA, How to Use, Training, Subscription (highlighted), News & Events, and a search bar. The main content area is titled 'Process / Subscription' and contains a paragraph about the governance of MedDRA. Below this, a section titled 'Here's how to subscribe to MedDRA:' lists nine steps for subscription. To the right, there are sections for 'Help Yourself' and 'Related Documents'.

Process / Subscription

Under the governance of the ICH MedDRA Management Committee, MedDRA is continuously enhanced to meet the evolving needs of all its users around the world. Sustainability of a high quality terminology needs an income stream and the ICH MedDRA Management Committee has opted for a licensing model that provides access to the terminology free of charge to regulatory authority, non-profit, direct patient care provider, educational institutes and at a fair cost shared by its commercial users through an annual subscription fee.

Here's how to subscribe to MedDRA:

1. If your organisation is headquartered in Japan, please contact the Japanese Maintenance Organization at <https://www.pmrj.jp/mo/ptp/indexe.php>, otherwise continue to Step 2.
2. Determine the type of subscription applicable for your organisation.
3. Determine the rate that is applicable for the subscription type.
4. Complete the online subscription form.
5. If you are requesting a commercial subscription, please upload an annual report or a signed statement from your organisation on letterhead describing total revenue or turnover for its most recently completed fiscal year.
6. Your subscription includes English, Chinese, Czech, Dutch, French, German, Hungarian, Italian, Portuguese, and Spanish. If you wish to purchase MedDRA in Japanese, please select Japanese under Additional Language at the bottom of the online subscription form page.
7. Submit your online subscription form.
8. You may save or print a copy of the completed subscription form after submission.
9. The MISO will email an invoice to the designated billing point of contact for payment if applicable. Upon receipt of payment, the MISO will provide the information to download MedDRA.

For subscription renewals complete the online renewal form.

Help Yourself
Get answers to some of your immediate questions via the MedDRA Self-Service Application

Contact the JMO to subscribe to MedDRA in Japan

Related Documents:
Overview of Services and Tools
How to share MedDRA data
Related Links:
Renewal Form
Subscription Form
Subscription Types
Subscription Rates
Special Licence Agreement



MedDRA Implementation Strategy



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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MedDRA

Organizational Implementation Strategy

- No single method for all organizations
- Implementation approach depends on factors such as size of organization
- MSSO provides many tools and resources to assist implementation

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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

Procedures

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Downloading MedDRA Release Files

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Downloading MedDRA Release Files



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

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

- This video can be streamed in English, Chinese, French, Korean, Spanish, and Russian

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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://mmb.meddra.org>

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MedDRA

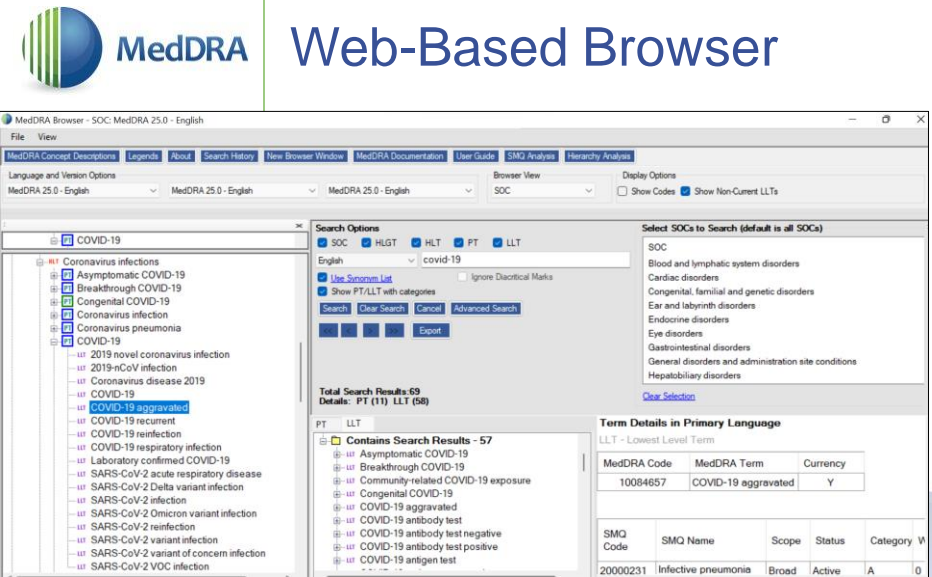
MSSO's MedDRA Browsers (cont)

- 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 screenshot displays the MedDRA Web-Based Browser interface. At the top left is the MedDRA logo. The main title is "Web-Based Browser". Below this is a navigation bar with tabs: "MedDRA Concept Descriptions", "Legends", "About", "Search History", "New Browser Window", "MedDRA Documentation", "User Guide", "SMQ Analysis", and "Hierarchy Analysis". The interface is divided into several sections:

- Language and Version Options:** MedDRA 25.0 - English, MedDRA 25.0 - English, MedDRA 25.0 - English, Browser View: SOC, Display Options: ☐ Show Codes, ☒ Show Non-Current LLTs.
- Search Options:** SOC, HLGT, HLT, PT, LLT. Search term: covid-19. Buttons: Search, Clear Search, Cancel, Advanced Search, Export.
- Select SOC to Search (default is all SOC's):** A list of System Organ Classes (SOCs) including 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.
- Search Results:** Total Search Results: 63. Details: PT (11), LLT (58). A list of results is shown, including "COVID-19 aggravated".
- Term Details in Primary Language:** LLT - Lowest Level Term. Table with columns: MedDRA Code, MedDRA Term, Currency. Row 1: 10084657, COVID-19 aggravated, Y.
- SMQ Table:** Table with columns: SMQ Code, SMQ Name, Scope, Status, Category. Row 1: 20000231, Infective pneumonia, Broad, Active, A, 0.

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The slide features the MedDRA logo and the title "Installing the MedDRA Desktop Browser". To the right is an icon of a laptop with a checkmark. The main content consists of two bullet points:

- There is an instructional video describing how to download the MedDRA Desktop Browser (MDB) and import release files into the MDB on the "Tools" section of the MedDRA Training Materials page on the website (www.meddra.org)
- This video can be streamed in English, Chinese, French, German, Korean, and Spanish

A URL is provided: <https://www.meddra.org/training-materials>

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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 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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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, and other languages with an available translation of the full MTS:PTC document)	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, and other languages with an available translation of the full DRP:PTC document)	Update as needed

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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.	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

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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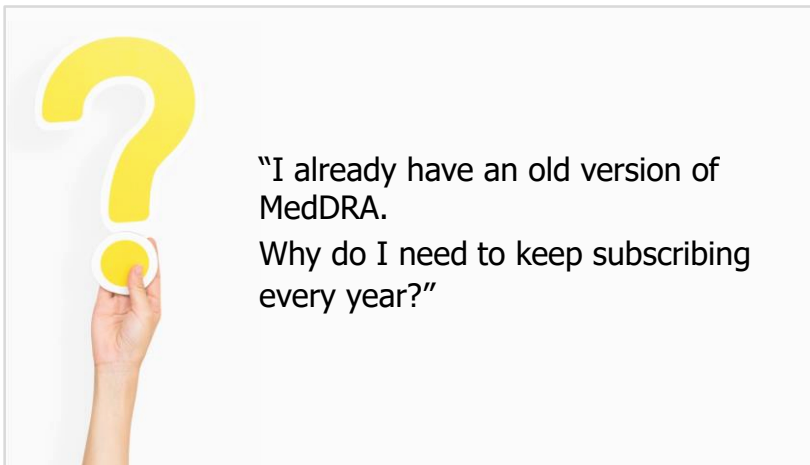
MedDRA Versioning

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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
- Appendix 4.1 Versioning in the MedDRA Term Selection: Points to Consider document
- MSSO videocast – MedDRA Version Updates
- 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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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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