



**MedDRA**  
Medical Dictionary  
for Regulatory Activities

# Getting Started with MedDRA



**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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MedDRA

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MedDRA

## 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

## 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 Management Committee (industry, regulators, multi-national, other interested parties)



**Educational offerings**  
Foster use of MedDRA through communications and educational offerings

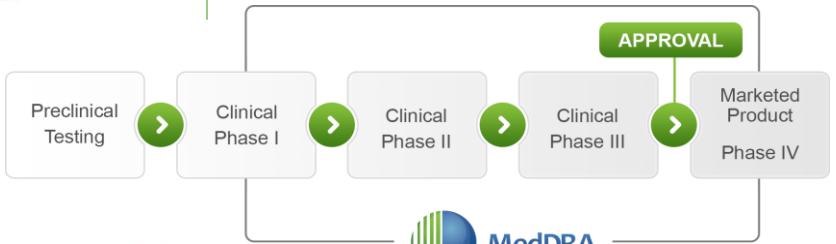


**JMO**  
Partner organization for Japanese-language MedDRA

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## Where MedDRA is Used





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

**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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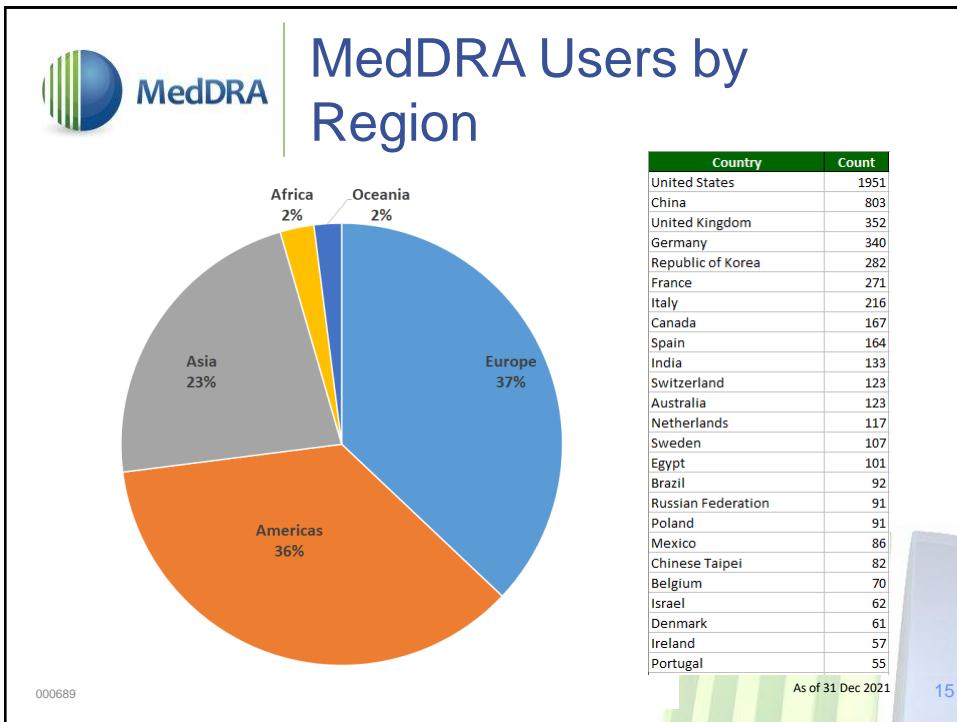
## Global View



MedDRA is in 130 countries

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## MedDRA 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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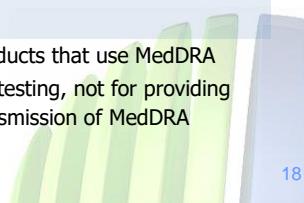


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## Types of MedDRA Subscriptions

- 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 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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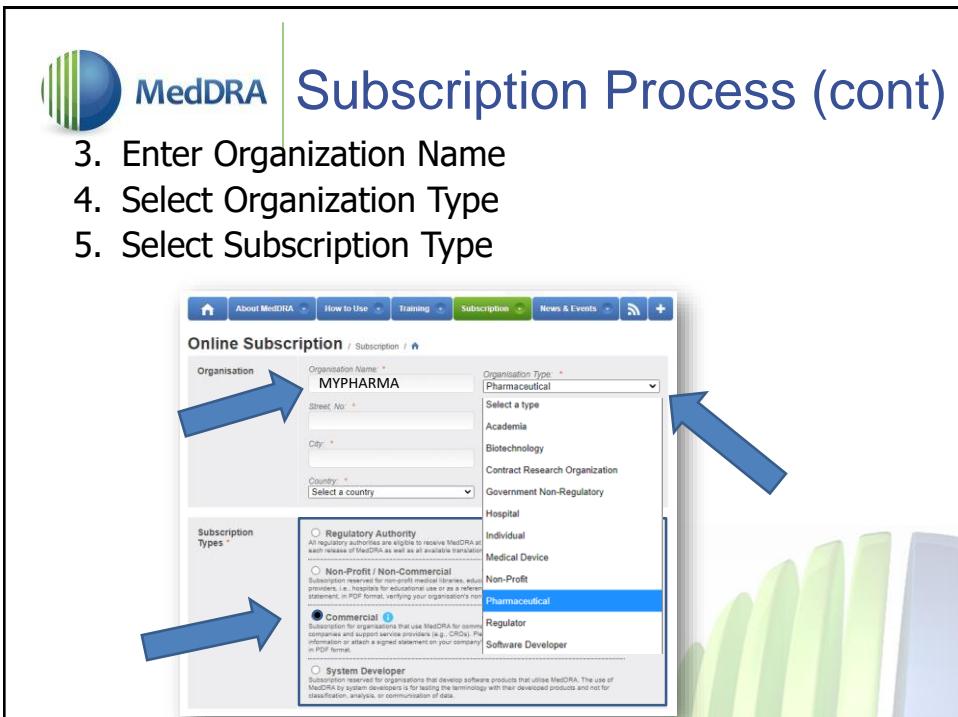
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**MedDRA** Subscription Process

1. Go to MedDRA website ([www.meddra.org](http://www.meddra.org))
2. Under Subscription, click on Online Subscription

The screenshot shows the MedDRA website homepage. The 'Subscription' menu item is highlighted in green. A blue arrow points to the 'Online Subscription' link under the 'Subscription' menu. The 'Online Subscription' page is visible on the right, showing sections for 'Process', 'Online Renewal', 'Subscription Types', 'Subscription Rates', and 'Special Licence'. A COVID-19 update box is also present. The page number '21' is visible in the bottom right corner.



**MedDRA** Subscription Process (cont)

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

The screenshot shows the 'Online Subscription' form. Blue arrows point to three specific fields: 'Organization Name' (containing 'MYPHARMA'), 'Organization Type' (set to 'Pharmaceutical'), and 'Subscription Types' (with 'Commercial' selected). The 'Subscription Types' section includes options for Regulatory Authority, Non-Commercial, Commercial (selected), and System Developer.



MedDRA

## Subscription Process (cont)

- 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** i  
 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](http://www.myfinancialinfo.com)

Or paste a link to the appropriate web page

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## Commercial License Financial Information

**Letterhead**

Or

**English**  
**USD**

**Signed**

**PDF**

The total income for MYPHARMA for the most recent fiscal period is 30.000.000 US dollars.

www

**Five Year Financial Summary**

Year	2016	2017	2018	2019	2020
Net Revenue	15.88	15.88	15.88	15.88	15.88
Net Income	-0.03	-0.19%	-0.19%	-0.19%	-0.19%
EPS	0.00	0.00	0.00	0.00	0.00
EPS Growth	+2.85%	+2.85%	+2.85%	+2.85%	+2.85%

**Income Statement**

Year	2016	2017	2018	2019	2020
Revenue	15.88	15.88	15.88	15.88	15.88
Cost of Goods Sold	2.00	2.00	2.00	2.00	2.00
Operating Expenses	5.00	5.00	5.00	5.00	5.00
Net Income	0.00	0.00	0.00	0.00	0.00
General Expenses	0.00	0.00	0.00	0.00	0.00
Research And Development	0.00	0.00	0.00	0.00	0.00



## 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)

<b>Contact Information</b>	
<b>Contact Type</b> * <input type="button" value="Select contact type"/>	
<b>Contact details</b>	
First Name * <input type="text"/>	Last Name * <input type="text"/>
Email  * <input type="text"/>	Confirm Email * <input type="text"/>
<hr/> <b>Add another Contact</b>	
<input data-bbox="928 679 950 691" type="button" value="+"/>	
<b>Terms and Conditions</b>	→ <a href="#">Read Terms &amp; Conditions</a>
	<input type="checkbox"/> I agree with <a href="#">Terms &amp; Conditions</a>
<hr/> <b>Submitting your Application Form</b>	
<input type="button" value="Next"/>	

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## MedDRA

## Subscription Process (cont)

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

→ [Read Terms & Conditions](#)  [I agree with Terms & Conditions](#)

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. Subscriptions are automatically renewed for subsequent consecutive 12 month periods, unless the Subscriber gives the other party the 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 increase the Subscribers of the then current applicable subscription fee by

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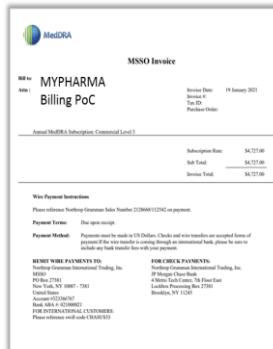
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## Subscription Process (cont)

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



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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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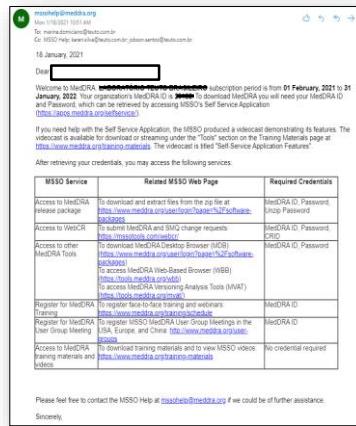
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## Subscription Process (cont)

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



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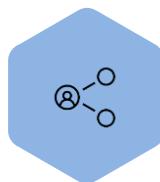
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## MedDRA Data Sharing



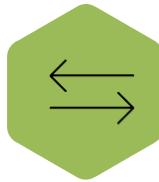
### Access

Subscription grants access to MedDRA for one year



### 3<sup>rd</sup> 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

Process / Subscription / [Help](#)

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 organization is headquartered in Japan, please contact the Japanese Maintenance Organization at <https://www.pmj.jp/jmojph/index.php>, otherwise continue to Step 2.
2. Determine the type of subscription applicable for your organization.
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 organization 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 MSSO will email an invoice to the designated billing point of contact for payment if applicable. Upon receipt of payment, the MSSO will provide the information to download MedDRA.

For subscription renewals complete the online renewal form.

WBB PIC Contact FAQs Downloads

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:](#)  
[Subscription Form](#)  
[Subscription Types](#)  
[Subscription Rates](#)  
[Special Licence Agreement](#)

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## MedDRA Implementation Strategy

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## 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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## 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

A photograph of an open book. The title 'Procedures' is printed on the cover. A page number '35' is visible on the right page. The book is set against a light background.

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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))

<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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**MSSO's MedDRA Browsers**



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



**Mobile MedDRA Browser**  
<https://mmb.meddra.org>



**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)


MedDRA

# Web-Based Browser

File View
MedDRA Concept Descriptions Legends About Search History New Browser Window MedDRA Documentation User Guide SMQ Analysis Hierarchy Analysis

Language and Version Options
Browser View
Display Options

MedDRA 25.0 - English
MedDRA 25.0 - English
MedDRA 25.0 - English
SOC

Show Codes
 Show Non-Current LLTs

COVID-19
 

- [Coronavirus infections](#)
- [Asymptomatic COVID-19](#)
- [Breakthrough COVID-19](#)
- [Congenital COVID-19](#)
- [Coronavirus infection](#)
- [Coronavirus pneumonia](#)
- [COVID-19](#)
  - [2019 novel coronavirus infection](#)
  - [2019-nCoV infection](#)
  - [Coronavirus disease 2019](#)
  - [COVID-19](#)
  - [COVID-19 aggravated](#)
  - [COVID-19 recurrent](#)
  - [COVID-19 reinfection](#)
  - [COVID-19 respiratory infection](#)
  - [SARS-CoV-2 and COVID-19](#)
  - [SARS-CoV-2 acute respiratory disease](#)
  - [SARS-CoV-2 Delta variant infection](#)
  - [SARS-CoV-2 infection](#)
  - [SARS-CoV-2 Omicron variant infection](#)
  - [SARS-CoV-2 reinflection](#)
  - [SARS-CoV-2 variant infection](#)
  - [SARS-CoV-2 variant of concern infection](#)
  - [SARS-CoV-2 VOC infection](#)

**Search Options**

SOC
 HLGT
 HLT
 FT
 LLT

Use Synonyms List
 Show PT-LLT with categories
 Ignore Diacritical Marks

Search
Clear Search
Cancel
Advanced Search

Expert
Print
Copy
Print

Total Search Results: 69

Details: PT (11) LLT (58)

PT	LLT
<input type="checkbox"/> Contains Search Results - 57 <ul style="list-style-type: none"> <li><input type="checkbox"/> <a href="#">Asymptomatic COVID-19</a></li> <li><input type="checkbox"/> <a href="#">Breakthrough COVID-19</a></li> <li><input type="checkbox"/> <a href="#">Community-related COVID-19 exposure</a></li> <li><input type="checkbox"/> <a href="#">Congenital COVID-19</a></li> <li><input type="checkbox"/> <a href="#">COVID-19 aggravated</a></li> <li><input type="checkbox"/> <a href="#">COVID-19 antibody test</a></li> <li><input type="checkbox"/> <a href="#">COVID-19 antibody test negative</a></li> <li><input type="checkbox"/> <a href="#">COVID-19 antibody test positive</a></li> <li><input type="checkbox"/> <a href="#">COVID-19 antigen test</a></li> </ul>	

Term Details in Primary Language

LLT - Lowest Level Term

MedDRA Code	MedDRA Term	Currency
10008457	COVID-19 aggravated	Y

SMQ Code	SMQ Name	Scope	Status	Category	V
20000231	Infective pneumonia	Broad	Active	A	0

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# Installing the MedDRA Desktop Browser



- 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](https://www.meddra.org))  
<https://www.meddra.org/training-materials>
- This video can be streamed in English, Chinese, French, German, Korean, and Spanish



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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](http://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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## 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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## 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 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 – 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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## 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](http://www.meddra.org)
- Email
  - [mssohelp@meddra.org](mailto:mssohelp@meddra.org)
- Frequently Asked Questions
  - [www.meddra.org/faq](http://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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## Question and Answer Session

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