



MedDRA
Medical Dictionary
for Regulatory Activities

What's New with MedDRA Version 28.1 and the MSSO



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MedDRA

Webinar Introduction



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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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MedDRA

Topics

- What's New with MedDRA Version 28.1
 - Summary of Changes (including SMQs)
- Version 28.1 Addition Highlights
- Proactive Maintenance
- MedDRA Translations
- Update on *Points to Consider (PtC)* Documents
- Update on MedDRA Mapping Initiatives
- Information Technology Tools Update
- Upcoming Events
- Question and Answer Session

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MedDRA

What's New with MedDRA Version 28.1

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 **MedDRA Version 28.1**

- Release on 1 September 2025
- A simple release
 - Changes at PT and LLT level only
 - No changes at SOC, HLGT, or HLT level
- Change request summary:
 - MSSO considered 1,412 change requests, including SMQ requests (not including translation updates)
 - Approved: 1,032
 - Not approved: 367
 - Suspended: 13
- Changes reflect the differences between v28.0 and v28.1

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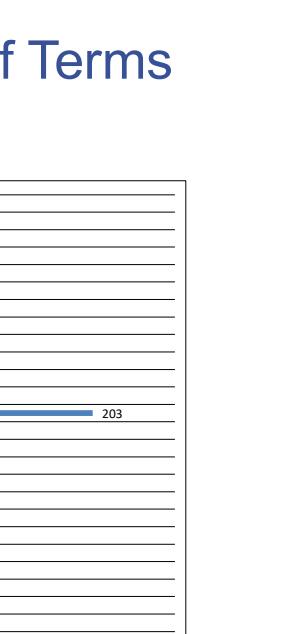


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 **Net Change of Terms per SOC**

SOC Category	Net Change of Terms
Blood and lymphatic system disorders	34
Cardiac disorders	45
Congenital, familial and genetic disorders	100
Ear and labyrinth disorders	4
Endocrine disorders	45
Eye disorders	53
Gastrointestinal disorders	79
General disorders and administration site	22
Hepatobiliary disorders	9
Immune system disorders	24
Infections and infestations	58
Injury, poisoning and procedural complications	73
Investigations	203
Metabolism and nutrition disorders	46
Musculoskeletal and connective tissue disorders	46
Neoplasms benign, malignant and unspecified	86
Nervous system disorders	80
Pregnancy, puerperium and perinatal conditions	28
Product issues	16
Psychiatric disorders	31
Renal and urinary disorders	26
Reproductive system and breast disorders	25
Respiratory, thoracic and mediastinal disorders	74
Skin and subcutaneous tissue disorders	30
Social circumstances	6
Surgical and medical procedures	164
Vascular disorders	57

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Summary of Standardized MedDRA Query (SMQ) Changes

- No new SMQs added in Version 28.1
- As of MedDRA 28.1, there are 110 SMQ Topics
 - Some SMQs are hierarchical (containing subordinate SMQs) which increases the total to 230 individual SMQs
- Maintained with each release of MedDRA
 - 225 PT changes (adds, modifications to existing terms) in MedDRA 28.1
- If you have a need for a new SMQ, use the MSSO [WebCR tool](#) to submit a request
- See MedDRA Version 28.1 SMQ Introductory Guide for detailed information on all SMQs

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Version 28.1 Addition Highlights

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New CAR T-cell Investigation Terms

- CAR T-cell therapies use genetically modified T-cells to target tumor cells
- New investigation terms have been added to describe specific testing in research and monitoring
- These tests help to:
 - Check if CAR T-cells are expanding as expected
 - Measure the number and location of modified cells
 - Ensure the genetic modification is safe
 - Detect risks like uncontrolled cell proliferation

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Examples of CAR T-cell Investigation Terms

- LLT *CAR T-cell expansion in peripheral blood*
- LLT *CAR transgene level by in-situ hybridization*
- LLT *CAR transgene level by quantitative PCR*
- LLT *Insertion site analysis*
- LLT *Short tandem repeat test for chimerism*

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Corneal epitheliopathy



Ophthalmologic Terms Are >5% of Version 28.1 Additions

- These terms span a wide range of eye conditions, diagnostic techniques, and surgical procedures including:

Type of Term	Example
Conditions of the cornea and front of eye	PT <i>Corneal epitheliopathy</i>
Conditions of the posterior eye globe	LLT <i>Silicone particles in vitreous</i>
Disorders of the optic nerve and retina	LLT <i>Posterior ischemic optic neuropathy</i>
Procedural terms	LLT <i>Descemet membrane endothelial keratoplasty</i>
Diagnostic tools and imaging techniques	LLT <i>Scanning laser ophthalmoscopy</i>

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Proactive Maintenance

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Proactivity Request Review

- Proactive maintenance process allows users to highlight inconsistencies or suggest corrections and improvements
- Prior examples included:
 - Review placement of "abrasion" terms
 - Review placement of dental restoration terms
 - Add chemical burn "grade" terms (e.g., first degree) to MedDRA
- There were no new proactivity proposals implemented in Version 28.1
- Proposals should be sent to mssohelp@meddra.org
- Providing a detailed justification is helpful in evaluation of your request

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MedDRA Translations

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MedDRA Translations

Available MedDRA Translations (27)		
Arabic	Brazilian Portuguese	Chinese
Croatian	Czech	Dutch
English	Estonian	Finnish
French	German	Greek
Hungarian	Icelandic	Italian
Japanese	Korean	Latvian
Lithuanian	Norwegian	Polish
Portuguese	Russian	Slovak
Slovenian	Spanish	Swedish
Translations Under Development		
Bulgarian	Danish	Maltese
Romanian	Uzbek	

- Norwegian, Slovak, and Slovenian translations expected around time of Version 28.1 implementation
- Uzbek was recently added to the list of translations under development

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French Translation Update

- MSSO identified a French terminology reference (Terminologia Anatomica or TA) endorsed by the official reference for the French medical dictionary (Académie de médecine)
- MSSO consulted with French speaking regulatory authorities and they agreed that this is the appropriate reference
- MSSO updated the existing French translation using this reference

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Transition of the French version of MedDRA to TA

- About 1,400 MedDRA terms will be renamed using TA
- Examples:
 - PT Fibrillation auriculaire -> PT Fibrillation atriale
 - PT Fracture de la rotule -> PT Fracture de la patella
- Implemented in MedDRA Version 28.1

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Update on *Points to Consider* (PtC) Documents



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New Training Video Available

- MedDRA Points to Consider Companion Document (CD) Release 3.0, September 2024
 - Addition of new Section 5: Manufacturing and Quality System Issues
- Training developed to help users better understand this new content in CD
- Videocast with recorded Q&A session
 - Provides guidance on coding specific product manufacturing deviations and non-conformances
 - Practical coding examples related to manufacturing and quality system issues

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MedDRA.org “Instructional Videos” Page

Instructional Videos / Training / [Home](#)

How To...	
Topic	Language
How to Get Started with MedDRA	Chinese / English / French / Korean / Russian / Spanish
How to Download MDB and Upload MedDRA Files	Chinese / English / French / German / Korean / Russian / Spanish
How to Download MedDRA Release Files	Chinese / English / French / Korean / Russian / Spanish
How to Find and Register for MedDRA Trainings	Chinese / English / French / Korean / Russian / Spanish
How to Submit a Change Request	Chinese / English / French / Korean / Russian / Spanish
How to Submit an Online MedDRA Subscription	Chinese / English / French / Korean / Russian / Spanish
How to Use the SSA (Self-Service Application)	Chinese / English / French / Korean / Russian / Spanish
How to Use the WEB (Web Based Browser)	English

Coding Manufacturing and Quality System Issues with MedDRA	
Topic	Language
Coding Manufacturing and Quality System Issues with MedDRA	English

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Update on MedDRA Mapping Initiatives



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SNOMED CT – MedDRA Mapping

- Latest release published on 30 April 2025, based on:
 - MedDRA v27.1 (September 2024)
 - January 2025 release of SNOMED CT International Edition
 - Most changes in this release come as a result of changes in SNOMED CT and MedDRA that allow new or improved mappings
- Updated annually (next release April 2026)
- Bi-directional mapping



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ICD-10 to MedDRA Mapping

- Latest release published on 24 June 2025, based on:
 - WHO 2019 International Core Version of ICD-10
 - MedDRA v28.0 (March 2025)
- Updated twice annually (next due January 2026)
- Changes in the latest release include:
 - Remapping of 11 ICD-10 terms to a better matching MedDRA Lowest Level Term (LLT)
 - New mappings of 125 ICD-10 terms that were previously designated as out of scope or unmapped

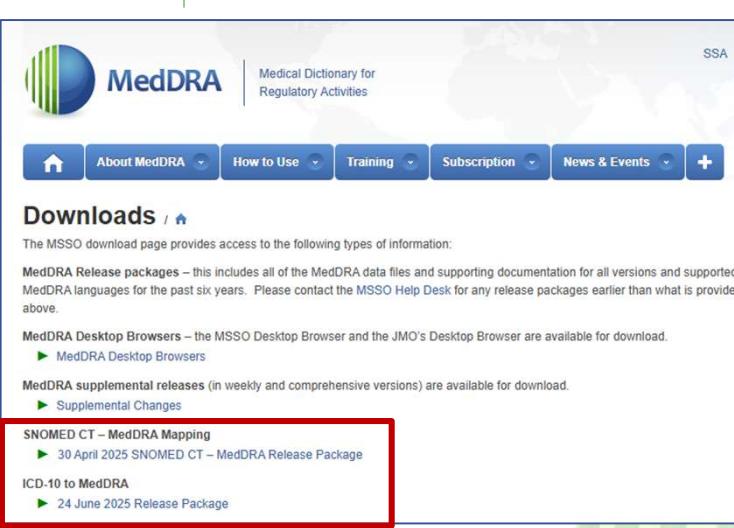
Mapping contains ~11K terms

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MedDRA.org “Downloads” Page



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

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

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

- ▶ MedDRA Desktop Browsers

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

- ▶ Supplemental Changes

SNOMED CT – MedDRA Mapping

- ▶ 30 April 2025 SNOMED CT – MedDRA Release Package

ICD-10 to MedDRA

- ▶ 24 June 2025 Release Package

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IMDRF* to MedDRA Mapping

- Updated **Annex E** (Clinical Signs and Symptoms or Conditions) published on IMDRF website on 3 March 2025 with updated mapping from Annex E to MedDRA

IMDRF code: IMDRF/AE WG/N43FINAL:2025 Updated Annexes (Release No. 2025) Published date: 3 March 2025

JSON Format
↓ Annex A: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Medical Device Problem
JSON (171.89 kb)

JSON Format
↓ Annex E: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Health Effects - Clinical Signs and Symptoms or Conditions
JSON (419.01 kb)

- IMDRF and ICH (with MSSO support) to extend the IMDRF mappings to map IMDRF **Annex A** (Medical Device Problem) to MedDRA

*International Medical Device Regulatory Forum

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Information Technology Tools Update

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MedDRA Desktop Browser (MDB) Update

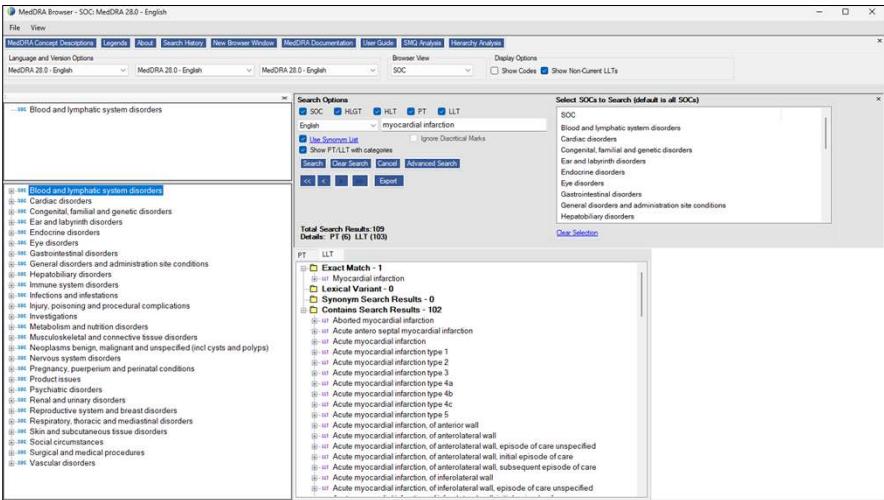
- Update to match the interface changes made in the new Web-Based Browser (WBB)
 - A simpler look
 - Optimizing for search and display of search results
 - Kept all functions in legacy MDB
 - Hierarchy Analysis
 - SMQ Analysis
- Released in July 2025
- Legacy MDB 4.1 will continue to be available

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Legacy MDB User Interface



The screenshot shows the MedDRA Browser interface with the search term 'myocardial infarction' entered. The search results pane displays 109 results, with 97 being 'Exact Match' and 2 being 'Lexical Variant'. The results list includes various medical terms such as 'Acute myocardial infarction', 'Myocardial infarction', and 'Myocardial infarction, initial episode of care'. A 'Select SOCs to Search' dialog box is open, listing categories like 'Blood and lymphatic system disorders', 'Cardiovascular disorders', and 'Endocrine disorders'.

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MedDRA Browser - SOC: MedDRA 28.0 - English

Language and Version Options
MedDRA 28.0 - English SDC SMQ X

Search: myocardial infarction Total Search Results: 109 Details: PT (6) LLT (109)

PT : 6 LLT : 109

Exact Match - 1
Lexical Variant - 0
Synonym - 0
Contains - 102

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MedDRA | Accessing New MDB 5.0

- From meddra.org website Tools Page
- Login required

MedDRA Desktop Browsers / [About MedDRA](#)

MedDRA Desktop Browser Version 5.0

The latest version of the MedDRA Desktop Browser includes the following enhancements:

- SMQ Analysis
- Hierarchy Analysis
- Exporting data in all user-selected languages
- Advanced Search capability
- Secondary SOC path extraction

Download the MedDRA Desktop Browsers

[MDB 5.0](#) (highlighted)

[MDB 4.1](#)

[MedDRA/J Browser](#)

Related Links

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Download Application Programming Interface (API)

- Over 600 organizations are using or testing with the MedDRA APIs the MSSO created
- In 2025 (expected in early 4th quarter), a new Download API will be deployed
 - Download MedDRA data files in .asc or JSON format (e.g., llt.asc, pt.asc)
 - Download files in all supported languages
 - Includes mappings as separate download
- Will be assessed as a GxP (good practice) API
- Zip files with .asc data will continue to be produced

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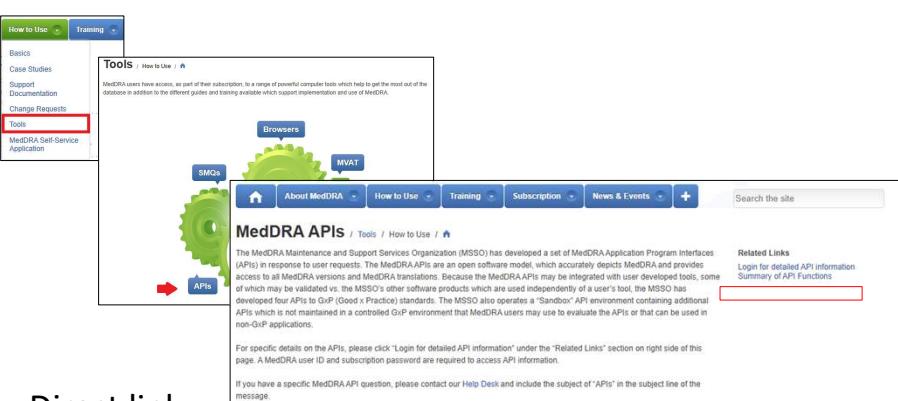
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API Information

- Where can I go to find information on the APIs?



Direct link:

<https://www.meddra.org/meddra-apis>

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Upcoming Events



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Latin America User Group Meeting

- Meeting Type: In person
- Date: 02 September 2025
- Location: São Paulo, Brazil
- Time: 9:00 to 17:30 Brasília Time
- Meeting Language: Brazilian Portuguese
- Registration for this meeting is closed. If you wish, you may go to "MSSO Events" page and sign up for the "Waiting List" in case additional seats become available

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Korean MedDRA – WHODrug Joint User Group Meeting

- Meeting Type: In person
- Date: 13 November 2025
- Location: Seoul, South Korea
- Time: 10:00 to 16:30 Korean Standard Time
- Meeting Language: Korean
- Registration: Registration portal is now open on the “MSSO Events” page of the MedDRA website when available

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Indian User Group Meeting

- Meeting Type: In person
- Date: 17 February 2026
- Location: Hyderabad, India (site to be determined)
- Time: 9:00 to 17:00 Indian Standard Time
- Meeting Language: English
- Registration: More details to be posted to “MSSO Events” page on MedDRA website when available

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MedDRA Booth Exhibits at Upcoming Meetings

Meeting	Meeting Details
7 th International Society of Pharmacovigilance (ISoP) Latin American Chapter Symposium	20-22 August 2025 Merida, Mexico Booth #4
KoNECT International Conference	22-24 September 2025 Seoul, Republic of Korea Booth #42
International Society of Pharmacovigilance (ISoP) 2025 Annual Meeting	24-27 October 2025 Cairo, Egypt Booth: To be announced
Society of Clinical Data Management	4-6 December 2025 Hyderabad, India Booth #5

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Thank You!

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