MedDRA
Medical Dictionary for Regulatory Activities

What's New with MedDRA Version 28.0 and the MSSO

ICH harmonisation for better health 1

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MedDRA

Webinar Introduction

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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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Topics

- What's New with MedDRA Version 28.0
  - –Summary of Changes (including SMQs)
- Proactive Maintenance
- MedDRA Translations
- Update on *Points to Consider (PtC)* Documents
- Update on MedDRA Mapping Initiatives
- MSSO Staff Update
- MedDRA Data Sharing

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Topics (cont)

- Web-Based Browser (WBB) Update
- Training Update – MedDRA Learning Management System (LMS)
- Upcoming Meetings

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What's New with MedDRA Version 28.0

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MedDRA Version 28.0

- Release on 1 March 2025
- A complex release
  - Potential changes at all five levels of MedDRA
- Change request summary:
  - MSSO considered 1,620 change requests, including SMQ requests (not including translation updates)
    - Approved: 1,207
    - Not approved: 411
    - Suspended: 2
- Changes reflect the differences between v27.1 and v28.0

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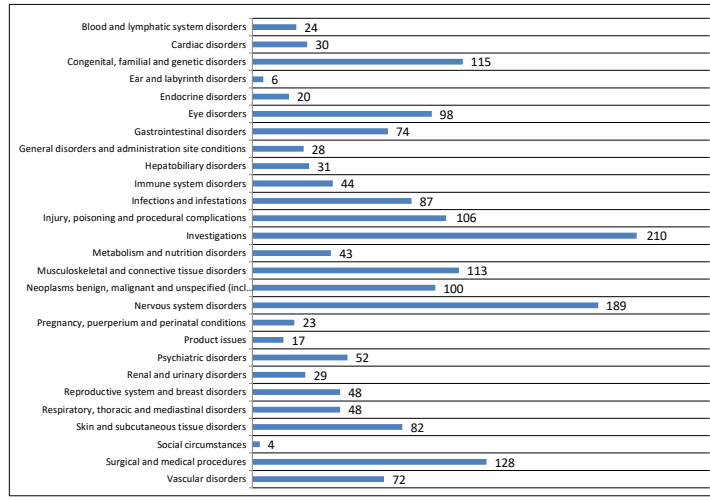
Net Change of Terms per SOC



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Summary of Complex Changes

- No changes at SOC or HLGT levels
- In Version 28.0, two HLTs were added and an existing HLT was merged
- HLT change summary:
  - 2 new

New HLT	To SOC
Quality system issues	Product issues
Rhabdoviral infections	Infections and infestations

  - 1 merged

HLT	To HLT	To SOC
Rabies viral infections	Rhabdoviral infections	Infections and infestations

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Summary of Standardized MedDRA Query (SMQ) Changes

- No new SMQs added in Version 28.0
- As of MedDRA 28.0, 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
  - 289 PT changes (adds, modifications to existing terms) in MedDRA 28.0
- The *Neurodevelopmental Disorders (SMQ)* Expert Working Group has decided not to develop this topic into an SMQ because of methodologic and data interpretation concerns, they will prepare a summary report which will be posted to the MedDRA website

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Summary of SMQ Changes (cont)

- If you have a need for a new SMQ, use the MSSO WebCR tool to submit a request
- See MedDRA Version 28.0 SMQ Introductory Guide for detailed information on all SMQs

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Version Report

Report Title	Total Unique Terms between selected versions
New LLTs including New PTs	789
New PTs	291
Promotions	23
Demotions	35
LLTs under different PTs	151
LLT (excl PT) Primary SOC Chg	17
PT Primary SOC Changes	5
MedDRA Term Name Changes	1
MedDRA Code Switches	0
Currency Changes	2
Complex Changes	3
SMQ Changes	0
PT Changes in SMQs	289
LLT Changes in SMQs	678

Proactive Maintenance

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
- Proposals should be sent to mssohelp@meddra.org
- Providing a detailed justification is helpful in evaluation of your request

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Proactivity Request Review (cont)

- Two proactivity requests implemented in MedDRA v28.0
- A user asked for a review of term placement under HLT *Sexuality issues*. Following our review, LLT *Not sexually active* was moved under PT *Sexual abstinence* for better placement.
- A user requested a review of terms under HLGT *Sleep disorders and disturbances* for improved and consistent placement. Following our review, 23 changes were implemented including addition of a new PT *Sleep-related breathing disorder*. Please see batch #20119771 in WebCR for complete details.

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MedDRA Translations

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MedDRA Translations

Available MedDRA Translations (24)		Under Development
Arabic	Hungarian	Bulgarian
Brazilian Portuguese	Icelandic – October 2024	Danish
Chinese	Italian	Maltese
Croatian	Japanese	Norwegian
Czech	Korean	Romanian
Dutch	Latvian	Slovak
English	Lithuanian	Slovenian
Estonian	Polish	
Finnish	Portuguese	
French	Russian	
German	Spanish	
Greek	Swedish	

- Many of the newer EU translations support electronic Prescribing Information Initiative

001201

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Update on *Points to Consider (PtC)* Documents

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Version and Date Change MTS:PTC

MedDRA® TERM SELECTION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users

Release 4.~~24~~25

March ~~20242~~2025

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Summary of Changes for Version 28.0 MTS:PTC

- MTS:PTC
  - Sections: 3.2 Death and Other Patient Outcomes and 3.3.3 Fatal suicide attempt
    - Clarification of the wording on outcomes and seriousness criteria
  - Section 3.28.1
    - Minor editorial change

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Version and Date Change DRP:PTC

MedDRA® DATA RETRIEVAL AND PRESENTATION: POINTS TO CONSIDER

ICH-Endorsed Guide for MedDRA Users on Data Output

Release 3.245

March 20245

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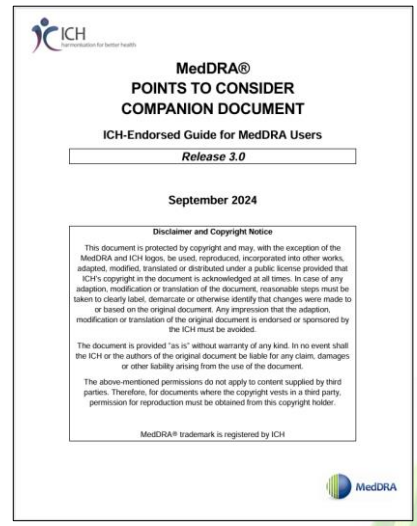
Summary of Changes for Version 28.0 DRP:PTC

- DRP:PTC
  - Section 2.6 Versioning
    - Editorial change: Removal of the reference to the MedDRA versioning description in MTS:PTC

PtC Companion Document



ICH

MedDRA®
POINTS TO CONSIDER
COMPANION DOCUMENT

ICH-Endorsed Guide for MedDRA Users

Release 3.0

September 2024

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MedDRA

PTC Companion Document Release 3, September 2024

- Changes made to existing sections:
  - Section 1 Introduction
  - Section 2 Data Quality
  - Section 3 Medication Errors
  - Section 4 Product Quality Issues
- New Section 5 added: Manufacturing and Quality System Issues
  - Provides guidance on coding specific product manufacturing deviations and non-conformances
  - Examples on how specific scenarios can be coded

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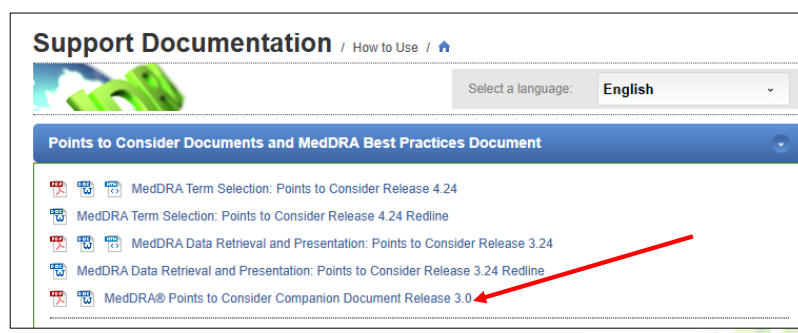
PTC Companion Document



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Update on MedDRA Mapping Initiatives

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SNOMED CT – MedDRA Mapping

- Latest release published on 30 April 2024
  - Based on:
    - MedDRA v26.1 (September 2023)
    - January 2024 release of SNOMED CT International Version
- Changes coming from SNOMED CT and MedDRA maintenance updates
- Updated annually (next release April 2025)
- Bi-directional mapping

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ICD-10 to MedDRA Mapping

- Latest release published on 28 January 2025, based on:
  - WHO 2019 International Core Version of ICD-10
  - MedDRA 27.1 September 2024
- Updated twice annually (next due June 2025)

Mapping contains ~11K terms

ICD-10 Chapter Number 2019 International Core Version	ICD-10 Chapter 2019 International Core Version	ICD-10 Code 2019 International Core Version	ICD-10 Term 2019 International Core Version	Mapped MedDRA LLT v27.1	Mapped MedDRA LLT Code v27.1	Map Attribute	MedDRA PT v27.1	MedDRA PT Code v27.1
I	Certain infectious and parasitic diseases	A00	Cholera	Cholera	10008631	Equivalent	Cholera	10008631
I	Certain infectious and parasitic diseases	A06.1	Chronic intestinal amoebiasis	Intestinal amoebiasis	10062811	Loss of Information	Amoebic dysentery	10001986
XX	External causes of morbidity and mortality	W49	Exposure to other and unspecified inanimate mechanical forces	None		Unmapped	None	

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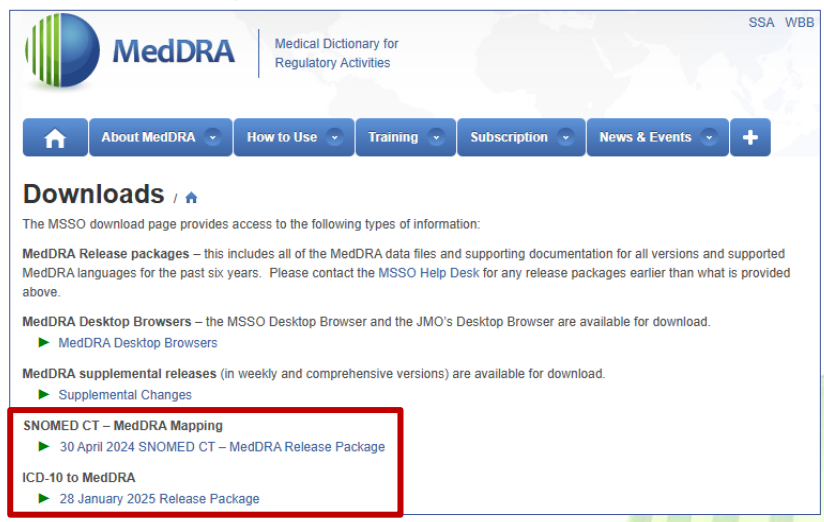
MedDRA.org Downloads Page



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ICD-11 – MedDRA Mapping

- Continuation of joint activities between WHO and ICH with MSSO supporting to develop ICD-11 to MedDRA mappings
- Currently developing ICD-11 to MedDRA mapping with different system chapters

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IMDRF to MedDRA Mapping

- The International Medical Device Regulators Forum (IMDRF) has developed harmonized terminologies for reporting adverse events related to medical devices
  - Annex E (Health Effects – Clinical Signs, Symptoms and Conditions Terms and Codes) mapped to MedDRA in a collaborative effort between IMDRF and ICH
- Annex E with the corresponding MedDRA terms and codes is available on the IMDRF website
- Next update is expected in March 2025

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MedDRA Mapping Reference

Mapping	Description	Maintenance	Availability
SNOMED CT and MedDRA	Bi-directional mapping of a subset of high frequency pharmacovigilance terms between SNOMED CT and MedDRA	Cooperatively maintained by SNOMED International and the MSSO	Software packages | MedDRA
ICD-10 to MedDRA	Uni-directional mapping of WHO 2019 international core version of ICD-10 to MedDRA	Cooperatively maintained by WHO and the MSSO	Software packages | MedDRA
WHO-ART Bridge	Maps WHO-ART Included Terms to MedDRA LLTs	MSSO updates the mapping with each release of MedDRA	Contact the MSSO Help Desk MSSOHelp@meddra.org
Common Terminology Criteria for Adverse Events (CTCAE)	Terminology developed by the US National Cancer Institute (NCI) utilized for Adverse Event reporting. A grading (severity) scale is provided for each AE term. Each term listed is a MedDRA LLT.	Maintained by US National Cancer Institute	https://ctep.cancer.gov/protocoldevelopment/electronic_applications/ctc.htm
NICHD Pediatric Adverse Events Terminology	Pediatric Adverse Events Terminology Subset Mapped to MedDRA LLTs	Maintained by the US National Institute of Child Health and Human Development (NICHD)	https://evs.nci.nih.gov/ftp1/Pediatric_Terminologies/NICHD/About.html
International Medical Device Regulators Forum (IMDRF)	Clinical Signs, Symptoms and Conditions terms/codes (Annex E) provides terminology to describe the observed condition of the affected persons associated with the medical device adverse event. Terms are mapped to MedDRA LLTs.	IMDRF maintains Annex E in coordination with input for MedDRA from the MSSO Next release is scheduled for March 2025	https://www.imdrf.org/documents/terminologies-categorized-adverse-event-reporting-aer-terms-terminology-and-codes
International Neonatal Consortium (INC) Neonatal AE Severity Scale (NAESS)	International Neonatal Consortium (INC) developed a neonatal adverse event severity scale to help researchers use a common approach when reporting adverse events. Each term is mapped to a MedDRA LLT.	Updates produced by International Neonatal Consortium (INC)	https://evs.nci.nih.gov/ftp1/Pediatric_Terminologies/INC/About.html
Maternal and Fetal Adverse Event Terminology (MFAET)	A system of definitions and grading of maternal and fetal adverse events. Each term includes a definition, a MedDRA LLT, and a severity scale.	Maintained by the EVERREST International Adverse Event Consensus Group	https://www.ucl.ac.uk/womens-health/research/maternal-and-fetal-medicine/prenatal-therapy/current-projects-professor-anna-david-0

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MSSO Staff Update

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New MSSO Staff

- Nicolas Thiry joins the MSSO to provide French translation support, training, and local support
  - Pharmacovigilance expert with over 20 years of experience
  - Founded Telos-C, a medical data coding company
  - Based in Belgium

MSSO Training Staff

MedDRA Data Sharing

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MedDRA Data Sharing

- New to MedDRA and/or not sure about MedDRA data sharing rules?
  - MedDRA subscription is an enterprise license meaning anyone within your organization can use MedDRA and MSSO tools
  - MedDRA cannot be shared with unlicensed third parties
  - You can check the MedDRA subscription status of business partners with the MSSO's Self Service application
  - More information is available in the MedDRA Data Sharing document

Web-Based Browser (WBB) Update

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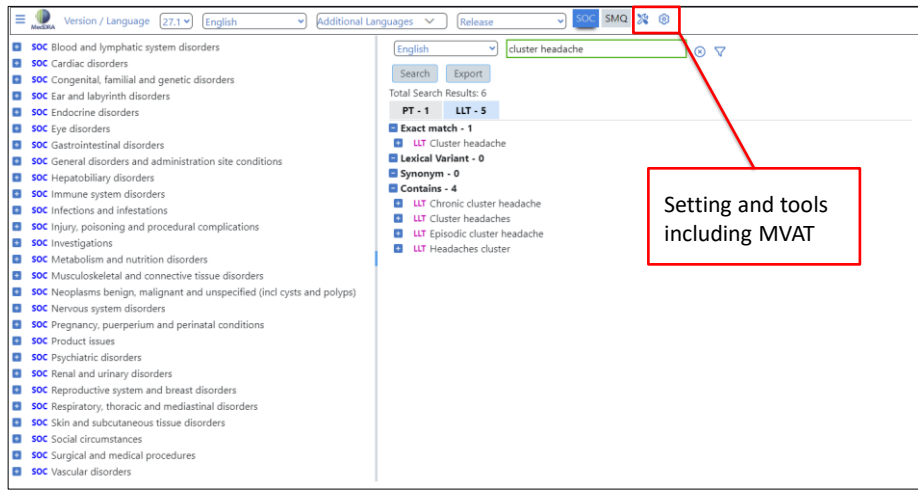
New WBB

- Updated Web-Based Browser (WBB)
  - Launched December 2024
  - Mainly changes to user interface (a simpler look)
  - Optimizing interface for search
  - All existing functions are available
  - Added MedDRA Version Analysis Tool (MVAT) functions
  - Translation change request submission
  - Mappings

MedDRA New WBB



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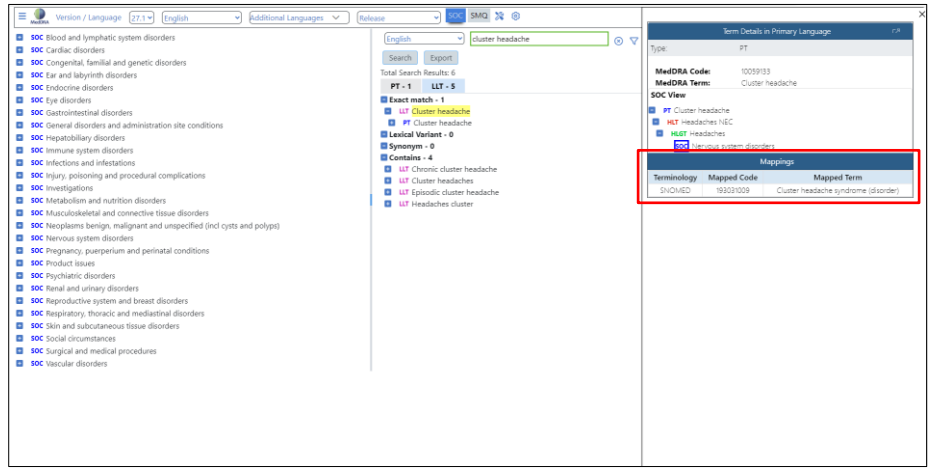
MedDRA New WBB



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New WBB

- New WBB URL – https://wbb.meddra.org
- Same login credentials
- The new WBB will run in parallel to the legacy WBB and MVAT applications
- Allows time for users to transition
- Encourage you to start using the new WBB / MVAT

Training Update – MedDRA Learning Management System (LMS)

MedDRA Learning Management System (LMS)

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

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Accessing MedDRA LMS

- How to access MedDRA LMS?
  - Enter the MedDRA LMS URL in your web browser: meddra.matrixlms.com
  - Link in the MSSO Welcome Letter sent to new and annually to renewed subscribers

MedDRA Learning Management System (LMS)	The MedDRA LMS is an interactive platform for self-directed e-learning about MedDRA and its use for coding and analysis. To access the MedDRA LMS: meddra.matrixlms.com To create a new learner account, follow the instructions in the LMS Guide: MedDRA LMS Guide	MedDRA ID and Password are needed to generate an API access key

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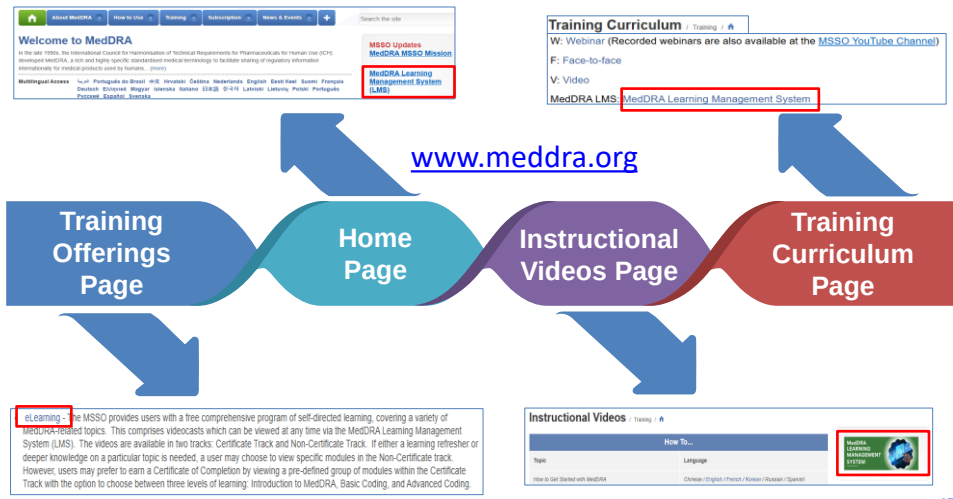
Accessing MedDRA LMS From MedDRA Website



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How to Create an Account

- Instructions on how to create an account are available on the [MSSO YouTube Channel]

Recorded MedDRA LMS Orientation Webinar

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Accessing MedDRA LMS (cont)

- Available to all MedDRA subscribers as part of their subscription
- A user needs to create an account to access MedDRA LMS and retain learning records
- No limit on the number of accounts per organization

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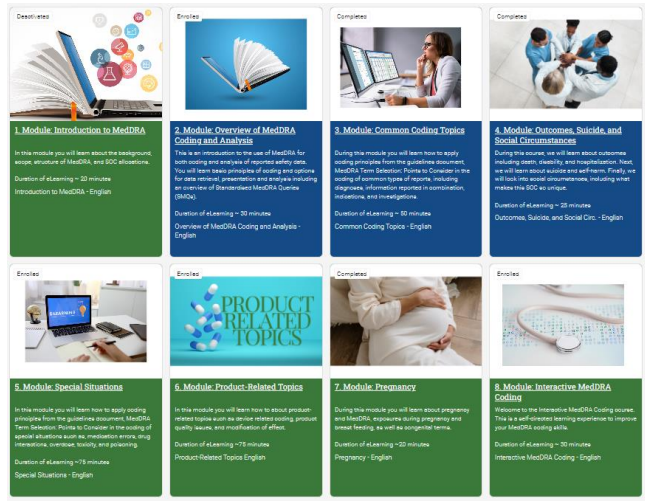
MedDRA LMS Offerings

- 8 learning modules covering a wide range of topics



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MedDRA LMS Offerings (cont)

- All modules are available in Certificate Track and non-Certificate Track
  - Certificate Track – Completion Certificate for each completed track
  - Non-Certificate Track – "Well Done" badge for each completed module

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MedDRA LMS Offerings (cont)

- English Modules are available
- Modules in other languages (Chinese, French, Korean, Russian, and Spanish) are published as they become available
- We would like to hear from you - send your feedback and questions to the MSSO Help Desk at mssohelp@meddra.org

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Upcoming Meetings

European User Group Meeting

- Meeting type: Face-to-face, no virtual component
- Date: 08 April 2025
- Time: 9:00 – 17:00 local time
- Meeting Language – English
- Agenda: Available on MedDRA website
- Location: Warsaw, Poland
- Registration: Available online on MedDRA website, deadline is 25 March 2025

US MedDRA – WHODrug Joint User Group Meeting

- Meeting type: Face-to-face, no virtual component
- Date: 11 June 2025 (WHODrug Meeting 12 June)
- Time: 9:00 – 16:00 local time
- Meeting Language – English
- Agenda – To be determined
- Location: San Francisco, California
- Registration: Online registration is available on the MSSO Events page of the MedDRA website

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Chinese User Group Meeting

- Meeting Type: Face-to-face, no virtual component
- Time: May 2025, date to be announced
- Location: Shanghai, China
- Meeting Language: Chinese
- More details to be posted to MSSO Events page on MedDRA Website when available

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Latin America User Group Meeting

- Meeting Type: Face-to-face, no virtual component
- Time: September 2025, date to be determined
- Location: São Paulo, Brazil
- Meeting Language: Brazilian Portuguese
- More details to be posted to MSSO Events page on MedDRA website when available

Thank You!

Question and Answer Session