



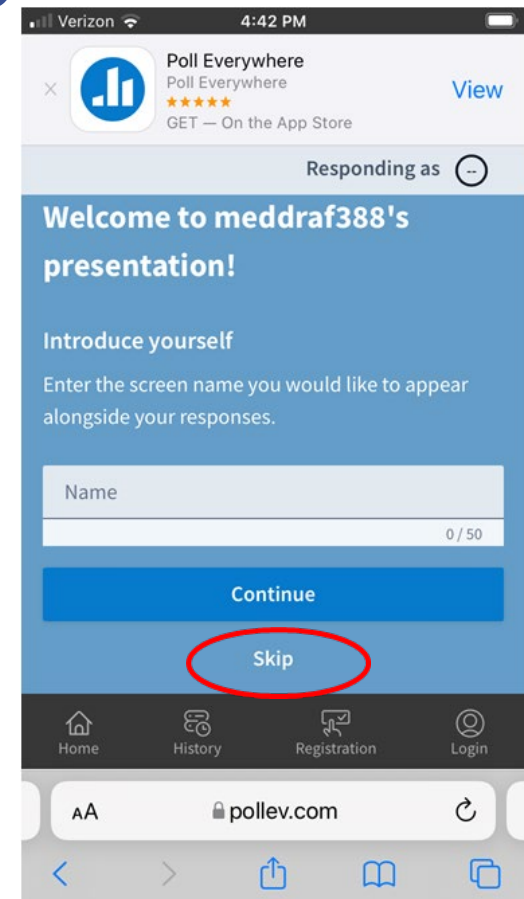
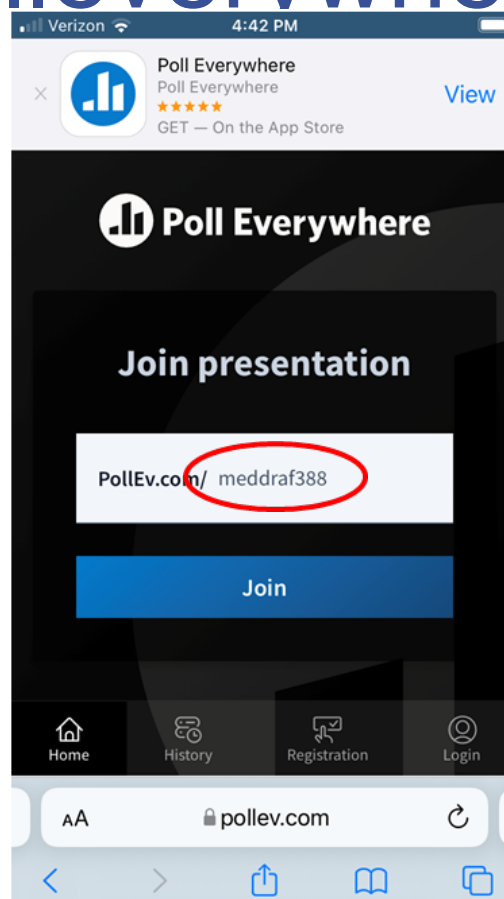
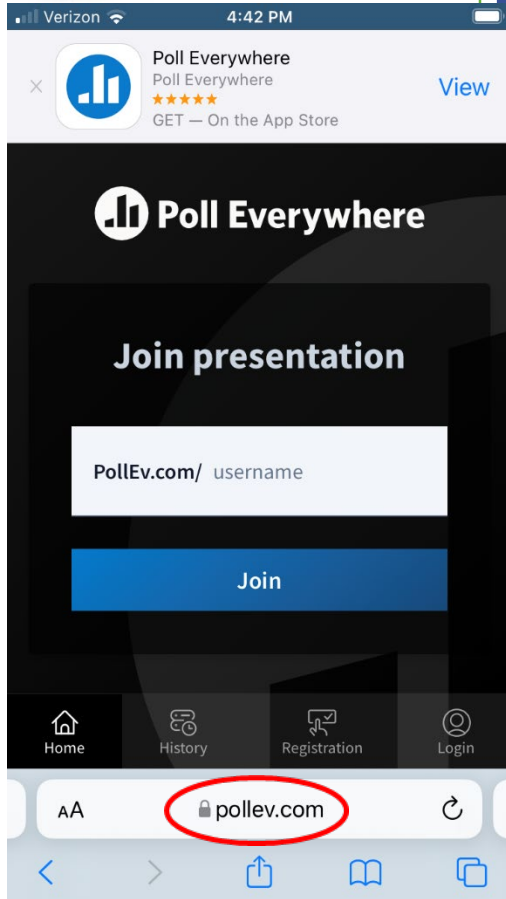
Ask the MSSO

March 23, 2022





Participate at Polleverywhere



1. Open an internet browser on your computer or cell phone
2. Go to **PolleV.com**

3. Enter **meddraf388** as the "username"
4. Click **Join**

5. Click **Skip**
6. Respond to activity



MedDRA

Participate at Polleverywhere

- Or scan the QR code to join





MedDRA

Webinar format

- Up to 90 minutes
- Question and answer format
 - Answer questions submitted in advance
 - Address questions submitted through the Question Panel
- We might not be able to answer all questions in the time allotted for this webinar
- We are unable to address specific coding requests
- The webinar is being recorded
 - If there are no technical issues in the recording, it will be posted to the MSSO YouTube channel





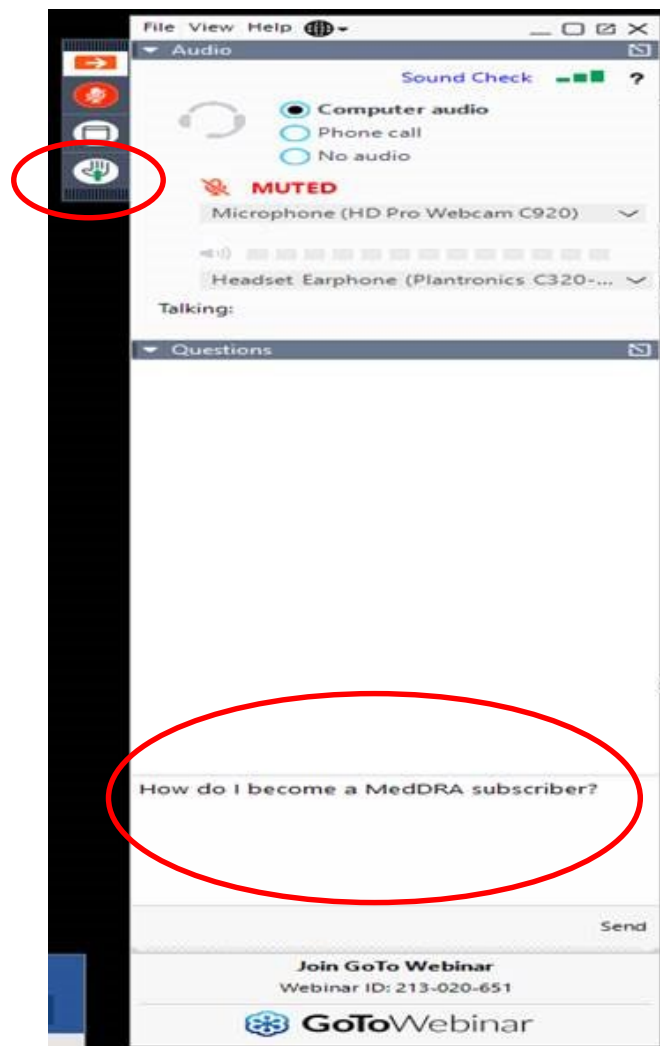
- The submitted question will be shown on the screen and read to the group
- An MSSO panelist will respond to the question





MedDRA

GoToWebinar Panel





MedDRA

MSSO Staff



Dr. Anna Zhao-Wong



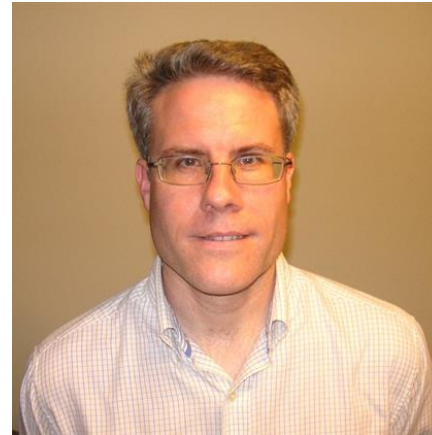
Dr. Judy Harrison



Ms. Hannah Eaton



Mr. Pat Revelle



Mr. Brian O'Hare



MedDRA

Question #1

What is the list of EEA translation languages? What is the process to translate MedDRA into a new language? Who is involved in the translation?





MedDRA

EEA Translations

Release expected first half of 2022	Started in 2022	Remaining EEA Languages 2023 - 2024	
Greek	Estonian	Bulgarian	Lithuanian
Latvian	Finnish	Croatian	Romanian
Maltese	Icelandic	Danish	Slovak
Polish	Norwegian	Irish	Slovenian
Swedish			



MedDRA

Current and Planned MedDRA Translations



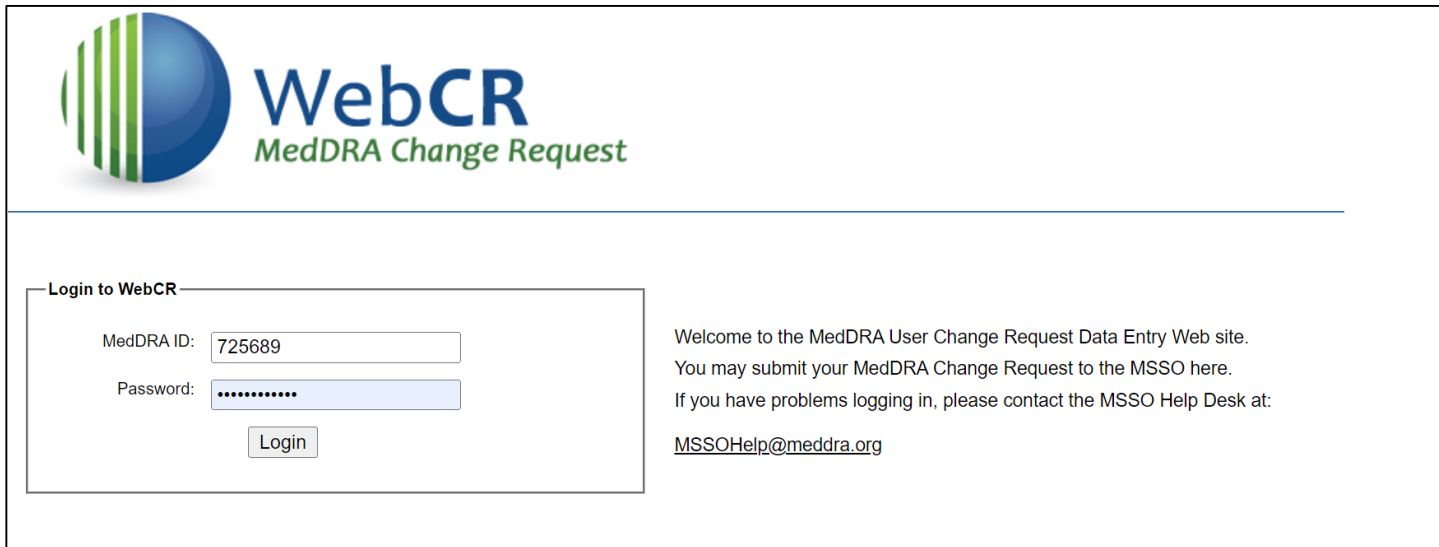


How are the translations checked from English to different languages? In case of any errors detected in a translation, are there mechanisms in place to fix them, or to request a review?



Translation Update Request - WebCR

- <https://mssotools.com/webcr>

A screenshot of the WebCR login page. The page features the WebCR logo at the top left, which includes the text "WebCR" in blue and "MedDRA Change Request" in green below it. Below the logo is a login form titled "Login to WebCR". The form contains two input fields: "MedDRA ID:" with the value "725689" and "Password:" with a masked password of ".....". A "Login" button is positioned below the password field. To the right of the form, there is a welcome message: "Welcome to the MedDRA User Change Request Data Entry Web site. You may submit your MedDRA Change Request to the MSSO here. If you have problems logging in, please contact the MSSO Help Desk at: MSSOHelp@meddra.org".

- MedDRA Password – Same as used for the Web-Based Browser / MVAT
 - Allows submission of Translation Update Requests only
- Change Request Password / ID – allows submission of all change request types



Translation Update Request - WebCR



Freeze Date for MedDRA Version 25.1
1 June 2022 17:00 U.S. EDT

Your Role: Translation updates only
Subscriber:

- [WebCR Quick Start Guide](#)
- [MedDRA Documentation](#)
- [MedDRA Privacy Statement](#)
- [Change Request Information](#)

Subscriber CR

Please select from the action items below.

Translation Changes ▶




- Home
- View Submitted Change Requests
- Search MedDRA Terms
- Search CR History
- Logout



Translation Update Request - WebCR

Rename Translated Term (all fields are required)

English Term Name 
Feeling hot

MedDRA Code
10016334

Language
Chinese

Current Translated Term Name (read-only)
发热感

Replacement Translated Term Name **3**
感觉热


OR

1

2

Justification statement is required

Please do not include any company name or specific product name information in your justification statements.

Justification 
Please change the translation of "Feeling hot" to from 发热感 to 感觉热, which more accurately reflects the meaning of this term.

4

Attach supporting document (Optional)

Attachment
Choose File No file chosen

For multiple attachments, please zip files and submit.

Save Cancel **5**





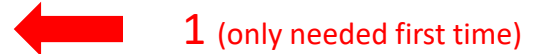
Translation Update Request - WebCR

You have 2 unsubmitted translation change requests ▾

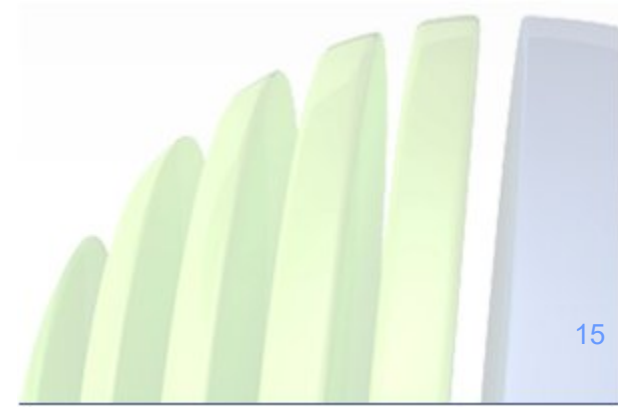
[Submit Translation Change Requests](#)



Emails associated with batch: (Separated by semicolon without spaces)



	Batch#	CR Action	Proposed Term	Term Level	Term Name	Term Level	Term Name	Term Level	Term Name	
Select	50115431	Rename Translated Term	Headache	Code#	10019211	Language	Chinese	Current translated term	头痛	Delete
Select	50115431	Rename Translated Term	CHARGE syndrome	Code#	10064063	Language	Chinese	Current translated term	CHARGE 综合征	Delete





Will SNOMED CT and MedDRA Maps be included in regular MedDRA releases? Will terms in the maps be deleted from one release to another? In other words, do new maps contain all the mappings of previous release or releases?





- First production release in April 2021
- Separate download from MedDRA releases

Downloads /

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 2021 Release Package](#)

▶ [2 November 2021 Supplemental Release](#)



SNOMED CT – MedDRA Maps (cont)

- Next release in April 2022
- Based on
 - MedDRA v24.1 (September 2021)
 - January 2022 release of SNOMED CT International Version
- Includes
 - New mapped terms (~250 requests through MapCR)
 - Relevant COVID-19 terms
 - Changes resulting from version updates in both terminologies (new content, MedDRA currency changes, SNOMED CT inactivations)



SNOMED CT – MedDRA Maps (cont)

- New content example

Release	LLT	SNOMED CT FSN
2021	Pharyngotonsillitis	Not available
2022	Pharyngotonsillitis	Pharyngotonsillitis (disorder)

- Inactivation and remap example

Release	LLT	SNOMED CT FSN
2021	Immune-mediated thrombocytopenic purpura	Immune thrombocytopenic purpura (disorder)
		Immune thrombocytopenic purpura (disorder) Inactivated
2022	Immune-mediated thrombocytopenic purpura	Immune thrombocytopenia (disorder)



Are all IMDRF terms mapped to MedDRA? How many terms have been mapped to date to the IMDRF from MedDRA?

Does the MSSO provide a change list that affect IMDRF coded terms? Where is a list of IMDRF and MedDRA mapping?



IMDRF Annex E – MedDRA Mapping

- International Medical Device Regulators Forum
- See Technical Documents on www.imdrf.org

IMDRF code: IMDRF/AE WG/N43 FINAL:2022 Updated Annexes (Release 2022) Published date: 8 March 2022

- Annex A: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Medical Device Problem
[JSON \(164.89 kb\)](#) [XLSX \(52.73 kb\)](#)
- Annex B: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Type of Investigation [JSON \(12.73 kb\)](#) [XLSX \(14.1 kb\)](#)
- Annex C: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Investigation Findings [JSON \(49.2 kb\)](#) [XLSX \(24.94 kb\)](#)
- Annex D: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Investigation Conclusion
[JSON \(15.39 kb\)](#) [XLSX \(15.77 kb\)](#)
- Annex E: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Health Effects - Clinical Signs and Symptoms or Conditions
[JSON \(364.01 kb\)](#) [XLSX \(179.15 kb\)](#)
- Annex F: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Health Effects - Health Impact
[JSON \(20.41 kb\)](#) [XLSX \(17.27 kb\)](#)
- Annex G: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Medical Device Component
[JSON \(84.56 kb\)](#) [XLSX \(34.61 kb\)](#)
- Appendix B: IMDRF terminologies for categorized Adverse Event Reporting (AER) - Change Log [XLSX \(92.7 kb\)](#)
- Release Notes: IMDRF terminologies for categorized Adverse Event Reporting (AER) [TXT \(1.82 kb\)](#)

Mapped to MedDRA

Change Log



IMDRF Annex E – MedDRA Mapping (cont)

- Updated in March each year
- ~800 Annex E terms mapped to MedDRA

Annex Approval Date: 27 January 2022					
Level 1 Term	Level 2 Term	Level 3 Term	Code	Definition	Non-IMDRF Code
Nervous System			E01	Nervous System	
	Balance Problems		E0101	A feeling of falling down which can occur whether the person is standing, sitting or lying down.	MedDRA:10049848:Balance disorder
	Brain Injury		E0102	Damage to the brain.	MedDRA:10060690:Traumatic brain injury
		Encephalocele	E010201	Hernia of brain substance and meninges through a congenital or traumatic opening of the skull.	MedDRA:10014617:Encephalocele
	Cerebral Edema		E0103	A swelling in the brain caused by the presence of excessive fluid.	MedDRA:10008107:Cerebral edema
	Cerebral Hyperperfusion Syndrome		E0104	Unexpected increase in cerebral blood flow after carotid endarterectomy (CEA) or carotid artery stenting (CAS).	MedDRA:10064730:Cerebral hyperperfusion



MedDRA

Question #6

I heard that there would be an ICD-10 to MedDRA mapping. Will the MSSO maintain that mapping?



- As supported by the MedDRA Management Committee, the MSSO has completed the initial development of an ICD-10 to MedDRA mapping
- International Classification of Diseases (ICD-10), 2019 International version
 - Used for coding of national mortality and morbidity statistics
- Currently under review
- Expected release in 2022





ICD-10 to MedDRA Mapping (cont)

- Mapping contains ~11K terms
- Mapping will be available in spreadsheet format from the MedDRA.org site
- MSSO will maintain the mapping based on MedDRA and ICD-10 updates as well as user input



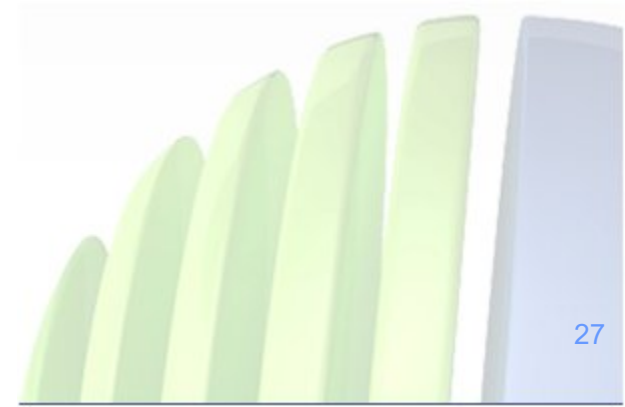
- The MedDRA MC has also supported exploration with WHO of the development and maintenance of mappings between ICD-11 and MedDRA
- Larger task given the larger number of ICD-11 terms
- Will be maintained by the MSSO in coordination with WHO
- More details to follow as this mapping develops



MedDRA

Question #7

How do I extract the list of terms in a specific SMQ?





MedDRA

Question #8

Are all the COVID-19 update terms under the COVID-19 SMQ?



- Cumulative list of COVID-19 related terms in spreadsheet on COVID-19 page on MedDRA website

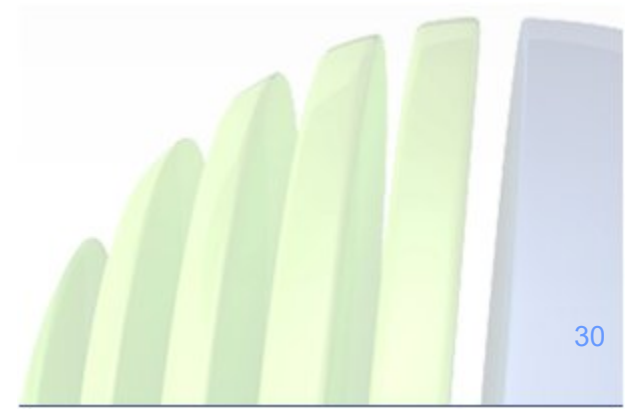
10087403	TTS	Thrombosis with thrombocytopenia syndrome	Thrombocytopenias	Blood and lymphatic system disorders	v25.0
10087404	Vaccine-induced immune thrombotic thrombocytopenia	Thrombosis with thrombocytopenia syndrome	Thrombocytopenias	Blood and lymphatic system disorders	v25.0
10087402	VITT	Thrombosis with thrombocytopenia syndrome	Thrombocytopenias	Blood and lymphatic system disorders	v25.0
10086803	Primary vaccination failure	Vaccination failure	Therapeutic and nontherapeutic responses	General disorders and administration site conditions	v25.0
10086804	Secondary vaccination failure	Vaccination failure	Therapeutic and nontherapeutic responses	General disorders and administration site conditions	v25.0
10086861	Breakthrough COVID-19	Breakthrough COVID-19	Coronavirus infections	Infections and infestations	v25.0
10086863	Breakthrough SARS-CoV-2 infection	Breakthrough COVID-19	Coronavirus infections	Infections and infestations	v25.0
10086862	COVID-19 post vaccine	Breakthrough COVID-19	Coronavirus infections	Infections and infestations	v25.0
10086864	SARS-CoV-2 infection post vaccine	Breakthrough COVID-19	Coronavirus infections	Infections and infestations	v25.0
10086576	COVID-19 reinfection	COVID-19	Coronavirus infections	Infections and infestations	v25.0
10087001	SARS-CoV-2 Delta variant infection	COVID-19	Coronavirus infections	Infections and infestations	v25.0
10087352	SARS-CoV-2 Omicron variant infection	COVID-19	Coronavirus infections	Infections and infestations	v25.0

- **SMQ *COVID-19***

- Focused query specific for COVID-19
- General signs/symptoms, investigations, treatments, and vaccination terms are not included



Is the abbreviation "NOS" intended to mean that the verbatim does not otherwise specify / qualify the named diagnosis or that there is not a MedDRA LLT that specifically matches the primary term?





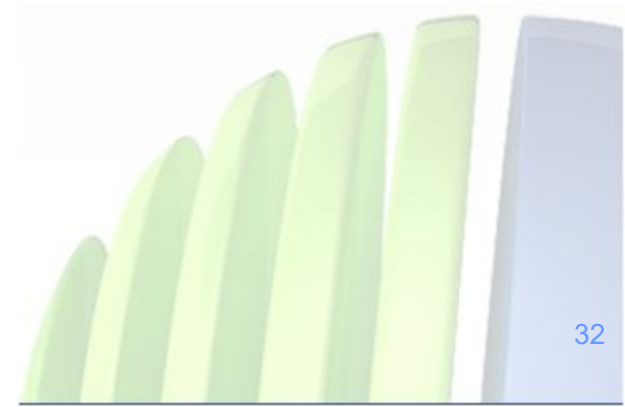
Not Otherwise Specified (NOS)

- Only found at LLT level
- As of v6.1, no additional NOS terms are accepted
- Not every “plain” term has an NOS counterpart
- Sometimes used in mappings to terminologies that have “unspecified” terms, e.g., ICD-10

Verbatim	LLT Selected	Comment
Cluster headache	Cluster headache	Select the specific term
Headache	Headache	
Headache type not specified	Headache NOS	Consider using NOS term if verbatim specifically mentions “not specified” or “unspecified”. Document in conventions.



The MedDRA Desktop Browser is great in cases of travel and poor internet connection. Does the MSSO plan to implement supplemental terms to MDB?





MedDRA

Question #11

Can MedDRA coding be used in non-drug clinical trials just to code conditions and events of interest for publication purposes?





MedDRA

Question #12

What is the maximum number of secondary SOCs available for a term in MedDRA?





MedDRA

Question #13

Does a MedDRA license allow you to use past versions of the dictionary or only the current version?





Get in Contact!

Contact /

MedDRA MSSO

12975 Worldgate Drive Herndon, VA 20170-6008
USA

E-mail: mssohelp@meddra.org or use the form below.

Direct: +1-571-508-1491

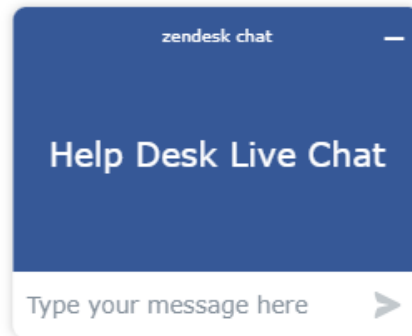
Help Yourself

Get answers to some of your immediate questions
via the [MedDRA Self-Service Application](#)

Follow us on Social Media



Instructional Videos on *How to Follow the MSSO on Social Media* are
available in [Chinese](#) / [English](#) / [Spanish](#).



Social Media Channels

Connect with us in: Please scan the appropriate QR
code
to join the MedDRA group on WhatsApp or WeChat.



WhatsApp English/Spanish: French:

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Groupe de WhatsApp



MedDRA - French speakers
à l'aide d'un groupe



Russian:

MedDRA RU Users Support
WhatsApp group



WeChat

Chinese:



MedDRA MSSO
帮助: 508.1491.1491



MedDRA

Medical Dictionary
for Regulatory Activities

Thank you for joining today!

msohelp@meddra.org

