



What's New MedDRA Version 28.0

March 2025
001203



ACKNOWLEDGEMENTS

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1. DOCUMENT OVERVIEW

This *What's New* document contains information on the origins and types of changes made to the Medical Dictionary for Regulatory Activities (MedDRA) between Versions 27.1 and 28.0.

Section 2, Version 28.0 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 28.0, highlights changes in Version 28.0 related to change request submissions, new initiatives, information on Standardised MedDRA Queries (SMQs), and any recent updates to software tools provided by the MSSO.

Section 4, Summary of Changes, contains details on:

- The impact of this version on the terminology (in tables)
- Impact on the records in MedDRA files
- MedDRA term and SMQ counts
- LLTs in MedDRA that had a currency status change

All updated documentation associated with this version is located in the distribution file in Adobe® Portable Document Format (PDF) or, for some documents, Microsoft Excel. Please refer to the Readme.txt file for a complete listing.

The Maintenance and Support Services Organization (MSSO) Help Desk can be reached at mssohelp@meddra.org.

2. VERSION 28.0 CHANGE REQUESTS

2.1 TERMINOLOGY CHANGES

Changes to MedDRA result from user change requests, from proactivity requests submitted by MedDRA users, and from internal change requests. Internal change requests result from MSSO maintenance activities and from special working group activities in which the MSSO participates.

MedDRA Version 28.0 is a complex change version which means changes may be made at all levels of the MedDRA hierarchy.

Change requests involve both MedDRA updates and SMQ changes. There was a total of 1,620 change requests processed for this version; 1,207 change requests were approved and implemented, and 411 change requests were not approved. There are, in addition, 2 change requests suspended for further consideration and resolution beyond this version.

Information on specific changes (e.g., new terms added, LLT promotions, PT demotions, PT primary SOC changes, etc.) which occurred since the prior MedDRA release can be obtained via the Version Report included with each respective MedDRA download. In addition, users may wish to use the [MedDRA Version Analysis Tool](#) (MVAT) which is an online tool that compares any two MedDRA versions – including non-consecutive versions – to identify changes. The output of MVAT, which compares MedDRA Version 27.1 to Version 28.0 is identical to the Version Report provided in the MedDRA zip file download. MVAT is provided free of charge to MedDRA users as part of their subscription.

Between MedDRA releases, the MSSO makes available English [weekly supplemental update](#) files, which are approved changes that will be implemented for the next MedDRA version. Additionally, supplemental changes may be viewed in the MedDRA Web-Based Browser or MVAT via the “supplemental view” feature. Supplemental information may be helpful for users to identify changes that will be implemented in the next release.

An explanation of all changes considered (approved and not approved) for MedDRA Version 28.0 is accessible as a cumulative Detail Report included in the MedDRA English version download. Users may review all change requests considered by the MSSO from MedDRA Version 5.1 to the present in [WebCR](#).

Figure 2-1 (shown below) summarizes all changes made per System Organ Class (SOC) and may be useful to measure the impact of changes to a specific area of MedDRA. The data are derived from the difference in counts of primary and secondary PT/LLTs, HLTs, and HLGs for Version 28.0 (shown in Table 4-5) and the corresponding information for Version 27.1. Additionally, LLT currency status changes are calculated in Figure 2-1.

Please see Section 4 for a summary of the changes in MedDRA Version 28.0.

Version 28.0 Change Requests

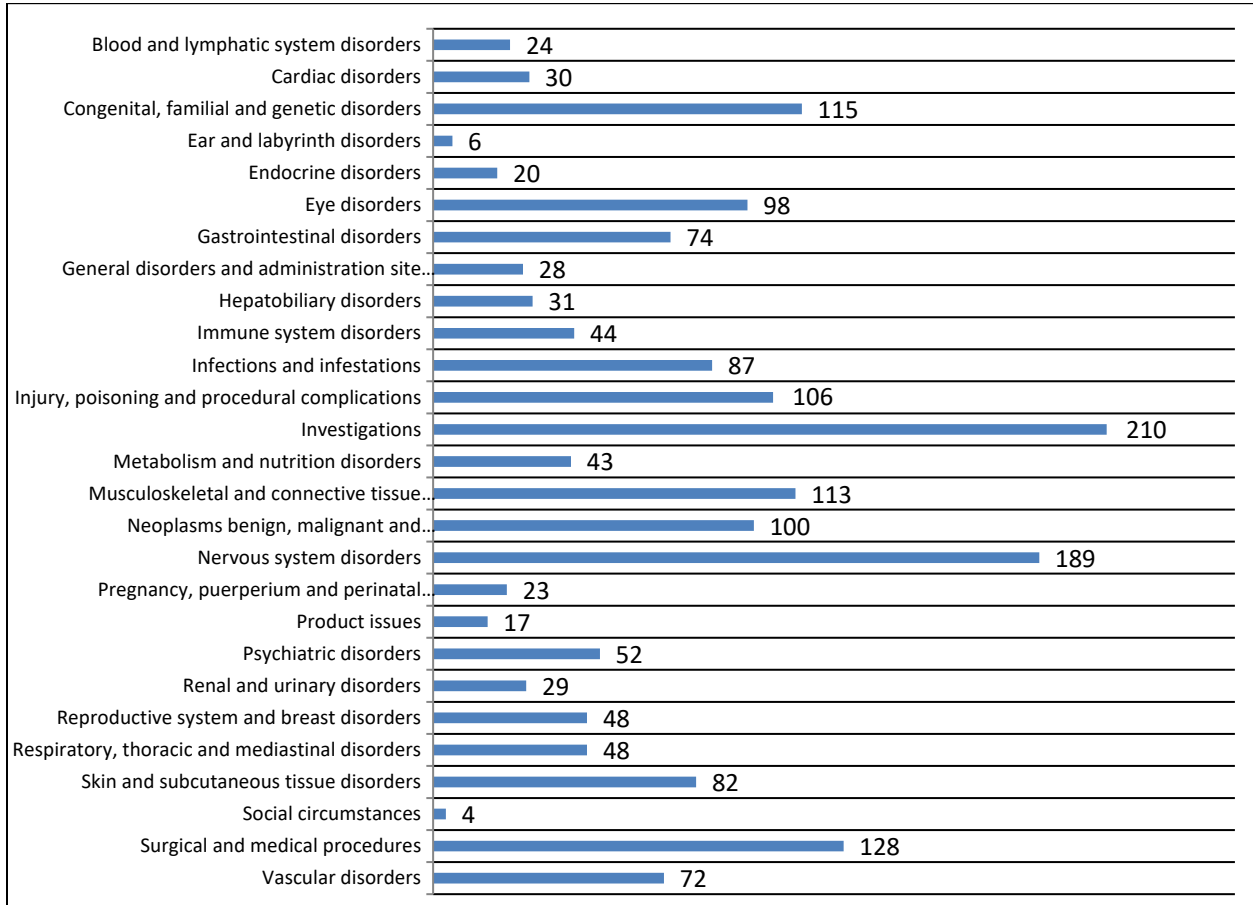


Figure 2-1 Net Changes of Terms per SOC

2.2 COMPLEX CHANGES

The proposals for complex changes considered during Version 28.0 included those submitted by users and those internally identified by the MSSO during change request processing.

Complex change proposals were posted on the MedDRA website for feedback from the MedDRA user community from 2 August 2024 to 27 September 2024. Complex changes were followed by further internal review and consensus discussions which resulted in the final approved set of 3 complex changes.

The complex changes implemented in Version 28.0 are summarized below. Please see the “Related Documents” on the [Change Request section](#) of the MedDRA website for specific details.

At the SOC level: No changes were made to existing SOC's.

At the HLG T level: No changes were made to existing HLG T's.

At the HLT level: There were two High Level Terms (HLT's) added and an existing HLT merged because of complex changes in Version 28.0.

The changes are as follows:

New HLTs

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

Table 2-1 New HLTs

Merged HLTs

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

Table 2-2 Merged HLT

With the addition of HLG T *Product quality, supply, distribution, manufacturing and quality system issues* in Version 19.0, MedDRA was broadened to include a terminology ready to use for coding of manufacturing and quality system issues. New HLT *Quality system issues* allows the addition of important concepts relating to quality system issues.

Replacing HLT *Rabies viral infections* with new HLT *Rhabdoviral infections* broadens the HLT so it can encompass the addition of new terms for diseases caused by other viruses of the Rhabdoviridae family.

3. NEW DEVELOPMENTS IN VERSION 28.0

3.1 STANDARDISED MedDRA QUERIES (SMQs)

No new SMQs have been added for MedDRA Version 28.0. There were 289 approved PT changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA 28.0 Version Report. With the release of MedDRA 28.0, there are 110 Level 1 SMQ topics (i.e., main topics) with a total of 230 SMQs which includes sub-SMQs under the Level 1 SMQs.

The Neurodevelopmental Disorders (SMQ) Expert Working Group, working with the MSSO to consider development of Neurodevelopmental disorders (SMQ), has decided not to develop this topic into an SMQ. The group concluded that the approach does not present a scientifically sound methodology, and that the proposed SMQ did not lead to interpretable data.

The Expert Working Group is developing a report summarizing the group's work on the Neurodevelopmental Disorders (SMQ) development, which will be posted on the MedDRA website.

3.2 PROACTIVITY REQUESTS

The proactive maintenance process allows MedDRA users to propose general changes to MedDRA outside of the established change request process. These proactivity requests may address inconsistencies, make corrections, or suggest improvements. During the Version 28.0 change request processing period, the MSSO implemented two proactivity proposals. See below for details. The MSSO publishes and updates a list of all proposals received and their status on the [Change Request](#) section of the MedDRA website.

The MSSO is interested in learning about any ideas that users may have about “proactive” improvements to MedDRA. Please email your ideas for “proactive” MedDRA improvements to the MSSO [Help Desk](#). Be as specific as possible in describing your suggestion(s) and include a justification which explains why you think your proposal should be implemented.

3.2.1 Consistency of term placement in HLT *Sexuality issues*

A MedDRA user requested a review of the underlying terms in HLT *Sexuality issues* for adequacy of placement. After the review, LLT *Not sexually active* was moved under PT *Sexual abstinence* for better placement.

3.2.2 Consistency of term placement in HLGT *Sleep disorders and disturbances*

A MedDRA user requested a review of the underlying terms in *HLGT Sleep disorders and disturbances* for improved and consistent placement. As a result of this review, a total of 23 changes were implemented including the addition of new PT *Sleep-related breathing disorder*. Many of the updates focused on adding secondary links to PTs for consistency. Below is an example of the updates made. Please see batch # 20119771 in WebCR for a complete list of changes.

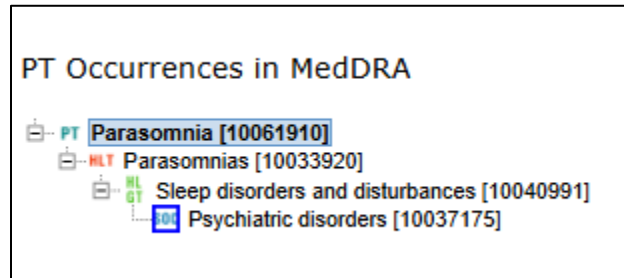


Figure 3-1 PT Occurrence in MedDRA v27.1

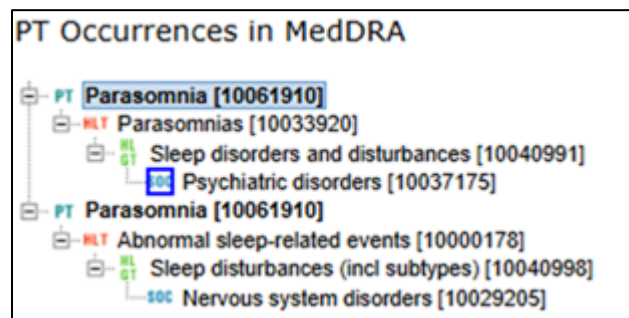


Figure 3-2 PT Occurrence in MedDRA v28.0

3.3 NEW MedDRA LANGUAGES DEPLOYED AND UNDER DEVELOPMENT

The MSSO continues to work on new languages to enable more users to apply MedDRA in their native language and facilitate global communication of MedDRA coded data. The Icelandic translation of MedDRA was released in October 2024 and will begin regular maintenance with the MedDRA 28.0 release. With the release of Icelandic, there are 24 MedDRA languages available to users.

Icelandic is part of the 17 European Economic Area (EEA) official languages, approved for translation by the MedDRA Management Committee in 2020, which are needed to support the electronic product information initiative. Note that this initiative includes the translation of MedDRA terms only and does not include MedDRA user documentation.

Presently, Bulgarian, Maltese, Norwegian, Romanian, Slovak and Slovenian translations are EEA MedDRA translations in development. These languages will be

New Developments in Version 28.0

translated and made available when completed. Please see the multilingual access section (i.e., middle of the page) of the [MedDRA Home page](#) for the list of currently supported languages. The MSSO will provide estimated release dates for these languages as they become available.

3.4 UPDATED MedDRA WEB-BASED BROWSER / MVAT

In December of 2024 the MSSO deployed a newly redesigned [Web-Based Browser \(WBB\)](#) and MedDRA Version Analysis Tool (MVAT). The big change is the redesign of the user interface. The design goal was to simplify the interface and focus on searching since this is the most frequently used WBB function. All the features in the legacy WBB are included in the new WBB with a few additions:

- This update merges the legacy WBB and MedDRA Version Analysis Tool (MVAT) into one application. Users will be able to run Version and Data Impact Reports alongside searching and browsing the MedDRA hierarchy
- Users can log into [WebCR](#) directly from inside the WBB to submit term translation update change requests
- Users can configure the settings of the WBB (e.g., languages, MedDRA codes on/off, search filters, documentation options) and they are stored locally and remembered in the navigation bar when the user starts the WBB the next time.
- Users can select from all supported MedDRA languages to search without having to first select the language to browse the MedDRA hierarchy

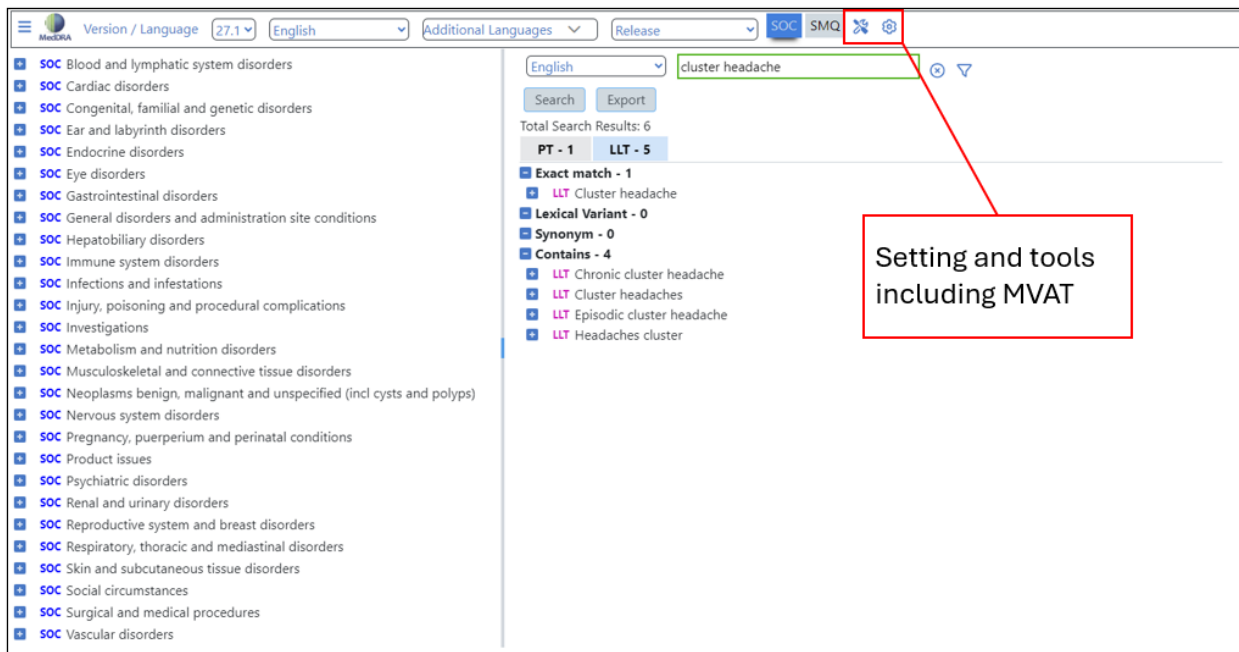


Figure 3-3 New Web-Based Browser

New Developments in Version 28.0

The credentials needed to log into the updated WBB are the same as the legacy WBB. The MSSO plans to run the WBB in parallel to the legacy WBB and MVAT applications until the end of 2025. After that, the legacy WBB and MVAT applications will be retired.

4. SUMMARY OF CHANGES

4.1 SUMMARY OF IMPACT ON THE TERMINOLOGY

The tables below (Tables 4-1 through 4-5) summarize the impact on MedDRA in Version 28.0. For detailed information on the changes to Version 28.0, please see the MedDRA Version Report in MVAT.

File Name	Number of Records in V27.1	Number of Records in V28.0	Change
hlgt.asc	337	337	0
hlgt_hlt.asc	1,756	1,757	1
hlt.asc	1,738	1,739	1
hlt_pt.asc	39,102	39,553	451
llt.asc	88,985	89,774	789
meddra_history_english.asc	139,017	140,162	1,145
meddra_release.asc	1	1	0
mdhier.asc	41,363	41,838	475
pt.asc	26,641	26,920	279
soc.asc	27	27	0
soc_hlgt.asc	354	354	0
intl_ord.asc	27	27	0
smq_list.asc	230	230	0
smq_content.asc	96,124	96,822	698

Table 4-1 MedDRA Term File Counts

The MedDRA history and release files are optional files for use with the MedDRA Desktop Browser (MDB) release 3.0.2 Beta and up. These files are not part of the MedDRA schema.

Summary of Changes

The table below identifies the number of current vs. non-current terms.

LLT Changes

Level	Currency Status	v27.1	v28.0
LLT	Current Terms	79,661	80,448
LLT	Non-current Terms	9,324	9,326
LLT	Total LLTs ¹	88,985	89,774

Table 4-2 Summary of Impact on LLTs

¹Total LLTs include PTs as they are also in the LLT distribution file.

New SMQs

Level	Net Change	v27.1	v28.0
1	0	110	110
2	0	82	82
3	0	20	20
4	0	16	16
5	0	2	2

Table 4-3 Summary of Impact on SMQs

4.2 SUMMARY OF IMPACT ON RECORDS IN MedDRA FILES

The table below lists the consecutive files, associated MedDRA tables and the number of records contained in each consecutive file. A zero indicates that the file has not changed since the prior consolidated MedDRA release. The table below summarizes the impact on MedDRA in Version 28.0. Please see the MedDRA Version Report in MVAT for details.

Summary of Changes

File Name	Number of Records in Table
hlgt.seq	0
hlgt_hlt.seq	3
hlt.seq	3
hlt_pt.seq	611
llt.seq	966
mdhier.seq	649
pt.seq	355
soc.seq	0
soc_hlgt.seq	0
intl_ord.seq	0

Table 4-4 Summary of Impact on Records in MedDRA Files

4.3 MedDRA TERM COUNTS BY SOC

The table below shows term counts by SOC for HLGTS, HLTs, primary and secondary PTs and LLTs, and primary PTs and LLTs. Note that the number of LLTs also includes PTs.

SOC	LLTs (Primary) ¹	PTs (Primary) ¹	LLTs (Primary and Secondary) ²	PTs (Primary and Secondary) ²	HLTs ³	HLGTS ³
<i>Blood and lymphatic system disorders</i>	1,288	341	4,718	1,171	87	17
<i>Cardiac disorders</i>	1,640	404	2,726	727	36	10

Summary of Changes

SOC	LLTs (Primary) ¹	PTs (Primary) ¹	LLTs (Primary and Secondary) ²	PTs (Primary and Secondary) ²	HLTs ³	HLGTs ³
<i>Congenital, familial and genetic disorders</i>	4,710	1,901	4,710	1,901	100	19
<i>Ear and labyrinth disorders</i>	478	106	955	252	17	6
<i>Endocrine disorders</i>	763	214	2,103	642	38	9
<i>Eye disorders</i>	2,785	706	4,287	1,227	63	13
<i>Gastrointestinal disorders</i>	4,319	1,005	8,416	2,002	105	21
<i>General disorders and administration site conditions</i>	2,627	1,043	3,677	1,437	36	7
<i>Hepatobiliary disorders</i>	766	233	1,680	497	19	4
<i>Immune system disorders</i>	612	174	3,340	945	26	4
<i>Infections and infestations</i>	7,931	2,234	8,414	2,373	150	12
<i>Injury, poisoning and procedural complications</i>	7,463	1,440	10,721	2,840	79	9
<i>Investigations</i>	15,449	6,478	15,449	6,478	106	23
<i>Metabolism and nutrition disorders</i>	1,079	316	3,202	924	63	14

Summary of Changes

SOC	LLTs (Primary) ¹	PTs (Primary) ¹	LLTs (Primary and Secondary) ²	PTs (Primary and Secondary) ²	HLTs ³	HLGTs ³
<i>Musculoskeletal and connective tissue disorders</i>	2,910	545	7,437	1,588	59	11
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	9,215	2,164	10,166	2,537	201	39
<i>Nervous system disorders</i>	4,221	1,163	8,511	2,412	108	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1,735	256	3,163	708	48	8
<i>Product issues</i>	958	188	1,002	206	22	2
<i>Psychiatric disorders</i>	2,523	584	3,630	926	77	23
<i>Renal and urinary disorders</i>	1,329	388	2,881	834	32	8
<i>Reproductive system and breast disorders</i>	1,920	554	4,685	1,365	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1,988	618	4,809	1,342	49	12
<i>Skin and subcutaneous tissue disorders</i>	2,429	582	6,190	1,641	56	10
<i>Social circumstances</i>	699	304	699	304	20	7

Summary of Changes

SOC	LLTs (Primary) ¹	PTs (Primary) ¹	LLTs (Primary and Secondary) ²	PTs (Primary and Secondary) ²	HLTs ³	HLGTs ³
<i>Surgical and medical procedures</i>	6,443	2,626	6,443	2,626	141	19
<i>Vascular disorders</i>	1,494	353	7,701	1,933	68	11
Total	89,774	26,920				

Table 4-5 MedDRA Term Counts by SOC

¹Primary count only includes the number of terms that are primarily linked to the designated SOC at either the LLT level or the PT level. The sums of primary LLTs and PTs match those in Tables 4-1 and 4-2.

²Total count includes the number of terms that are both primarily and secondarily linked to the designated SOC at either the LLT level or the PT level. Therefore, the sums of total LLTs and PTs are greater than those in Tables 4-1 and 4-2.

³The HLT and HLGT counts are not necessarily unique values given MedDRA's multi-axiality (see Section 2.2 of the Introductory Guide for a discussion of multi-axiality). There are some HLTs that are counted in more than one SOC. For example, HLT *Connective tissue disorders congenital* and HLGT *Musculoskeletal and connective tissue disorders congenital* are counted in both SOC *Congenital, familial and genetic disorders* and SOC *Musculoskeletal and connective tissue disorders*. The sums of HLTs and HLGTs are greater than those found in Table 4-1.

4.4 LLT CURRENCY STATUS CHANGES

The following table reflects two terms at the LLT level in MedDRA Version 28.0 that had a change in currency status along with the rationale for the changes.

Lowest Level Term	Currency Status Changed to	Rationale
Game keepers thumb	Non-current	LLT <i>Game keepers thumb</i> was changed to a status of non-current as it is grammatically incorrect and LLT <i>Gamekeeper's thumb</i> exists.
NSE	Non-current	The acronym 'NSE' can represent other concepts such as 'nonspecific esterase' (NSE) or 'Neurosensory element' (NSE) in addition to 'Neurone-specific enolase', for which the concept was added as an LLT. Therefore, to avoid potential confusion the status of LLT <i>NSE</i> was changed to non-current. The spelled out PT <i>Neurone-specific enolase</i> already exists.

Table 4-6 LLT Currency Changes