



What's New MedDRA Version 25.1

September 2022

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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 25.0 and 25.1.

Section 2, Version 25.1 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 25.1, highlights changes in Version 25.1 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 25.1 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 25.1 is a simple change version which means changes are made at the PT and LLT level of the MedDRA hierarchy only.

Change requests involve both MedDRA updates and SMQ changes. There was a total of 1,083 change requests processed for this version; 871 change requests were approved and implemented, and 210 change requests were not approved. There are, in addition, 2 change request 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 is similar to the Version Report. 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 MedDRA Web-Based Browser 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 25.1 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 gauge 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 HLGTS for Version 25.1 (shown in Table 4-5) and the corresponding information for Version 25.0. Additionally, LLT currency status changes are included in Figure 2-1.

Please see Section 4 for a summary of the changes in MedDRA Version 25.1.

Version 25.1 Change Requests

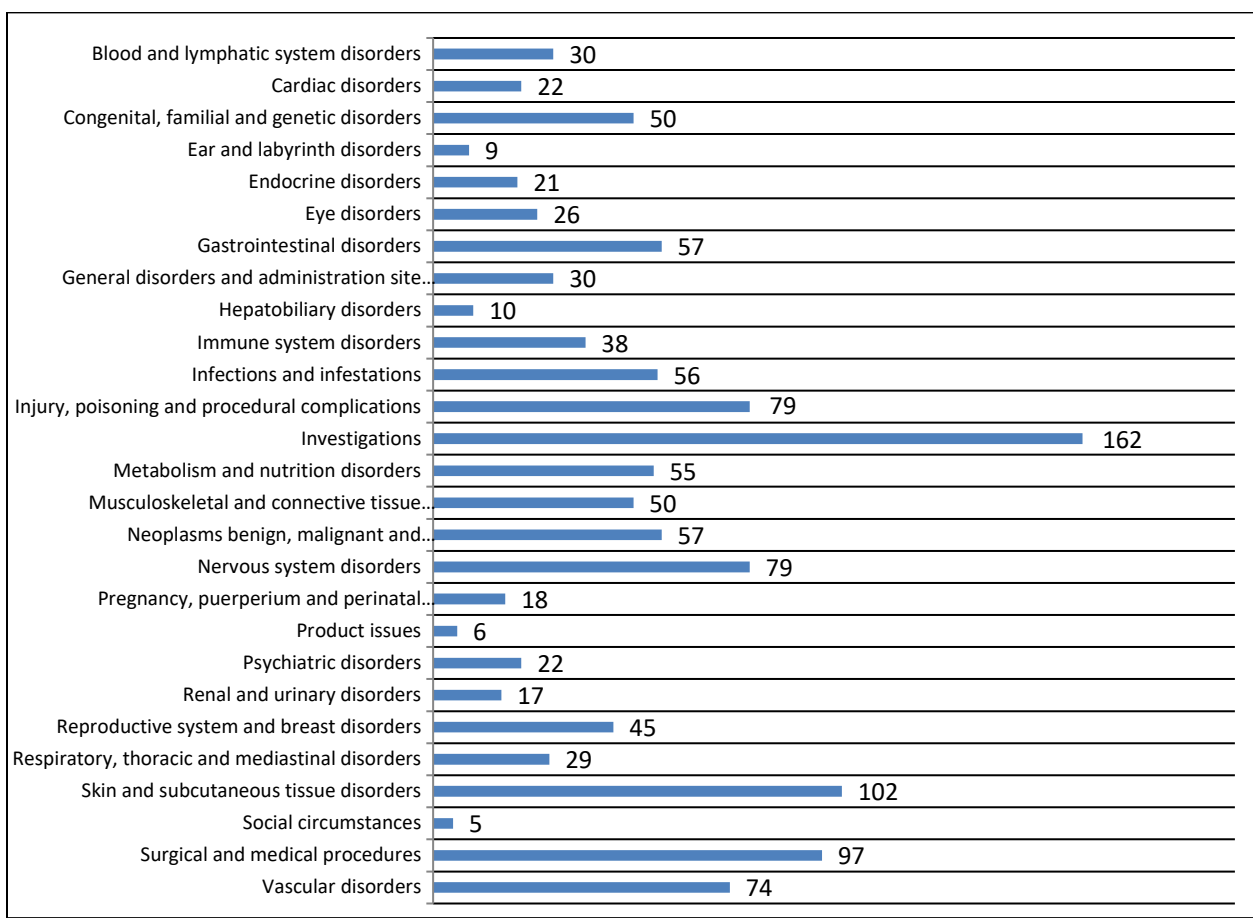


Figure 2-1 Net Changes of Terms per SOC

3. NEW DEVELOPMENTS IN VERSION 25.1

3.1 ADDITIONAL COVID-19 RELATED TERMS

The MSSO continued to add COVID-19 related terms in MedDRA Version 25.1 based upon MedDRA user requests. A total of 11 new COVID-19 related terms were added including terms related to vaccines which may be applicable in the context of COVID-19. See the table below for several examples:

LLT	PT	HLT	Primary SOC
Confirmed immunological vaccine failure	Vaccination failure	Therapeutic and nontherapeutic responses	General disorders and administration site conditions
COVID-19 rebound	COVID-19	Coronavirus infections	Infections and infestations
Vaccination booster dose	Immunisation	Immunisations	Surgical and medical procedures

Table 3-1 COVID-19 Term Examples

3.2 STANDARDISED MedDRA QUERIES (SMQs)

No new SMQs have been added for MedDRA Version 25.1. There were 202 approved PT changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA Version 25.1 Version Report.

3.3 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 25.1 change request processing period, there were no open or implemented proactivity requests. 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.

3.4 NEW MedDRA LANGUAGES DEPLOYED AND UNDER DEVELOPMENT

In 2020, the MedDRA Management Committee (MC) approved additional MedDRA translations for the European Economic Area (EEA) official languages. This includes up to a total of 17 additional European languages 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.

The MSSO released Swedish and Latvian MedDRA in May 2022. Presently, Estonian, Finnish, Greek, Icelandic, Maltese, Norwegian, and Polish translations are in development. The remaining languages in the EEA region will be translated and made available between the years of 2023 to 2024. The MSSO will provide estimated release dates for these languages as they become available.


Additionally, in July 2021 the MedDRA Management Committee approved an Arabic MedDRA translation. This translation began development in 2022 and will include all MedDRA user documentation. The MSSO expects to deploy the Arabic translation of MedDRA before the end of 2022.

3.5 MedDRA SELF-SERVICE APPLICATION UPDATE

In April 2022, the MSSO deployed updates to the MedDRA Self-Service Application (SSA) to further facilitate the use of this tool for MedDRA users. The SSA provides resources to users answers questions such as:

- Who is my MedDRA subscription point of contact?
- What is my MedDRA ID?
- What is my MedDRA subscription password?
- Can you confirm the subscription status of my business partners?
- How do I get a training certificate for training classes?

New Developments in Version 25.1



MedDRA *Self-Service Application*
Medical Dictionary for Regulatory Activities

[MedDRA privacy policy statement](#)

Home
User credentials
Subscription status
Subscription contact
Training
Help

Preferred language English ▼

English
 中文
 Čeština
 Nederlands
 Français
 Deutsch
 Magyar
 Italiano
 日本語
 한국어
 Latviešu
 Português
 Português do Brasil
 Русский язык
 Español
 Svenska

Welcome to the MedDRA Self-Service Application.

Please use the menu bar to choose your desired Self Service function. If you are unable to find the information you need, please contact the MSSO Help Desk. This application works best with the latest version of Chrome, Firefox or Microsoft Edge. The application retrieves pieces of important information related to your MedDRA subscription. Please see the help page for more purpose and when they are needed.

Credential	Purpose	Who can access
MedDRA ID	To register for MedDRA events, such as training, user group meetings, Blue Ribbon Panel (BRP) meetings, etc.	Users with a company email address and domain
MedDRA Password	Used together with MedDRA ID to access <ol style="list-style-type: none"> 1. Meddra.org Downloads page 2. MedDRA tools – WBB, MMB, MVAT, WebCR (translation CRs), MapCR, etc. 	Users with an email address at their company domain

Figure 3-1 Updated Self-Service Application with Multi-lingual interface

The deployed updates include two key features.

- A refreshed user interface with a multi-lingual option for all supported MedDRA languages
- Training certificates are now offered for both virtual and face-to-face training courses

These features improve the utility of the SSA and facilitate its use, particularly for non-English speakers.

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 25.1. For detailed information on the changes to Version 25.1, please see the MedDRA Version Report in MVAT.

File Name	Number of Records in V25.0	Number of Records in V25.1	Change
hlgt.asc	337	337	0
hlgt_hlt.asc	1,755	1,755	0
hlt.asc	1,737	1,737	0
hlt_pt.asc	37,186	37,468	282
llt.asc	85,091	85,668	577
meddra_history_english.asc*	133,409	134,220	811
meddra_release.asc*	1	1	0
mdhier.asc	39,352	39,647	295
pt.asc	25,412	25,592	180
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	92,226	92,825	599

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	v25.0	v25.1
LLT	Current Terms	75,787	76,364
LLT	Non-current Terms	9,304	9,304
LLT	Total LLTs ¹	85,091	85,668

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	v25.0	v25.1
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 25.1. 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	0
hlt.seq	0
hlt_pt.seq	384
llt.seq	677
mdhier.seq	405
pt.seq	234
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>	1,249	324	4,561	1,123	87	17
<i>Cardiac disorders</i>	1,563	384	2,588	688	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>	4,337	1,733	4,337	1,733	100	19
<i>Ear and labyrinth disorders</i>	456	102	919	245	17	6
<i>Endocrine disorders</i>	726	204	1,986	609	38	9
<i>Eye disorders</i>	2,670	674	4,096	1,152	63	13
<i>Gastrointestinal disorders</i>	4,137	957	8,072	1,898	105	21
<i>General disorders and administration site conditions</i>	2,550	1,020	3,553	1,389	35	7
<i>Hepatobiliary disorders</i>	728	222	1,590	473	19	4
<i>Immune system disorders</i>	580	167	3,113	885	26	4
<i>Infections and infestations</i>	7,672	2,146	8,097	2,272	150	12
<i>Injury, poisoning and procedural complications</i>	7,183	1,356	10,241	2,686	78	9
<i>Investigations</i>	14,707	6,156	14,707	6,156	106	23
<i>Metabolism and nutrition disorders</i>	1,037	307	3,017	880	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>	2,790	518	7,130	1,492	59	11
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	8,950	2,073	9,821	2,421	201	39
<i>Nervous system disorders</i>	3,996	1,077	8,022	2,233	108	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1,708	249	3,081	676	48	8
<i>Product issues</i>	912	180	942	194	21	2
<i>Psychiatric disorders</i>	2,471	566	3,475	865	77	23
<i>Renal and urinary disorders</i>	1,299	385	2,787	809	32	8
<i>Reproductive system and breast disorders</i>	1,854	531	4,538	1,298	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1,905	595	4,634	1,292	49	12
<i>Skin and subcutaneous tissue disorders</i>	2,333	567	5,904	1,572	56	10
<i>Social circumstances</i>	670	289	670	289	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>	5,746	2,468	5,746	2,468	141	19
<i>Vascular disorders</i>	1,439	342	7,375	1,849	68	11
Total	85,668	25,592				

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

No currency changes occurred for MedDRA Version 25.1.