



What's New MedDRA Version 26.1

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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 26.0 and 26.1.

Section 2, Version 26.1 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 26.1, highlights changes in Version 26.1 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 26.1 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 26.1 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 1,605 change requests processed for this version; 1,359 change requests were approved and implemented, and 241 change requests were not approved. There are, in addition, five 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 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 26.1 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 HLGs for Version 26.1 (shown in Table 4-5) and the corresponding information for Version 26.0. Additionally, LLT currency status changes are included in Figure 2-1.

Please see Section 4 for a summary of the changes in MedDRA Version 26.1.

Version 26.1 Change Requests

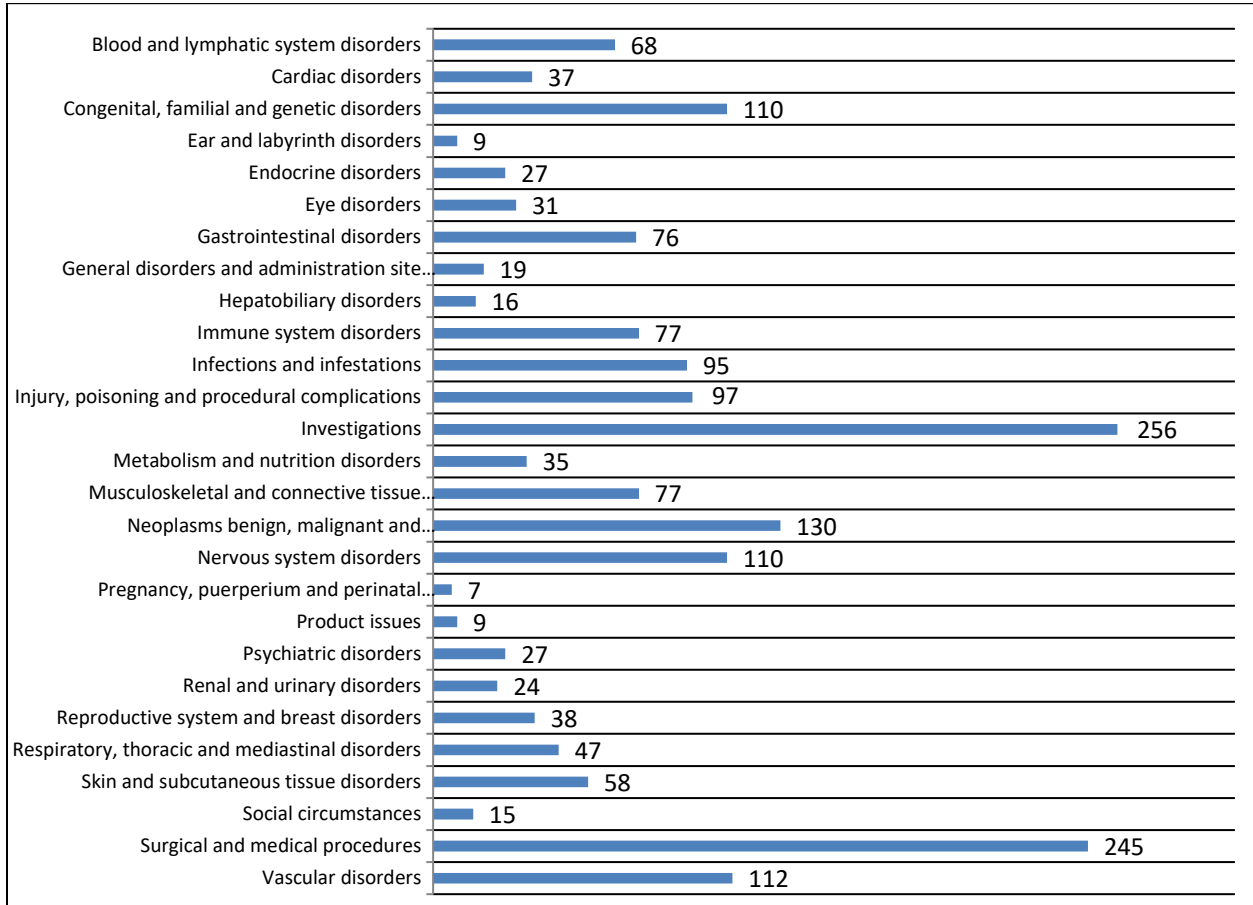


Figure 2-1 Net Changes of Terms per SOC

3. NEW DEVELOPMENTS IN VERSION 26.1

3.1 ICD-10 TO MedDRA MAPPING

The MSSO is pleased to announce the availability of the ICD-10 to MedDRA uni-directional mapping. The mapping was developed in a collaboration between the World Health Organization (WHO) and the International Council for Harmonisation (ICH) with MSSO supporting this effort. The ICD-10 to MedDRA uni-directional mapping is available from the [Downloads page](#) (MedDRA ID and password required) of the MedDRA website. The release package includes a spreadsheet with the mapping and a mapping convention document that describes how the mapping was developed. The map will continue to be updated to the latest release of MedDRA.

WHO and ICH with MSSO supporting, plan to continue their joint activities to develop bi-directional ICD-11 – MedDRA mappings. These mappings will support the interoperability between ICD-10/11 data that provides critical knowledge on the extent, causes and consequences of human disease and death worldwide with MedDRA that facilitates global regulatory decision making on the safety and efficacy of medicinal products. These mappings will extend the utility of both ICD-10/11 and MedDRA through a much broader access to data coded in both terminologies. The specific release date of the ICD-11 – MedDRA mappings is yet to be determined.

WHO and ICH plan to maintain the mappings based on user feedback as well as changes in the underlying terminologies. This will ensure the utility of the maps as medicine continues to evolve.

For any questions, please contact the MSSO Help Desk at mssohelp@meddra.org.

3.2 STANDARDISED MedDRA QUERIES (SMQs)

No new SMQs have been added for MedDRA Version 26.1. There were 311 approved PT changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA Version 26.1 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 26.1 change request processing period, there were no 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

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 newest available language is Estonian.

Estonian is part of the 17 European Economic Area (EEA) official languages, approved 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, Croatian, Finnish, Icelandic, Lithuanian, Maltese, Norwegian, and Slovenian translations are in development. The remaining languages in the EEA region will be translated and made available in 2024 or by early 2025. Please see the multilingual access section 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.

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 26.1. For detailed information on the changes to Version 26.1, please see the MedDRA Version Report in MVAT.

File Name	Number of Records in V26.0	Number of Records in V26.1	Change
hlgt.asc	337	337	0
hlgt_hlt.asc	1,755	1,755	0
hlt.asc	1,737	1,737	0
hlt_pt.asc	37,984	38,380	396
llt.asc	86,714	87,592	878
meddra_history_english.asc*	135,727	136,944	1,217
meddra_release.asc*	1	1	0
mdhier.asc	40,187	40,613	426
pt.asc	25,916	26,180	264
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	93,785	94,737	952

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	v26.0	v26.1
LLT	Current Terms	77,408	78,283
LLT	Non-current Terms	9,306	9,309
LLT	Total LLTs ¹	86,714	87,592

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	v26.0	v26.1
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 26.1. 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	586
llt.seq	1,069
mdhier.seq	650
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>	1,262	332	4,644	1,149	87	17
<i>Cardiac disorders</i>	1,595	388	2,659	705	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>	4,513	1,810	4,513	1,810	100	19
<i>Ear and labyrinth disorders</i>	464	104	933	248	17	6
<i>Endocrine disorders</i>	746	209	2,031	621	38	9
<i>Eye disorders</i>	2,718	684	4,165	1,175	63	13
<i>Gastrointestinal disorders</i>	4,240	985	8,238	1,945	105	21
<i>General disorders and administration site conditions</i>	2,589	1,029	3,621	1,416	35	7
<i>Hepatobiliary disorders</i>	743	227	1,635	485	19	4
<i>Immune system disorders</i>	602	175	3,230	916	26	4
<i>Infections and infestations</i>	7,786	2,180	8,238	2,313	150	12
<i>Injury, poisoning and procedural complications</i>	7,294	1,396	10,479	2,758	78	9
<i>Investigations</i>	15,051	6,289	15,051	6,289	106	23
<i>Metabolism and nutrition disorders</i>	1,051	309	3,100	902	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>	2,836	525	7,260	1,530	59	11
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	9,079	2,115	9,980	2,473	201	39
<i>Nervous system disorders</i>	4,098	1,118	8,226	2,308	108	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1,725	253	3,123	689	48	8
<i>Product issues</i>	923	180	954	194	21	2
<i>Psychiatric disorders</i>	2,492	571	3,528	884	77	23
<i>Renal and urinary disorders</i>	1,312	387	2,829	820	32	8
<i>Reproductive system and breast disorders</i>	1,886	542	4,603	1,326	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1,939	599	4,715	1,311	49	12
<i>Skin and subcutaneous tissue disorders</i>	2,381	576	6,033	1,605	56	10
<i>Social circumstances</i>	685	296	685	296	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>	6,115	2,556	6,115	2,556	141	19
<i>Vascular disorders</i>	1,467	345	7,542	1,889	68	11
Total	87,592	26,180				

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.

Summary of Changes

4.4 LLT CURRENCY STATUS CHANGES

The following table reflects three terms at the LLT level in MedDRA Version 26.1 that had a change in currency status along with the rationale for the changes.

Lowest Level Term	Currency Status Changed to	Rationale
Peritoneal washing	Non-current	'Peritoneal washing' and 'peritoneal lavage' are two different concepts. However, lavage and washing could be misinterpreted as synonyms. Therefore, a new PT <i>Peritoneal washing cytology</i> was added to HLT <i>Gastrointestinal histopathology procedures</i> to differentiate it from existing PT <i>Peritoneal lavage</i> . As a result of this change, existing PT <i>Peritoneal washing</i> was demoted to an LLT under the new PT <i>Peritoneal washing cytology</i> , and the status of LLT <i>Peritoneal washing</i> was changed to non-current to avoid this confusion.
Post MI	Non-current	MI is ambiguous abbreviation as it may refer to different concepts such as mitral incompetence, myocardial infarction or myocardial ischemia.
RA	Non-current	The acronym RA is ambiguous abbreviation as it may refer to reactive arthritis, refractory anemia, or rheumatoid arthritis.

Table 4-6 LLT Currency Changes