



What's New MedDRA Version 27.1

September 2024

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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 27.0.

Section 2, Version 27.1 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 27.1, highlights changes in Version 27.1 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 27.1 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 27.1 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 1,295 change requests processed for this version; 968 change requests were approved and implemented, and 325 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 27.0 to Version 27.1 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 27.1 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 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 27.1 (shown in Table 4-5) and the corresponding information for Version 27.0. Additionally, LLT currency status changes are calculated in Figure 2-1.

Please see Section 4 for a summary of the changes in MedDRA Version 27.1.

Version 27.1 Change Requests

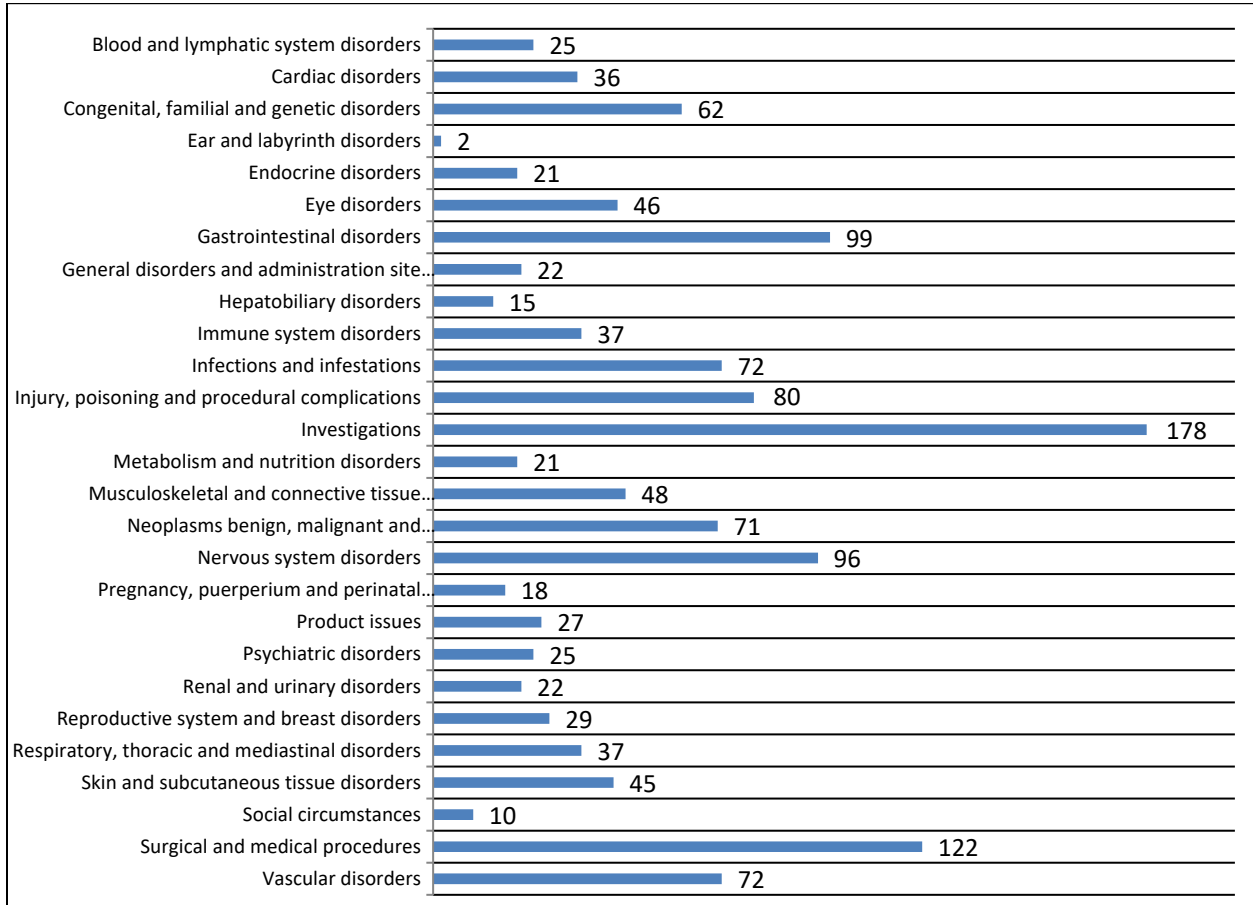


Figure 2-1 Net Changes of Terms per SOC

3. NEW DEVELOPMENTS IN VERSION 27.1

3.1 STANDARDISED MedDRA QUERIES (SMQs)

No new SMQs have been added for MedDRA Version 27.1. There were 222 approved PT changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA 27.1 Version Report. With the release of MedDRA 27.1, 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.

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 27.1 change request processing period, the MSSO implemented one proactivity proposal. 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 for Sexually Transmitted Infections with Body Site

A MedDRA user requested a review of inconsistencies in the representation of certain anatomically qualified, sexually transmitted infections at the LLT and PT level with respect to their placement within “genital”, “anal”, “anogenital”, “perianal” and “anorectal” concepts in MedDRA.

After the review, the MSSO added two new PTs, promoted one LLT and moved three LLTs to improve the organization and representation of these concepts in MedDRA. See the tables below for details.

New PT	Primary HLT	Primary SOC
Anorectal herpes	Herpes viral infections	Infections and infestations
Anorectal herpes zoster	Herpes viral infections	Infections and infestations

New Developments in Version 27.1

Promoted to PT	Primary HLT	Primary SOC
Herpes simplex anorectal	Herpes viral infections	Infections and infestations

Table 3-1 New and Promoted Sexually Transmitted Infection PTs

All three PTs are secondarily linked to HLT *Anal, rectal, perianal and perirectal infections* in SOC *Gastrointestinal disorders*.

Moved LLT	From PT v27.0	To PT v27.1
Anal herpes	Genital herpes	Anorectal herpes
Perianal herpes zoster	Genital herpes zoster	Anorectal herpes zoster
Perianal herpes simplex	Genital herpes simplex	Herpes simplex anorectal

Table 3-2 Moved Sexually Transmitted Infection LLTs

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 Croatian and Lithuanian translations of MedDRA were released in June 2024 and will begin regular maintenance with the MedDRA 27.1 release in September 2024. The Icelandic translation of MedDRA is nearing completion and as of this writing may be included with the release of MedDRA translations on 15 September 2024 or shortly afterwards. With the release of all three languages, there are 24 MedDRA languages available to users.

Croatian, Icelandic, and Lithuanian are 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 languages in development. These languages will be translated and made available in 2024 or 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 27.1. For detailed information on the changes to Version 27.1, please see the MedDRA Version Report in MVAT.

File Name	Number of Records in V27.0	Number of Records in V27.1	Change
hlgt.asc	337	337	0
hlgt_hlt.asc	1,756	1,756	0
hlt.asc	1,738	1,738	0
hlt_pt.asc	38,749	39,102	353
llt.asc	88,345	88,985	640
meddra_history_english.asc	138,081	139,017	936
meddra_release.asc	1	1	0
mdhier.asc	40,994	41,363	369
pt.asc	26,409	26,641	232
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	95,501	96,124	623

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	v27.0	v27.1
LLT	Current Terms	79,026	79,661
LLT	Non-current Terms	9,319	9,324
LLT	Total LLTs ¹	88,345	88,985

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	v27.0	v27.1
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 27.1. 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	441
llt.seq	744
mdhier.seq	481
pt.seq	294
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>	1,283	339	4,700	1,165	87	17
<i>Cardiac disorders</i>	1,622	399	2,704	719	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>	4,636	1,859	4,636	1,859	100	19
<i>Ear and labyrinth disorders</i>	465	104	951	250	17	6
<i>Endocrine disorders</i>	758	213	2,086	639	38	9
<i>Eye disorders</i>	2,745	693	4,220	1,196	63	13
<i>Gastrointestinal disorders</i>	4,288	998	8,356	1,986	105	21
<i>General disorders and administration site conditions</i>	2,615	1,035	3,660	1,426	36	7
<i>Hepatobiliary disorders</i>	759	230	1,656	490	19	4
<i>Immune system disorders</i>	608	173	3,305	936	26	4
<i>Infections and infestations</i>	7,870	2,215	8,347	2,353	150	12
<i>Injury, poisoning and procedural complications</i>	7,413	1,428	10,639	2,817	79	9
<i>Investigations</i>	15,310	6,407	15,310	6,407	106	23
<i>Metabolism and nutrition disorders</i>	1,069	314	3,165	918	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>	2,886	538	7,351	1,562	59	11
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	9,161	2,141	10,093	2,510	201	39
<i>Nervous system disorders</i>	4,177	1,144	8,374	2,361	108	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1,732	255	3,148	700	48	8
<i>Product issues</i>	946	186	989	203	21	2
<i>Psychiatric disorders</i>	2,512	581	3,596	908	77	23
<i>Renal and urinary disorders</i>	1,320	386	2,860	826	32	8
<i>Reproductive system and breast disorders</i>	1,910	553	4,651	1,350	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1,968	609	4,774	1,329	49	12
<i>Skin and subcutaneous tissue disorders</i>	2,417	580	6,123	1,626	56	10
<i>Social circumstances</i>	695	304	695	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>	6,334	2,607	6,334	2,607	141	19
<i>Vascular disorders</i>	1,486	350	7,645	1,916	68	11
Total	88,985	26,641				

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 five terms at the LLT level in MedDRA Version 27.1 that had a change in currency status along with the rationale for the changes.

Lowest Level Term	Currency Status Changed to	Rationale
Cervical agenesis	Non-current	To avoid potential ambiguity between the neck versus the cervix with existing term "cervical agenesis", the status of LLT <i>Cervical agenesis</i> was changed to non-current. New PT <i>Uterine cervix agenesis</i> was added to remove the ambiguity of the concept and LLT <i>Cervical agenesis</i> was demoted to the new PT.
Macular pigmentation	Non-current	New PT <i>Macular pigmentary changes</i> was added to HLT <i>Retinal structural change, deposit and degeneration</i> . To avoid confusion, existing PT <i>Macular pigmentation</i> , which can be a normal finding, was demoted under new PT <i>Macular pigmentary changes</i> and changed to a status of non-current.
Nikolsky's sign	Non-current	Three terms, PT <i>Nikolsky's sign positive</i> , PT <i>Nikolsky's sign negative</i> and PT <i>Nikolsky's sign test</i> were added to HLT <i>Skin histopathology and skin investigations NEC</i> in SOC <i>Investigations</i> . As a result, existing PT <i>Nikolsky's sign</i> was demoted under new PT <i>Nikolsky's sign positive</i> and changed to a status of non-current.
Parietal pain	Non-current	LLT <i>Parietal pain</i> was changed to a status of non-current due to its ambiguity with respect to the anatomic location. A new LLT <i>Parietal abdominal pain</i> was added to clarify the concept.
Saccadic eye movement	Non-current	Saccadic eye movement could be interpreted as normal saccadic eye movement versus a disorder. Therefore, the status of the term was changed to non-current. A new LLT/PT <i>Saccadic eye movement disorder</i> was added instead.

Table 4-6 LLT Currency Changes