



What's New MedDRA Version 28.1

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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 28.0 and 28.1.

Section 2, Version 28.1 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 28.1, highlights changes in Version 28.1 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 28.1 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 28.1 is a simple change version which means changes are made only at the PT and LLT levels of the MedDRA hierarchy.

Change requests involve both MedDRA updates and SMQ changes. There was a total of 1,412 change requests processed for this version; 1,032 change requests were approved and implemented, and 367 change requests were not approved. There are, in addition, 13 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 28.0 to Version 28.1 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 28.1 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 28.1 (shown in Table 4-5) and the corresponding information for Version 28.0. Additionally, LLT currency status changes are calculated in Figure 2-1.

Please see Section 4 for a summary of the changes in MedDRA Version 28.1.

Version 28.1 Change Requests

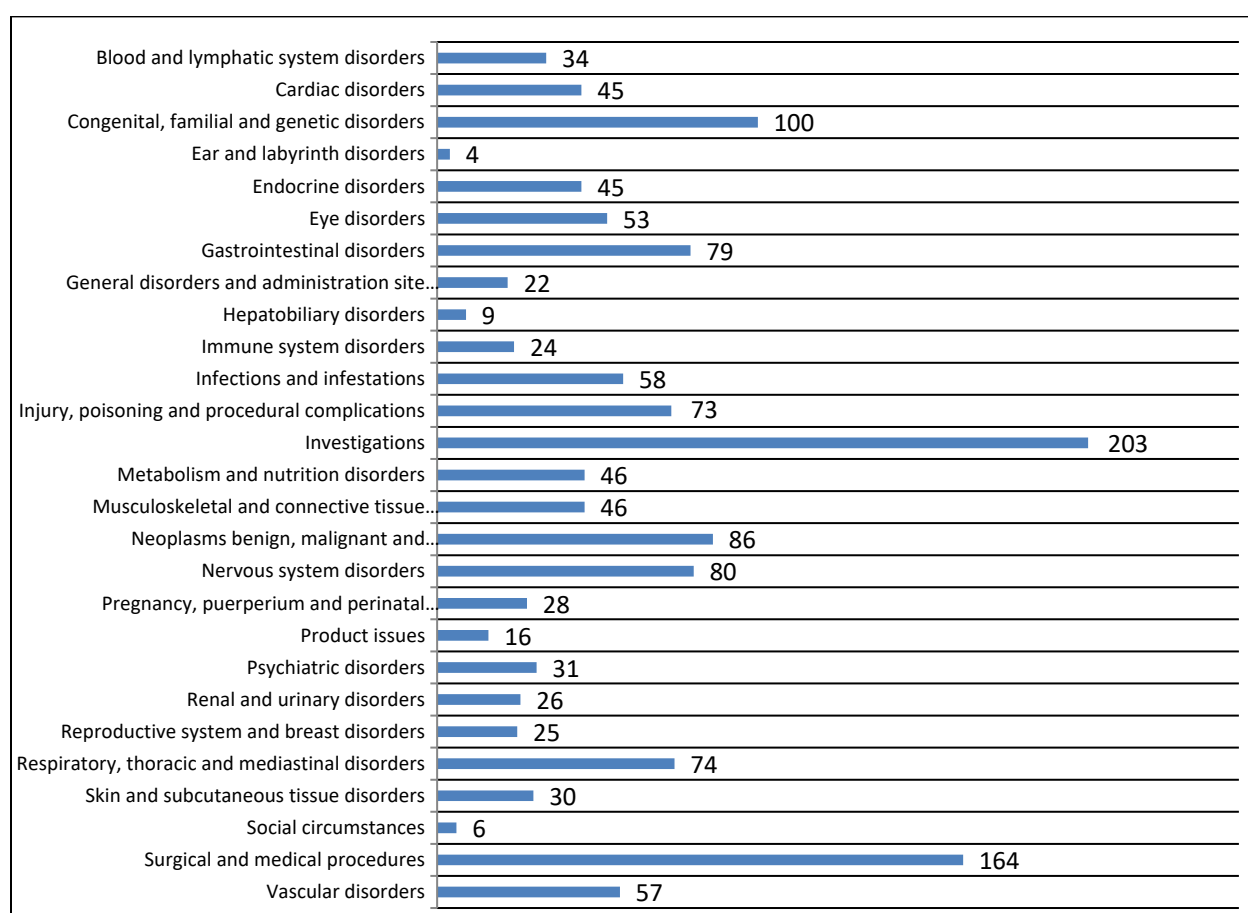


Figure 2-1 Net Changes of Terms per SOC

3. NEW DEVELOPMENTS IN VERSION 28.1

3.1 STANDARDISED MedDRA QUERIES (SMQs)

No new SMQs have been added for MedDRA Version 28.1. There were 225 approved PT changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA 28.1 Version Report. With the release of MedDRA 28.1, 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 28.1 change request processing period, no new proactivity proposals were implemented. 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.

3.3 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 MSSO expects to release three new languages either on or shortly after deployment of MedDRA 28.1 on 15 September – Norwegian, Slovak and Slovenian. With the release of these three languages, there are 27 MedDRA languages available to users.

Norwegian, Slovak, and Slovenian are part of the 17 European Economic Area (EEA) official languages, approved for translation by the MedDRA Steering 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, Danish, Maltese, and Romanian, translations are EEA MedDRA translations in development. Additionally, ICH approved a MedDRA Uzbek translation which has just started development.

These languages will be 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 FRENCH TRANSLATION TERMINOLOGIA ANATOMICA UPDATE

The Terminologia Anatomica (TA) is an international standard for human anatomical terminology. Released in 1998 under the auspices of the International Federation of Associations of Anatomists, it was created to progressively replace classical anatomical nomenclature worldwide..

Although there is no official translation of TA into French, the use of a francized version was endorsed in the 2010s by the dictionary of the Académie de médecine, the official reference for French medical terminology. This approval laid the foundation for implementing the French TA version in MedDRA terminology. Consequently, the French regulator ANSM and Health Canada agreed to support the project to rename about 1,400 MedDRA terms in MedDRA 28.1 from classical legacy terminology to TA. See below for a few examples.

English Term	Code	Previous French Translation	Updated Translation
Patella fracture	10034122	Fracture de la rotule	Fracture de la patella
Brain stem hematoma	10073231	Hématome du tronc cérébral	Hématome du tronc de l'encéphale
Spinal cord injury	10041552	Lésion de la moelle épinière	Lésion de la moelle spinale

Table 3-1 French Terminologia Anatomica Update Examples

Please see the 28.1 Version Report for the French translation of MedDRA for a complete list of term updates.

3.5 UPDATED MedDRA DESKTOP BROWSER

In July of 2025, the MSSO deployed a newly redesigned MedDRA Desktop Browser (MDB) version 5.0. The most significant change is the redesign of the user interface to match the redesigned Web-Based Browser deployed in December 2024. The design goal was to simplify the interface and focus on searching since this is the most frequently used MDB function. All the features in the legacy MDB are included in the new MDB. This includes a consolidated settings menu to allow users to customize the MDB to suit their needs. See the figure below.

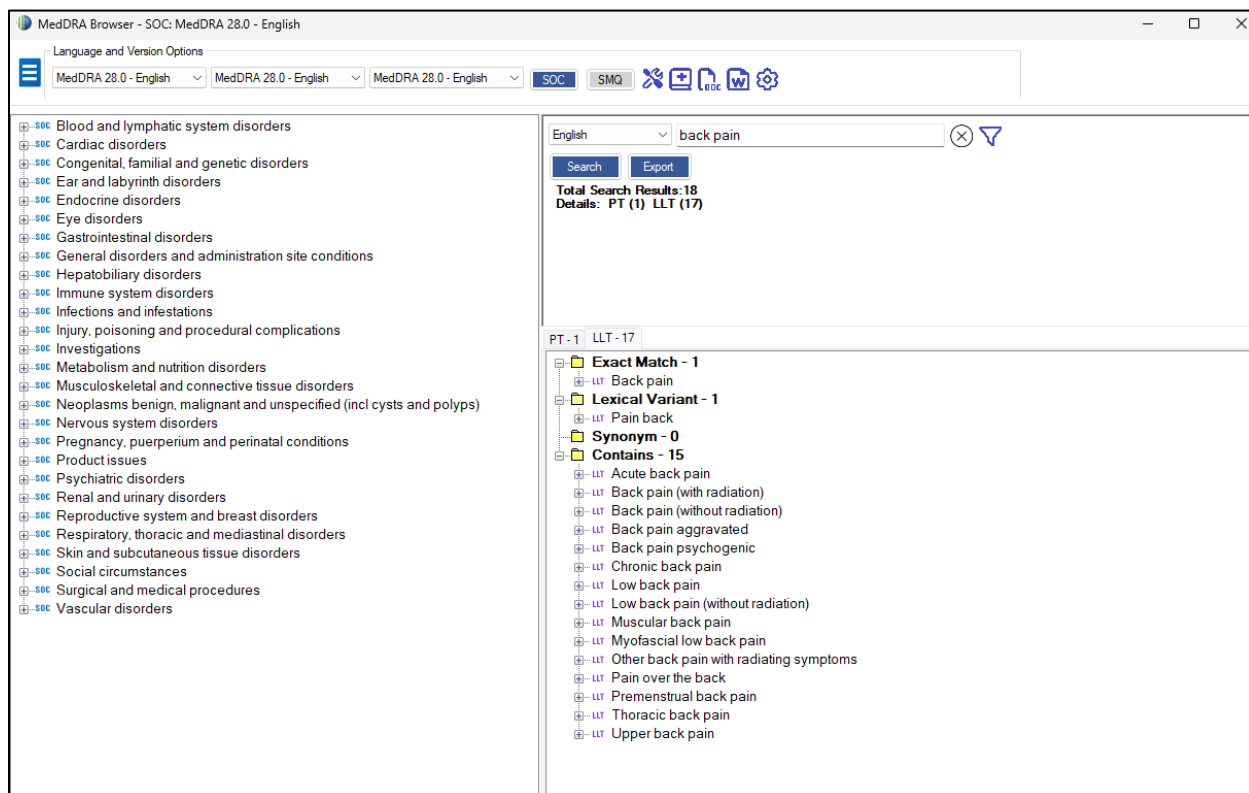


Figure 3-1 New Desktop Browser

The new MDB 5.0 may be found on the [Download page](#) of the MedDRA website which requires providing your MedDRA subscription ID and password. If you do not have your credentials, please use our [Self-Service Application](#) to obtain them.

The legacy MDB version 4.1 application will continue to be available on the MedDRA website.

If you have questions, please contact the MSSO Help Desk (mssohelp@meddra.org).

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 28.1. For detailed information on the changes to Version 28.1, please see the MedDRA Version Report in MVAT.

File Name	Number of Records in V28.0	Number of Records in V28.1	Change
hlgt.asc	337	337	0
hlgt_hlt.asc	1,757	1,757	0
hlt.asc	1,739	1,739	0
hlt_pt.asc	39,553	39,916	363
llt.asc	89,774	90,471	697
meddra_history_english.asc	140,162	141,148	986
meddra_release.asc	1	1	0
mdhier.asc	41,838	42,221	383
pt.asc	26,920	27,163	243
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	96,822	97,480	658

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	v28.0	v28.1
LLT	Current Terms	80,448	81,143
LLT	Non-current Terms	9,326	9,328
LLT	Total LLTs ¹	89,774	90,471

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	v28.0	v28.1
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 28.1. 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	445
llt.seq	820
mdhier.seq	477
pt.seq	285
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>	1,298	342	4,744	1,175	87	17
<i>Cardiac disorders</i>	1,661	411	2,760	738	36	10

Summary of Changes

SOC	LLTs (Primary)¹	PTs (Primary)¹	LLTs (Primary and Secondary)²	PTs (Primary and Secondary)²	HLTs³	HLGTs³
<i>Congenital, familial and genetic disorders</i>	4,777	1,934	4,777	1,934	100	19
<i>Ear and labyrinth disorders</i>	479	106	958	253	17	6
<i>Endocrine disorders</i>	764	214	2,140	650	38	9
<i>Eye disorders</i>	2,811	715	4,329	1,240	63	13
<i>Gastrointestinal disorders</i>	4,336	1,008	8,475	2,020	105	21
<i>General disorders and administration site conditions</i>	2,635	1,046	3,693	1,443	36	7
<i>Hepatobiliary disorders</i>	768	233	1,687	499	19	4
<i>Immune system disorders</i>	615	175	3,358	951	26	4
<i>Infections and infestations</i>	7,969	2,245	8,457	2,386	150	12
<i>Injury, poisoning and procedural complications</i>	7,498	1,449	10,775	2,859	79	9
<i>Investigations</i>	15,593	6,538	15,593	6,538	106	23
<i>Metabolism and nutrition disorders</i>	1,090	317	3,234	938	63	14

Summary of Changes

SOC	LLTs (Primary)¹	PTs (Primary)¹	LLTs (Primary and Secondary)²	PTs (Primary and Secondary)²	HLTs³	HLGTs³
<i>Musculoskeletal and connective tissue disorders</i>	2,923	548	7,476	1,596	59	11
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	9,269	2,177	10,230	2,557	201	39
<i>Nervous system disorders</i>	4,254	1,170	8,573	2,431	108	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1,741	258	3,183	716	48	8
<i>Product issues</i>	966	191	1,013	211	22	2
<i>Psychiatric disorders</i>	2,530	584	3,652	934	77	23
<i>Renal and urinary disorders</i>	1,338	393	2,897	844	32	8
<i>Reproductive system and breast disorders</i>	1,929	560	4,702	1,373	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	2,015	635	4,857	1,368	49	12
<i>Skin and subcutaneous tissue disorders</i>	2,440	584	6,210	1,647	56	10
<i>Social circumstances</i>	704	305	704	305	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>	6,564	2,669	6,564	2,669	141	19
<i>Vascular disorders</i>	1,504	356	7,744	1,946	68	11
Total	90,471	27,163				

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 three terms at the LLT level in MedDRA Version 28.1 that had a change in currency status along with the rationale for the changes.

Lowest Level Term	Currency Status Changed to	Rationale
Narcolepsy with cataplexy	Current	LLT Narcolepsy with cataplexy was changed to a status of current from non-current. Narcolepsy with cataplexy, currently called Narcolepsy type 1, includes cataplexy as one of the earliest symptoms and is associated with low cerebrospinal fluid (CSF) orexin (also called hypocretin) levels. While the term "narcolepsy with cataplexy" is no longer the official, preferred terminology, it is still widely understood and used, especially in informal contexts.
Purpura thrombopaenic thrombotic	Non-current	The British English spelling of this term is 'Purpura thrombopenic thrombotic', and not different from the American English spelling. Therefore, the status of LLT <i>Purpura thrombopaenic thrombotic</i> was changed to non-current.
Thrombocytopaenic purpura	Non-current	The British English spelling of this term is 'Thrombocytopenic purpura', and not different from the American English spelling. Therefore, the status of LLT Thrombocytopaenic purpura was changed to non-current.

Table 4-6 LLT Currency Changes