



What's New MedDRA Version 17.1

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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 17.0 and 17.1.

Section 2, Version 17.1 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 17.1, highlights changes in v17.1 related to change request submissions, new initiatives, and information on Standardised MedDRA Queries (SMQs).

Section 4, Summary of Changes, contains details on:

- Term history
- The impact of this version on the terminology (in tables)
- Impact on the records in MedDRA files
- MedDRA term and SMQ counts
- Modified Lowest Level Terms (LLT) and Preferred Term (PT) names
- All 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 International AT&T Toll Free at 1-877-258-8280 or mssohelp@meddra.org.

2. VERSION 17.1 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 v17.1 is a simple change version which means that changes are made at the PT and LLT level only.

Change requests involve both MedDRA updates and SMQ changes. There were a total of 1614 change requests processed for this version; 1214 change requests were approved and implemented, and 290 change requests were not approved. There are, in addition, 110 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 English language 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 [weekly supplemental update](#) files which are approved changes that will be implemented for the next MedDRA version. The supplemental files 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 v17.1 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 v5.1 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 v17.1 (shown in Table 4-6) and the corresponding information for v17.0. Additionally, term name changes and LLT currency status changes are included in Figure 2-1.

Please see Section 4 for a summary of the changes in MedDRA v17.1.

Version 17.1 Change Requests

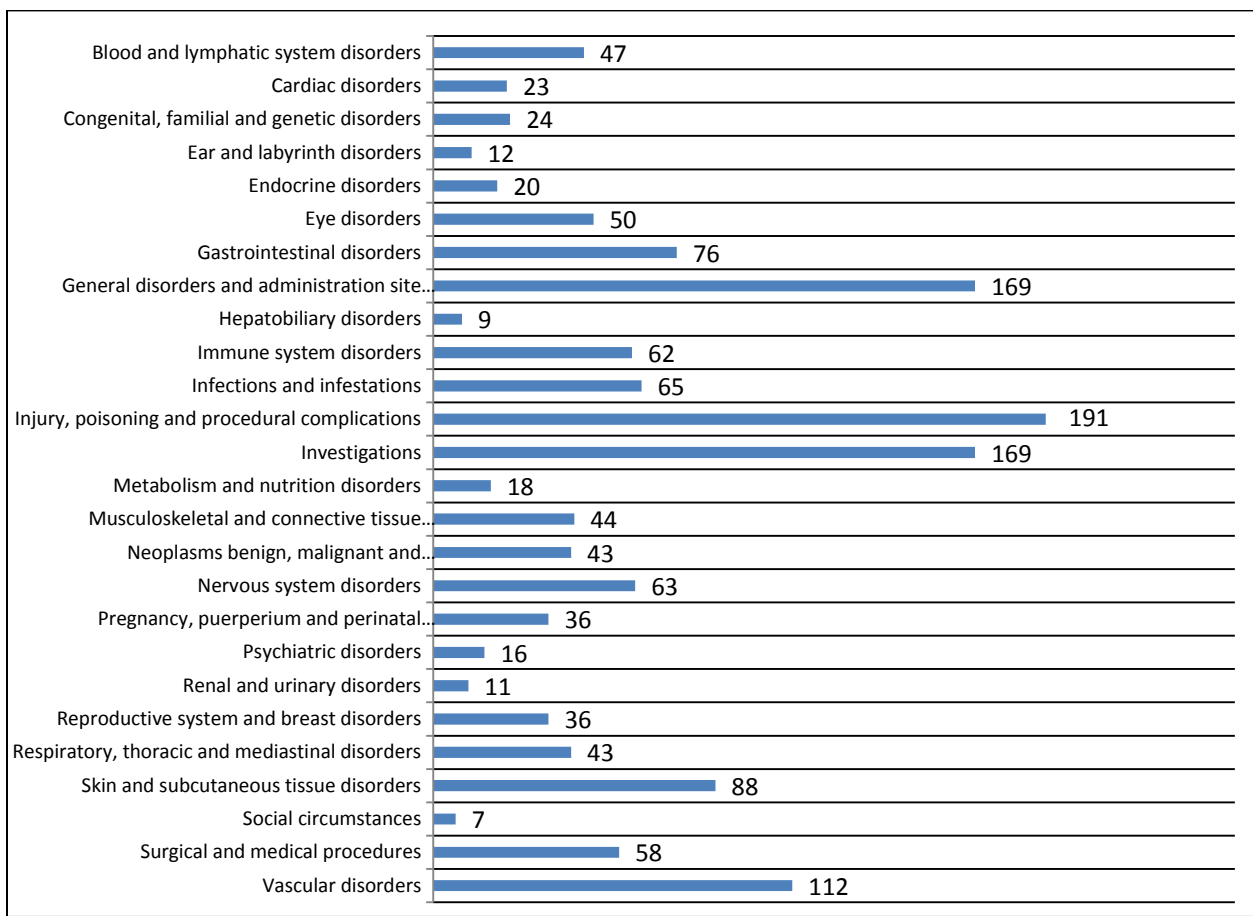


Figure 2-1. Net Changes of Terms per SOC

2.2 TRANSLATION CHANGES

2.2.1 French Translation Review

In an effort to review and improve the French translation of MedDRA, the MSSO is conducting a review of the translation of terms from English into French. This will be an ongoing effort that is expected to last several MedDRA releases. To assist MedDRA users to understand changes that have been implemented, the MSSO has included a spreadsheet in the French MedDRA v17.1 download which contains a list of all changes made. This spreadsheet indicates which translation changes are conceptual changes (i.e., change in meaning) versus those that are minor corrections such as spelling or modifications to diacritical marks. This spreadsheet will be included in all future versions of the French translation of MedDRA until the review is complete.

Please see the Change Request section of the MedDRA website if you wish to request an improvement in the translation of a term or terms in any non-English version of MedDRA.

2.2.2 Enhancing Translations at the LLT level

Due to language and culture differences, not every English LLT has a unique translation in other languages. For example, LLTs with British/American spelling and lexical variants (e.g., LLT *Haemorrhage* / LLT *Hemorrhage*, LLT *Back pain* / LLT *Pain back*) are often translated to the same term name. Additionally, synonymous LLTs may not have a unique translation in every language (e.g., LLT *Dry heaves* and LLT *Gagging* may not have different synonyms in the translated language). For this reason, duplicate translations are permitted at the LLT level under the same PT for non-English languages.

This maintenance approach, while helpful for consistency, is not always optimal as it may reduce the number of terms in a translation. To enhance the MedDRA languages, the MedDRA Management Board has approved a modification of the translation maintenance rules to allow the use of the language specific synonyms in place of duplicate translations where appropriate. See below for an example:

Code	English term	French term v17.0	French term v17.1
10063056	Faecal disimpaction	Désimpaction fécale	Evacuation d'un fécalome
10063058	Fecal disimpaction	Désimpaction fécale	Désimpaction fécale

These synonym translations must enhance the utility of the translation but retain the meaning of the original term. This enhancement has been applied proactively for many of the supported languages and will be part any future translation review.

3. NEW DEVELOPMENTS IN VERSION 17.1

3.1 STANDARDISED MedDRA QUERIES (SMQs)

Two new level 1 SMQs were released into production in MedDRA v17.1: SMQ *Proteinuria* and SMQ *Tubulointerstitial diseases*. There are now 96 level 1 SMQs in production as of this version. Please see the MedDRA v17.1 SMQ Introductory Guide for more information about the new SMQs including their inclusion and exclusion criteria.

3.2 PROACTIVITY REQUESTS

The proactive maintenance process allows MedDRA users to propose general changes to MedDRA outside of the established change request process to address inconsistencies, make corrections, or suggest improvements. During the v17.1 change request processing period, the MSSO evaluated four proactivity proposals submitted by MedDRA users. Of the four proposals two were implemented and two were not approved. See below for details on the implemented 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.

3.2.1 Hernia Terms

A MedDRA user pointed out that the placements of incarcerated, strangulated, and obstructive hernia terms (e.g., LLT *Incarcerated hernia* under PT *Hernia obstructive*) are not optimal as they are medically distinct concepts and should be represented separately. After reviewing the current placement of these terms, the MSSO medical team agreed these concepts should be represented as separate PTs. As a result of this review, the MSSO made 19 changes to existing terms and added 3 new PTs to represent these concepts at the PT level. See below for examples.

Term Name	Level	Change
Femoral hernia incarcerated	PT	New PT
Hiatus hernia strangulated	PT	New PT
Incarcerated hernia	PT	Promoted LLT
Strangulated hernia	PT	Promoted LLT

Table 3-1 Examples of hernia term changes

3.2.2 Pressure and Pain or Discomfort Terms

In a proactivity request submitted by a MedDRA user, the MSSO was asked to review inconsistencies in the mapping of LLTs containing “pressure” to PTs related to either “pain” or “discomfort.” As a result of this initiative, 9 changes to existing “pressure” terms were made to align “pressure” with the concept of “discomfort,” rather than “pain.” See below for examples.

LLT	PT in v17.0	PT in v17.1
Head pressure	Headache	Head discomfort
Sensation of pressure in eye	Abnormal sensation in eye	Ocular discomfort
Sinus pressure	Sinus headache	Paranasal sinus discomfort
Demoted PT		v17.1 PT
Sensation of pressure		Discomfort

Table 3-2 Examples of changes to placement of “pressure” terms

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 v17.1. These tables are intended only as a reference. For detailed information on the changes to v17.1, please see the MedDRA Version Report included within the English language download.

SOC, HLG T, HLT Changes

Level	Change Request Action	Net Change	v17.0	v17.1
SOC	Total SOCs	0	26	26
HLGT	New HLG Ts	0	0	0
	Merged HLG Ts	0	0	0
	Total HLG Ts ¹	0	334	334
HLT	New HLTs	0	0	0
	Merged HLTs	0	0	0
	Total HLTs ¹	0	1720	1720

Table 4-1 Summary of Impact on SOCs, HLG Ts, HLTs

MedDRA v17.1 is a simple change version which means changes are only made at the PT and LLT levels of the MedDRA hierarchy; hence there are no changes in the number of HLTs and HLG Ts.

¹ Total net change of HLG Ts or HLTs equals the number of new HLG Ts or HLTs minus the number of respective merged HLG Ts or HLTs.

Summary of Changes

PT Changes

Level	Change Request Action	v17.0	v17.1
PT	New PTs	280	281
	Promoted LLTs	41	32
	Demoted PTs	69	64
	Net Change ¹	252	249
	Total PTs	20559	20808

Table 4-2 Summary of Impact on PTs

¹Net change of PTs equals the number of new PTs plus the number of promoted LLTs minus the number of demoted PTs.

LLT Changes

Level	Change Request Action	Net Change	v17.0	v17.1
LLT	Total LLTs ¹	584	72637	73221

Table 4-3 Summary of Impact on LLTs

¹Total LLTs include PTs as they are also represented as LLTs.

New SMQs

Level	Net Change	v17.0	v17.1
1	2	94	96
2	0	82	82
3	0	20	20
4	0	12	12
5	0	2	2

Table 4-4 Summary of Impact on SMQs

4.2 SUMMARY OF IMPACT ON RECORDS IN MedDRA FILES

The table below summarizes the impact on MedDRA in v17.1. The table is intended only as a reference.

INTL_ORD.ASC	Added	0
	Removed	0
	Modified	0
SOC.ASC	Added	0
	Removed	0
	Modified	0
SOC_HLGT.ASC	Added	0
	Removed	0
	Modified	0
HLGT.ASC	Added	0
	Removed	0
	Modified	0
HLGT_HLT.ASC	Added	0
	Removed	0
	Modified	0
HLT.ASC	Added	0
	Removed	0
	Modified	0
HLT_PT.ASC	Added	562
	Removed	125
	Modified	0
MDHIER.ASC	Added	612
	Removed	147
	Modified	0
PT.ASC	Added	313
	Removed	64
	Modified	12

Summary of Changes

LLT.ASC	Added	584
	Removed	0
	Modified	395
SMQ_LIST.ASC¹	Added ¹	2
	Removed	0
	Modified	210
SMQ_CONTENT.ASC	Added	950
	Removed	0
	Modified	139

Table 4-5 Summary of Impact on Records in MedDRA Files

¹ The number of SMQs added includes both top level (Level 1) and sub-search SMQs.

4.3 MedDRA TERM COUNTS

The table below shows term counts by SOC for HLGTS, HLTs, primary and secondary PTs and LLTs, and primary PTs and LLTs.

SOC	LLTs* (Primary)¹	PTs (Primary)¹	LLTs* (Primary and Secondary)²	PTs (Primary and Secondary)²	HLTs³	HLGTS³
<i>Blood and lymphatic system disorders</i>	1093	265	4036	924	87	17
<i>Cardiac disorders</i>	1354	302	2208	543	36	10
<i>Congenital, familial and genetic disorders</i>	3231	1208	3231	1208	98	19
<i>Ear and labyrinth disorders</i>	416	81	760	190	17	6
<i>Endocrine disorders</i>	604	167	1640	476	38	9

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>Eye disorders</i>	2351	556	3514	925	64	13
<i>Gastrointestinal disorders</i>	3636	796	7153	1587	109	21
<i>General disorders and administration site conditions</i>	2522	842	3160	1054	49	9
<i>Hepatobiliary disorders</i>	609	175	1367	392	19	4
<i>Immune system disorders</i>	413	122	2338	613	26	4
<i>Infections and infestations</i>	6829	1808	7140	1889	149	12
<i>Injury, poisoning and procedural complications</i>	6051	961	8033	1770	67	7
<i>Investigations</i>	12990	5226	12990	5226	106	23
<i>Metabolism and nutrition disorders</i>	917	265	2444	689	63	14
<i>Musculoskeletal and connective tissue disorders</i>	2321	410	6000	1101	60	11
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	8311	1867	8950	2118	201	39

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>Nervous system disorders</i>	3316	848	6546	1702	107	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1597	213	2765	542	48	8
<i>Psychiatric disorders</i>	2187	486	2988	695	78	23
<i>Renal and urinary disorders</i>	1151	323	2466	674	32	8
<i>Reproductive system and breast disorders</i>	1675	456	3989	1091	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1579	476	3913	1042	48	11
<i>Skin and subcutaneous tissue disorders</i>	1932	449	4264	1176	56	10
<i>Social circumstances</i>	600	252	600	252	20	7
<i>Surgical and medical procedures</i>	4325	1985	4325	1985	140	19
<i>Vascular disorders</i>	1211	269	6109	1413	68	11
Total	73221	20808				

Table 4-6 MedDRA Term Counts

Summary of Changes

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 4-2 and 4-3.

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 4-2 and 4-3.

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 MODIFIED PT AND LLT NAMES

As part of ongoing MedDRA maintenance activities, existing PTs and LLTs can be modified (renamed) to correct for misspelling, double spacing, capitalization or other errors that meet the renaming criteria in MedDRA. This rename provision retains the original MedDRA code of the term and preserves its original meaning, and facilitates the reuse of the same MedDRA code for the renamed PT/LLTs.

The table below lists the 4 terms renamed in MedDRA v17.1.

Code	Level	Term Name in v17.0	Term Name in v17.1
10006611	LLT	Burkitt's tumor or lymphoma involving lymph nodes of inguinal region and lower limb.	Burkitt's tumor or lymphoma involving lymph nodes of inguinal region and lower limb
10011488	LLT	Cryptococcal neoformans meningitis	Cryptococcus neoformans meningitis
10028284	LLT	Muscae volante	Muscae volitantes
10074880	PT	Prevertebral soft issue swelling of cervical space	Prevertebral soft tissue swelling of cervical space

Table 4-7 Modified PT/LLT Names

Summary of Changes

4.5 LLT CURRENCY STATUS CHANGES

The following table reflects the 11 terms at the LLT level in MedDRA v17.1 that have a change in their currency status along with the rationale for the change.

Lowest Level Term	Currency Status Changed to	Rationale
Inappropriate formulation of drug administered	Current	Inappropriate formulation of drug administered is a recognized concept and will be made a current LLT. Note that LLT <i>Inappropriate formulation of vaccine administered</i> is also a current term in MedDRA.
Adverse local tissue reaction	Non-current	LLT <i>Adverse local tissue reaction</i> was made non-current because the concept could be interpreted to represent an administration site reaction or any local tissue reaction. To more specifically convey the nature of the concept, the MSSO added LLT <i>Adverse local tissue reaction around prosthesis</i> to PT <i>Medical device site reaction</i> .
ASPT	Non-current	The acronym ASPT could represent a number of differing concepts such as "All Safety Precautions Taken", "Asymptomatic Spontaneous Pneumothorax" and "Average Score Per Taxon"
Coronary artery disease aggravat.	Non-current	Truncated words are generally made non-current in MedDRA. Please note that the non-abbreviated spelling LLT <i>Coronary artery disease aggravated</i> is available.
Dissem. intravasc. coagulation	Non-current	Truncated words are generally made non-current in MedDRA. Please note that the spelled out LLT <i>Disseminated intravascular coagulation</i> exists in MedDRA.
Navicular fracture	Non-current	Navicular fracture is ambiguous because it can refer to the name of a bone in either the wrist or the foot. The MSSO added LLT <i>Scaphoid bone fracture</i> to PT <i>Wrist fracture</i> and LLT <i>Tarsal navicular bone fracture</i> to PT <i>Foot fracture</i> to provide coding options for both possible sites of navicular fracture.
Neuroleptic malignant synd. aggr.	Non-current	Truncated words are generally made non-current in MedDRA. The completely spelled out LLT <i>Neuroleptic malignant syndrome aggravated</i> exists in MedDRA.
Overdose effect	Non-current	Overdose effect represents a combination term of overdose and effect/event which can be represented by existing individual terms.
Pruritis	Non-current	LLT <i>Pruritis</i> is a misspelled word. The alternate correct spelling, LLT <i>Pruritus</i> , already exists in MedDRA.
Thyroid stim. hormone decreased	Non-current	Truncated words are generally made non-current in MedDRA. The completely spelled out LLT <i>Thyroid stimulating hormone decreased</i> exists in MedDRA.

Summary of Changes

Lowest Level Term	Currency Status Changed to	Rationale
Thyroid stim. hormone increased	Non-current	Truncated words are generally made non-current in MedDRA. The completely spelled out LLT <i>Thyroid stimulating hormone increased</i> exists in MedDRA.

Table 4-8 LLT Currency Changes