



What's New MedDRA Version 15.1

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ACKNOWLEDGEMENTS

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1. DOCUMENT OVERVIEW

This What's New document contains information on the source and types of changes made to the Medical Dictionary for Regulatory Activities (MedDRA) between Versions 15.0 and 15.1.

Section 2, Version 15.1 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 15.1, highlights changes in v15.1 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 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). 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@mssotools.com.

2. VERSION 15.1 CHANGE REQUESTS

2.1 TERMINOLOGY CHANGES

Changes to MedDRA result from both user change requests, proactivity requests submitted by MedDRA users, and internal change requests. Internal change requests result from MSSO maintenance activities as well as special working group activities in which the MSSO participates.

MedDRA v15.1 is a simple change version which means changes can be made only at the PT and LLT level of the MedDRA hierarchy.

Change requests involve both MedDRA updates and SMQ changes. There were a total of 1095 change requests processed for this version; 835 change requests were approved and implemented, and 229 change requests were rejected. There are, in addition, 31 change requests suspended for further consideration and resolution beyond this version.

Version 15.1 Change Requests

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 the English language MedDRA download. In addition, users may wish to use the [MedDRA Version Analysis Tool](#) (MVAT) which is an on-line 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 free to MedDRA users as part of their subscription.

An explanation of all changes considered (approved and not approved) for MedDRA v15.1 is accessible both as a cumulative Detail Report included in the MedDRA English version download and a [weekly supplemental update](#) file (for v15.1). In addition, users may review all change requests considered 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 HLGs for v15.1 (shown in Table 4-6) and the corresponding information for v15.0. 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 v15.1.

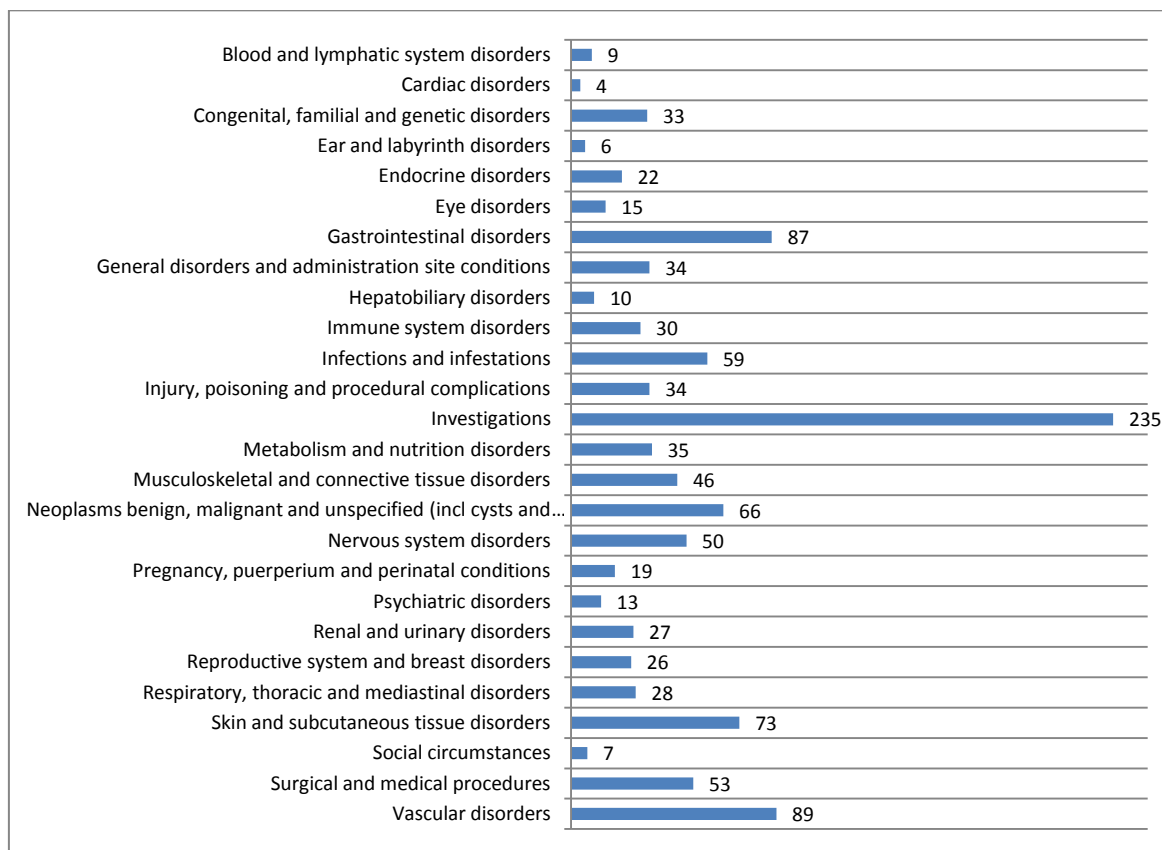


Figure 2-1. Changes per SOC

2.2 TRANSLATION CHANGES

In addition to terminology changes, there were 410 translation correction requests considered and 399 changes implemented to replace misspelled or mistranslated terms in the non-English versions of MedDRA. Below is a summary of the number of changes implemented and the language affected.

- 30 Chinese
- 1 Dutch
- 296 French
- 60 German
- 8 Italian
- 4 Spanish

The large number of changes to French MedDRA is due to efforts by the MSSO and the Canadian regulatory authority, Health Canada, to identify and correct issues with the French translation. Please see the [Change Request section](#) of the MSSO Web site if you wish to request corrections to a non-English version of MedDRA.

3. NEW DEVELOPMENTS IN VERSION 15.1

3.1 STANDARDISED MedDRA QUERIES (SMQs)

One new level 1 SMQ was released into production in MedDRA v15.1 – SMQ *Generalised convulsive seizures following immunisation*. There are now 87 level 1 SMQs in production as of this version. Please see the MedDRA v15.1 SMQ Introductory Guide for specific information about this new SMQ.

3.2 TERMS WITH MISSING AMERICAN OR BRITISH SPELLINGS COUNTERPARTS

Based upon a proactivity request submitted by a MedDRA user, the MSSO added missing American or British counterparts to existing MedDRA terms to improve MedDRA for coding and consistency. There were a total of 27 new terms added. See the table below for examples.

Existing term	Missing US or British Spelling Counterpart
LLT Oesophagram	LLT Esophagram
LLT Oesophageal neoplasm	LLT Esophageal neoplasm
LLT Esophageal leukoplakia	LLT Oesophageal leukoplakia

Table 3-1. Missing US and British Counterpart Terms

The MSSO is still reviewing MedDRA to identify additional missing American or British spelling counterparts to existing terms. Any missing counterparts will be added for MedDRA v16.0.

3.3 UPGRADED MedDRA DESKTOP BROWSER

The MSSO is pleased to announce an upgrade to the MedDRA Desktop Browser (MDB). The upgrade, beta version 3.1, has the following new features:

- A network-based installation option which allows IT departments to centrally install the MDB without having to install the program on every computer.

New Developments in Version 15.1

- A new synonym pair for haemorrhage / hemorrhage and bleeding for English MedDRA
- Synonym lists for each supported language
- An option to set the dual panel display to view two languages of the same MedDRA version as a default when starting the MDB.
- Ability to ignore diacritical marks when performing searches in non-English languages.
- A history file for each language
- Several bug fixes

The MDB can be obtained from the MSSO Web site under [downloads/tools](#). For further information on the new features, please view the [MDB enhancements video](#).

4. SUMMARY OF CHANGES

4.1 SUMMARY OF IMPACT ON THE TERMINOLOGY

The tables below (see Tables 4-1 through 4-5) summarize the impact on MedDRA in v15.1. These tables are intended only as a reference. For detailed information on the changes to v15.1, please see the MedDRA Version Report included within the [English language download](#).

SOC, HLGT, HLT Changes

Level	Change Request Action	Net Change	v15.0	v15.1
SOC	Total SOCs	0	26	26
HLGT	New HLGTs	0	0	0
	Merged HLGTs	0	0	0
	Total HLGTs ¹	0	335	335
HLT	New HLTs	0	0	0
	Merged HLTs	0	0	0
	Total HLTs ¹	0	1713	1713

Table 4-1. Summary of Impact on SOCs, HLGTs, HLTs

¹ Total net change of HLGTs/HLTs equals the number of new HLGTs/HLTs minus the number of merged HLGTs/HLTs.

Summary of Changes

PT Changes

Level	Change Request Action	v15.0	v15.1
PT	New PTs	270	228
	Promoted LLTs	20	27
	Demoted PTs	34	68
	Net Change ¹	256	187
	Total PTs	19550	19737

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	v15.0	v15.1
LLT	Total LLTs ¹	457	70177	70634

Table 4-3. Summary of Impact on LLTs

¹Total LLTs include PTs.

New SMQs

Level	Net Change	v15.0	v15.1
1	1	86	87
2	0	82	82
3	0	21	21

Summary of Changes

Level	Net Change	v15.0	v15.1
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 v15.1. 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	385
	Removed	110

Summary of Changes

	Modified	0
MDHIER.ASC	Added	410
	Removed	128
	Modified	0
PT.ASC	Added	255
	Removed	68
	Modified	7
LLT.ASC	Added	457
	Removed	0
	Modified	253
SMQ_LIST.ASC¹	Added ¹	1
	Removed	0
	Modified	203
SMQ_CONTENT.ASC	Added	775
	Removed ²	13
	Modified	152

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.

² The number of removed PTs represents terms moved from one SMQ to another.

Summary of Changes

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	HLT³	HLGT³
<i>Blood and lymphatic system disorders</i>	1008	242	3898	883	87	17
<i>Cardiac disorders</i>	1305	293	2146	526	36	10
<i>Congenital, familial and genetic disorders</i>	3115	1151	3115	1151	99	19
<i>Ear and labyrinth disorders</i>	425	81	752	185	17	6
<i>Endocrine disorders</i>	580	161	1558	447	38	9
<i>Eye disorders</i>	2362	534	3399	874	64	13
<i>Gastrointestinal disorders</i>	3527	757	6947	1498	109	21
<i>General disorders and administration site conditions</i>	2251	705	2803	882	49	9
<i>Hepatobiliary disorders</i>	597	169	1306	368	19	4

Summary of Changes

SOC	LLTs* (Primary)¹	PTs (Primary)¹	LLTs* (Primary and Secondary)²	PTs (Primary and Secondary)²	HLTs³	HLGTs³
<i>Immune system disorders</i>	433	120	2034	537	24	4
<i>Infections and infestations</i>	6568	1723	6871	1801	147	12
<i>Injury, poisoning and procedural complications</i>	5761	825	7421	1467	61	7
<i>Investigations</i>	12591	5023	12591	5023	106	23
<i>Metabolism and nutrition disorders</i>	890	253	2391	661	63	14
<i>Musculoskeletal and connective tissue disorders</i>	2253	399	5812	1035	60	11
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	7993	1751	8558	1981	203	40
<i>Nervous system disorders</i>	3206	807	6284	1599	107	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1584	207	2623	502	48	8
<i>Psychiatric disorders</i>	2175	482	2950	678	78	23

Summary of Changes

SOC	LLTs* (Primary)¹	PTs (Primary)¹	LLTs* (Primary and Secondary)²	PTs (Primary and Secondary)²	HLTs³	HLGTs³
<i>Renal and urinary disorders</i>	1125	312	2415	653	32	8
<i>Reproductive system and breast disorders</i>	1634	433	3790	1003	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1548	466	3766	992	48	11
<i>Skin and subcutaneous tissue disorders</i>	1886	426	3979	1032	56	10
<i>Social circumstances</i>	610	254	610	254	20	7
<i>Surgical and medical procedures</i>	4076	1909	4076	1909	140	19
<i>Vascular disorders</i>	1131	254	5714	1283	68	11
Total	70634	19737				

Table 4-6. MedDRA Term Counts

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 HLG T 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

Summary of Changes

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. This facilitates the reuse of the same MedDRA code for the renamed PT/LLTs.

The table below lists the PTs and LLTs renamed in MedDRA v15.1.

Code	Level	Term Name in v15.0	Term Name in v15.1
10021229	LLT	Idiopathic hypercalcuria	Idiopathic hypercalciuria
10027845	LLT	Monoclonal antibody conjugated with Actinides therapy	Monoclonal antibody conjugated with actinides therapy
10027846	LLT	Monoclonal antibody conjugated with Alpha amanitin therapy	Monoclonal antibody conjugated with alpha amanitin therapy
10027847	LLT	Monoclonal antibody conjugated with Astatine-211 therapy	Monoclonal antibody conjugated with astatine-211 therapy
10027848	LLT	Monoclonal antibody conjugated with Bismuth-212 therapy	Monoclonal antibody conjugated with bismuth-212 therapy
10027849	LLT	Monoclonal antibody conjugated with Boron-10 therapy	Monoclonal antibody conjugated with boron-10 therapy
10027850	LLT	Monoclonal antibody conjugated with Bromine-77 therapy	Monoclonal antibody conjugated with bromine-77 therapy
10027851	LLT	Monoclonal antibody conjugated with Diphtheria therapy	Monoclonal antibody conjugated with diphtheria therapy
10027852	LLT	Monoclonal antibody conjugated with Iodine-125 therapy	Monoclonal antibody conjugated with iodine-125 therapy
10027853	LLT	Monoclonal antibody conjugated with Iodine-131 therapy	Monoclonal antibody conjugated with iodine-131 therapy
10027854	LLT	Monoclonal antibody conjugated with Palladium-109 therapy	Monoclonal antibody conjugated with palladium-109 therapy

Summary of Changes

Code	Level	Term Name in v15.0	Term Name in v15.1
10027855	LLT	Monoclonal antibody conjugated with Pseudomonas extoxin therapy	Monoclonal antibody conjugated with pseudomonas extoxin therapy
10027856	LLT	Monoclonal antibody conjugated with Ricin therapy	Monoclonal antibody conjugated with ricin therapy
10027857	LLT	Monoclonal antibody conjugated with Scandium-47 therapy	Monoclonal antibody conjugated with scandium-47 therapy
10027858	LLT	Monoclonal antibody conjugated with Yttrium-90 therapy	Monoclonal antibody conjugated with yttrium-90 therapy
10029546	LLT	Non-granulomatous ulcerative jejunoileitis	Non-granulomatous ulcerative jejunoileitis
10072260	LLT	Amyloid related imaging abnormality-Oedema/Effusion	Amyloid related imaging abnormality-oedema/effusion
10072261	LLT	Amyloid related imaging abnormality-Edema/Effusion	Amyloid related imaging abnormality-edema/effusion

Table 4-7. Modified PT/LLT Names

4.5 LLT CURRENCY STATUS CHANGES

The following table reflects the 10 terms at the LLT level in MedDRA v15.1 that have a change in their currency status along with the rationale for that change.

Lowest Level Term	Currency Status Changed to	Rationale
Cervicoplasty	Non-current	LLT Cervicoplasty was made non-current as result of a clinical audit review and was done to avoid confusion of LLT <i>Cervicoplasty</i> with a uterine cervical procedure.
Eventration procedure	Non-current	Eventration procedure is an ambiguous term which could relate to both the removal of abdominal viscera as well as the repair of hernia/ local eventration. In a related change, request 2012158005, the MSSO added a new PT <i>Eventration repair</i> to represent the surgical treatment of a hernial eventration or a diaphragmatic eventration. PT <i>Eventration procedure</i> was demoted under the new PT <i>Eventration repair</i> in change request 2012158006 and made non-current as explained above.

Summary of Changes

Lowest Level Term	Currency Status Changed to	Rationale
Gastroesophageal junction ulcer haemorrhage	Non-current	Based upon a proactivity proposal submitted by a MedDRA user, the MSSO is adding missing British and American spelling counterparts of existing MedDRA terms to improve coding and consistency. LLT Gastroesophageal junction ulcer haemorrhage is a mix of US and British English spellings; therefore it is being made non-current. The British spelling LLT <i>Gastrooesophageal junction ulcer haemorrhage</i> was added in change request 2012145007 for MedDRA v15.1. US spelling LLT <i>Gastroesophageal junction ulcer hemorrhage</i> has been in MedDRA since v 6.1.
Labial itching	Non-current	"Labial" is ambiguous and could refer to both genital labial itching as well as to oral lip itching.
Long-chain acetyl-coenzyme A dehydrogenase deficiency	Non-current	The following LLTs were made non-current: LLT <i>Long-chain acetyl-coenzyme A dehydrogenase deficiency</i> , LLT <i>Medium-chain acetyl-coenzyme A dehydrogenase deficiency</i> , LLT <i>Short-chain acetyl-coenzyme A dehydrogenase deficiency</i> and LLT <i>Very long-chain acetyl-coenzyme A dehydrogenase deficiency</i> . Acyl CoA and Acetyl-CoA are different chemically. Acetyl CoA is at the end of the Lynen beta-oxidation spiral, the very last step before Krebs cycle - while acyl-CoA enzymes are right at the beginning (long aliphatic chains). When these terms were reviewed and approved for MedDRA v15.0 the "acyl" form of these terms should have been added instead of the 'acetyl' form. The 'acyl' forms of these terms have been added for v15.1. Because 'acetyl' is a distinct term and could be requested in the future, the MSSO opted to make these terms non-current rather than rename them.
Medium-chain acetyl-coenzyme A dehydrogenase deficiency	Non-current	See the explanation for LLT Long-chain acetyl-coenzyme A dehydrogenase deficiency
Perforated DU	Non-current	The acronym 'DU' is ambiguous and can be used to represent decubitus ulcer or to duodenal ulcer.
Reactivated DU	Non-current	The acronym 'DU' is ambiguous and can be used to represent decubitus ulcer or to duodenal ulcer.
Short-chain acetyl-coenzyme A dehydrogenase deficiency	Non-current	See the explanation for LLT Long-chain acetyl-coenzyme A dehydrogenase deficiency

Summary of Changes

Lowest Level Term	Currency Status Changed to	Rationale
Very long-chain acetyl-coenzyme A dehydrogenase deficiency	Non-current	See the explanation for LLT Long-chain acetyl-coenzyme A dehydrogenase deficiency

Table 4-8. LLT Currency Changes