



What's New MedDRA Version 16.0

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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 15.1 and 16.0.

Section 2, Version 16.0 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 16.0, highlights changes in v16.0 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 16.0 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 as well as special working group activities in which the MSSO participates.

MedDRA v16.0 is a complex change version which means changes can be made at all levels of the MedDRA hierarchy.

Change requests involve both MedDRA updates and SMQ changes. There were a total of 2537 change requests processed for this version; 2009 change requests were approved and implemented, and 433 change requests were not approved. There are, in addition, 95 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 the 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. Prior to a MedDRA release, 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 understand what changes will be implemented in the next release.

An explanation of all changes considered (approved and not approved) for MedDRA v16.0 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 HLGs for v16.0 (shown in Table 4-6) and the corresponding information for v15.1. 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 v16.0.

Version 16.0 Change Requests

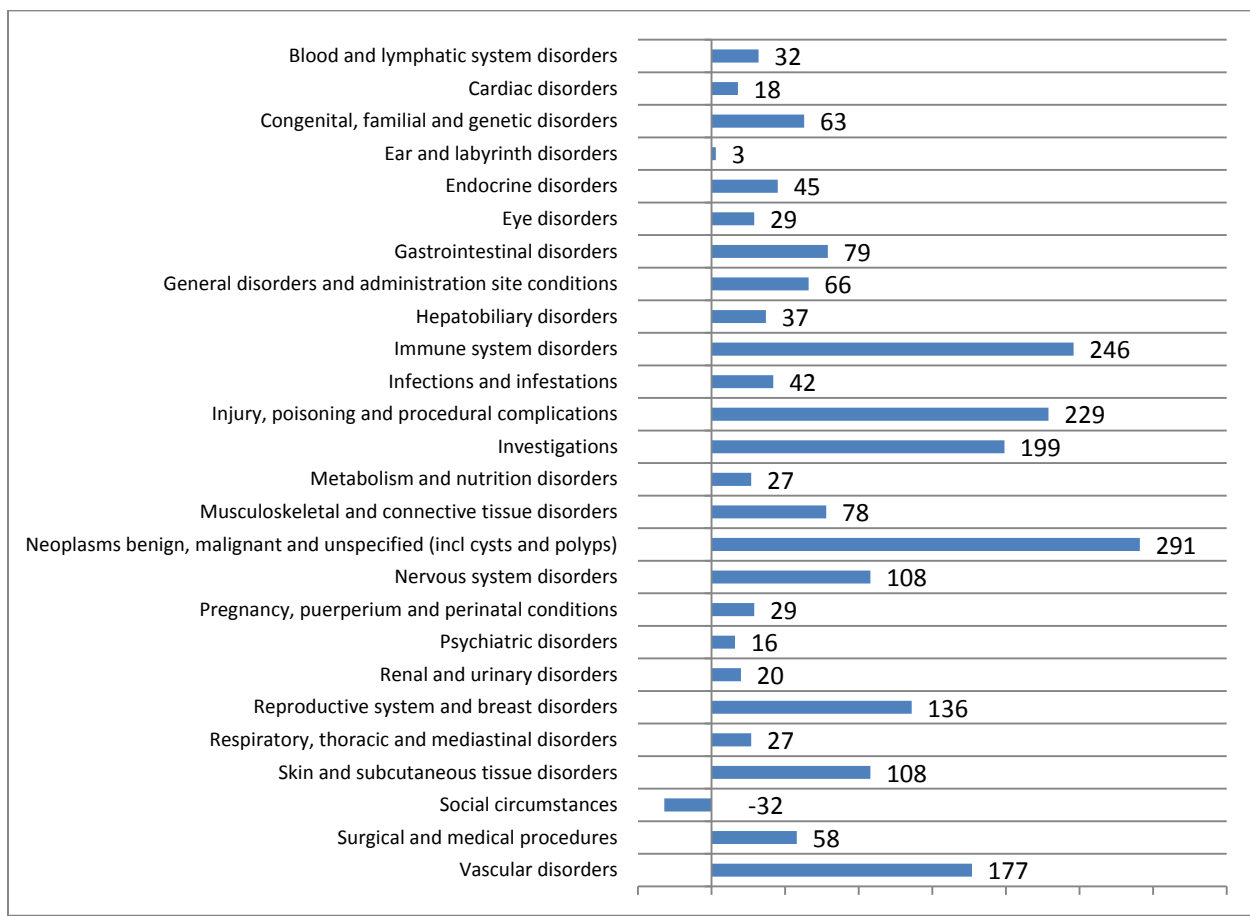


Figure 2-1. Net Changes of Terms per SOC

2.2 COMPLEX CHANGES

The proposals for complex changes considered during v16.0 included those submitted by users, special initiatives, and those internally identified by the MSSO during change request processing.

Complex change proposals were posted on the MSSO Web site for feedback from the MedDRA user community from 6 July 2012 to 31 July 2012. Complex changes were followed by further internal review and consensus discussions which resulted in the final approved set of 31 complex changes.

The complex changes implemented in v16.0 are summarized below. Please see the [Complex Change](#) section of the MSSO Web site for specific details.

At the SOC level: No changes were made to existing SOCs.

Version 16.0 Change Requests

At the HLGT level: There was one new High Level Grouping Term (HLGT) added and two HLGTs merged as a result of complex changes in v16.0. The changes are as follows:

New HLGTs

New HLGT	To SOC
Soft tissue neoplasms malignant and unspecified	Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Table 2-1. New HLGTs

Merged HLGTs

Merged HLGT	To HLGT	SOC
Soft tissue neoplasms malignant and unspecified (excl sarcomas)	Soft tissue neoplasms malignant and unspecified	Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Soft tissue sarcomas	Soft tissue neoplasms malignant and unspecified	Neoplasms benign, malignant and unspecified (incl cysts and polyps)

Table 2-2. Merged HLGTs

At the HLT level: There were 16 new High Level Terms (HLTs) added and 12 HLT merged as a result of the complex changes in v16.0. The changes are as follows:

New HLTs

New HLT	To HLGT	SOC
Accidental exposures to product	Medication errors	Injury, poisoning and procedural complications
Autoinflammatory diseases	Immune disorders NEC	Immune system disorders
Cell marker analyses	Cytogenetic investigations	Investigations

Version 16.0 Change Requests

New HLT	To HLGT	SOC
Coordination and balance disturbances	Neurological disorders NEC	Nervous system disorders
Exposures to agents or circumstances NEC	Exposures, chemical injuries and poisoning	Injury, poisoning and procedural complications
Foetal and neonatal conditions associated with product exposure	Exposures, chemical injuries and poisoning	Injury, poisoning and procedural complications
Fracture complications	Fractures	Musculoskeletal and connective tissue disorders
Fractures NEC	Fractures	Musculoskeletal and connective tissue disorders
Hair and nail disorders congenital	Skin and subcutaneous tissue disorders congenital	Congenital, familial and genetic disorders
Lacrimation disorders	Eye disorders NEC	Eye disorders
Non-occupational environmental exposures	Exposures, chemical injuries and poisoning	Injury, poisoning and procedural complications
Occupational exposures	Exposures, chemical injuries and poisoning	Injury, poisoning and procedural complications
Pathways and sources of exposure	Exposures, chemical injuries and poisoning	Injury, poisoning and procedural complications
Photosensitivity and photodermatitis conditions	Epidermal and dermal conditions	Skin and subcutaneous tissue disorders
Spinal column fractures	Fractures	Musculoskeletal and connective tissue disorders
Thoracic cage fractures non-spinal	Fractures	Musculoskeletal and connective tissue disorders

Table 2-3. New HLTs

Merged HLTs

Merged HLT	To HLT	SOC
Cell marker procedures	Cell marker analyses	Investigations
Cerebellar coordination and balance disturbances	Coordination and balance disturbances	Nervous system disorders
Exposures NEC (excl medication errors due to accidental exposures)	Exposures to agents or circumstances NEC	Injury, poisoning and procedural complications
Fractures NEC (excl pathological)	Fractures NEC	Musculoskeletal and connective tissue disorders
Hair disorders congenital	Hair and nail disorders congenital	Congenital, familial and genetic disorders
Lacrimal disorders	Lacrimation disorders	Eye disorders
Medication errors due to accidental exposures	Accidental exposures to product	Injury, poisoning and procedural complications
Nail disorders congenital	Hair and nail disorders congenital	Congenital, familial and genetic disorders
Pathological fractures and complications	Fracture complications	Musculoskeletal and connective tissue disorders
Photosensitivity conditions	Photosensitivity and photodermatitis conditions	Skin and subcutaneous tissue disorders
Spinal fractures (excl pathological)	Spinal column fractures	Musculoskeletal and connective tissue disorders
Thoracic cage fractures non-spinal (excl pathological)	Thoracic cage fractures non-spinal	Musculoskeletal and connective tissue disorders

Table 2-4. Merged HLTs

2.3 TRANSLATION CHANGES

In addition to terminology changes, there were 618 translation correction requests considered and 617 approved changes implemented to the non-English versions of MedDRA. Below is a summary of the number of changes implemented and the language affected.

- 2 Chinese
- 5 Dutch
- 57 French
- 20 German
- 1 Hungarian
- 10 Italian
- 522 Spanish

The large number of changes to Spanish MedDRA v16.0 is due to performance of a quality review to improve the Spanish 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 16.0

3.1 STANDARDISED MedDRA QUERIES (SMQs)

Three new level 1 SMQs were released into production in MedDRA v16.0 – SMQ *Chronic kidney disease*, SMQ *Hypersensitivity* and SMQ *Malignant lymphomas*. There are now 90 level 1 SMQs in production as of this version.

In addition to new SMQs, three sub-search SMQs were renamed to clarify their content. *Drug abuse (SMQ)* was renamed to *Drug abuse and dependence (SMQ)* to represent the drug dependence concepts included in this SMQ. *Bile duct related disorders (SMQ)* has been renamed as *Biliary tract disorders (SMQ)* to more accurately identify this grouping of disorders of the biliary tract which is not limited only to bile duct pathology. The third renamed SMQ, *Oropharyngeal conditions (excl neoplasms, infections and allergies) (SMQ)*, was reworded to more clearly describe the concepts included in this SMQ. (See table 3.1 below.)

Old SMQ name	New SMQ name
Drug abuse	Drug abuse and dependence
Bile duct related disorders	Biliary tract disorders
Oropharyngeal lesions, non-neoplastic, non-infectious and non-allergic	Oropharyngeal conditions (excl neoplasms, infections and allergies)

Table 3-1. Renamed SMQs

Other SMQ changes include the merging of existing SMQ *Site unspecified biliary disorders* to the renamed SMQ *Biliary tract disorders*. As a result of this merge, SMQ *Site unspecified biliary disorders* no longer exists as a separate SMQ. The merge was performed to group biliary tract disorder concepts under a single SMQ. Thus, the PTs that were under SMQ *Site unspecified biliary disorders* are now consolidated under renamed SMQ *Biliary tract disorders* (formerly SMQ *Bile duct related disorders*).

Please see the MedDRA v16.0 SMQ Introductory Guide for more information about the new SMQs and the changes described above.

Note: The MSSO discovered a discrepancy in which the MVAT generated version report does not list merged SMQ *Site unspecified biliary disorders* as a change in the “SMQ Changes” report. The underlying PTs, which moved under SMQ *Biliary tract disorders* are listed as expected in the “PT Changes in SMQs” report. The merge of SMQ *Site unspecified biliary disorders* has been added to the Version Report spreadsheet included in the MedDRA v16.0 release. This discrepancy will be addressed in a future release of MVAT.

3.2 EXPOSURE TERMS

Twenty four new exposure terms have been added and 68 changes to existing exposure terms have implemented for MedDRA v16.0. These changes are the result of efforts by the MSSO, regulatory authorities and industry experts to make exposure terms more self explanatory and easier to use for pharmacovigilance purposes. This work builds upon earlier efforts to improve exposure terms in MedDRA.

The exposure term changes were part of the complex change review process and were posted on the MSSO’s Web site for feedback by MedDRA users. The MSSO considered MedDRA user comments, input from regulatory and industry experts before implementing the v16.0 changes. Of particular note are the following points:

- A distinction has been made between exposure “to” versus exposure “via” terms (e.g., PT *Exposure to body fluid* and PT *Exposure via body fluid*) because this distinction is relevant to the representation of different exposure concepts and is of particular significance to toxicologic elements of pharmacovigilance. While the difference between “via” and “to” may appear subtle, the “via” terms indicate the vehicle by which the patient is exposed whereas “to” concepts identify the specific agent of exposure. For example, LLT *Exposure to body fluid* might be used to code medical history, when it may not be known whether the body fluid was infectious or contained some other harmful element. The “via” terms are meant to be used in combination with one or more additional term(s), for example, to code the agent of exposure, such as LLT *Hepatitis B*, and any resulting clinical consequences, such as LLT *Jaundice*. The MedDRA Introductory Guide has been updated to explain the distinction between “to” and “via” exposure terms.
- Five new HLTs are added to HLGT *Exposures, chemical injuries and poisoning* in SOC *Injury, poisoning and procedural complications*:

New Exposure Term HLTs
Pathways and sources of exposure
Exposures to agents or circumstances NEC
Non-occupational environmental exposures
Occupational exposures
Foetal and neonatal conditions associated with product exposure

Table 3-2. Exposure Term HLTs

Existing HLT *Exposures NEC (excl medication errors due to accidental exposures)* was replaced by new HLT *Exposures to agents or circumstances NEC*.

- One new HLT –HLT *Accidental exposures to product* – was added to HLGT *Medication errors* in SOC *Injury, poisoning and procedural complications*. This HLT

replaces existing HLT *Medication errors due to accidental exposures*. The new HLT is meant to contain terms that pertain to health-related products (e.g., prescription drug, medical device, nutritional supplement, OTC medication, etc.).

Please see the [Complex Change](#) section of the MSSO Web site for specific details on the exposure term hierarchy.

3.3 CHANGES TO SOC NEOPLASMS BENIGN, MALIGNANT AND UNSPECIFIED (INCL CYSTS AND POLYPS)

In April 2011, the MSSO held its seventh Blue Ribbon Panel (BRP7) to discuss potential improvements to SOC *Neoplasms benign, malignant and unspecified (incl cysts and polyps)*. Following an impact analysis and review of comments by MedDRA users on posted proposed changes to this SOC, the MedDRA Management Board supported the Panel's recommendations to:

- Improve histologic specificity at the PT level;
- Reference standard tumor classifications when adding new terms.

The MSSO implemented MedDRA Management Board endorsed recommendations which resulted in a total of 648 changes including 150 new terms and 498 changes to existing terms. For details on these changes, please review the Version Report spreadsheet included with the MedDRA v16.0 files.

An additional BRP7 recommendation to demote "stage" PTs (e.g., PT *Colorectal cancer stage I*, PT *Colorectal cancer stage II*, PT *Colorectal stage III*, etc) to LLTs will not be pursued at this time. Given the status of the recommendation, the MSSO does not plan to add additional "stage" PTs to MedDRA, especially for the newly added PT concepts nor as a "consistency" measure for existing concepts.

3.4 PROACTIVITY REQUESTS

The proactivity 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. The MSSO evaluated several proactivity proposals from MedDRA users and implemented two specific suggestions in MedDRA v16.0. See below for details.

The MSSO is interested to hear any ideas you 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 idea, and include a justification which explains why you think your proposal should be implemented.

3.4.1 Bruise, Contusion and Ecchymosis

MedDRA users suggested modifications to the placement of bruise, contusion and ecchymosis terms as there were some inconsistencies in how these terms were represented in MedDRA. After reviewing the proposals, the MSSO agreed that some changes were needed to harmonize the placement of bruise and contusion terms in a more consistent manner to facilitate coding and data analysis. A total of 67 changes were made. The MSSO developed a general convention on how to organize these terms which is listed below.

- Bruise terms are generally placed at the LLT level and linked to an appropriate contusion PT, with the exception that a specific *bruise* term may be at the PT level if it represents the common clinical use of the respective concept (e.g., PT *Increased tendency to bruise*).
- For those bruise LLTs that did not map to PT *Contusion*, a site-specific or procedure-specific contusion PT was added. For example, LLT *Penile bruise* is now under new PT *Penile contusion*, instead of PT *Penile haematoma*.
- For contusion LLTs that did not map to PT *Contusion*, a site-specific or procedure-specific contusion PT was added, generally in manner as described for bruise LLTs (e.g., LLT *Unspecified contusion of eye* to new PT *Eye contusion*).
- Because ecchymosis is a localized interstitial hemorrhage of usually a small quantity of blood, nonspecific ecchymosis LLTs will continue to be mapped to PT *Ecchymosis*, and site-specific ecchymosis LLTs will continue to be mapped to site-specific or procedure-specific PT hemorrhage terms (e.g., . LLT *Injection site ecchymosis* under PT *Injection site haemorrhage*).

For additional information on the conventions applied to bruise, contusion and ecchymosis terms, please click [here](#). For details on these changes, please review the Version Report spreadsheet included with the MedDRA v16.0 files.

3.4.2 Autoimmune disorders

The MSSO reviewed the placement of autoimmune disorder concepts classified as “systemic”. The review focused on providing additional links, or in some cases reassigning the primary SOC, of existing terms from SOC *Immune system disorders* to a SOC representing the site of manifestation. A total of 56 changes were made based on this review. Below are some examples of PTs that now have links to autoimmune related HLTs.

PT	HLT	Newly Added SOC Link	Primary SOC Change
Addison's disease	Endocrine autoimmune disorders	Immune system disorders (new secondary link)	Endocrine disorders (No change)
Multiple sclerosis	Autoimmune disorders NEC	Immune system disorders (new secondary link)	Nervous system disorders (No change)
Antiphospholipid syndrome	Blood autoimmune disorders	Not applicable	Changed from SOC Immune system disorders to Blood and lymphatic system disorders

Table 3-3. Autoimmune links

For details on these changes, please review the Version Report spreadsheet included with the MedDRA v16.0 files.

3.5 RENAME OF THE ASCII AND CONSECUTIVE FILE DOCUMENT

Bundled with every MedDRA release is a document which describes the MedDRA file schema. This document provides the information on the MedDRA file structure to assist data analytics professionals and software developers to create queries and software tools around MedDRA. This document had been called the “ASCII and Consecutive File Document.” In MedDRA v16.0, the name of this document changed to the “MedDRA Distribution File Format Document.” The new name better reflects the purpose of this document as not all MedDRA language translations (e.g., Chinese, Czech, and Hungarian) are encoded with ASCII (American Standard Code for Information Interchange) file format.

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 v16.0. These tables are intended only as a reference. For detailed information on the changes to v16.0, please see the MedDRA Version Report included within the [English language download](#).

SOC, HLGT, HLT Changes

Level	Change Request Action	Net Change	v15.1	v16.0
SOC	Total SOCs	0	26	26
HLGT	New HLGTs	1	0	1
	Merged HLGTs	2	0	2
	Total HLGTs ¹	-1	335	334
HLT	New HLTs	16	0	16
	Merged HLTs	12	0	12
	Total HLTs ¹	4	1713	1717

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	v15.1	v16.0
PT	New PTs	228	360
	Promoted LLTs	27	113
	Demoted PTs	68	153
	Net Change ¹	187	320
	Total PTs	19737	20057

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	v15.1	v16.0
LLT	Total LLTs ¹	692	70634	71326

Table 4-3. Summary of Impact on LLTs

¹Total LLTs include PTs.

New SMQs

Level	Net Change	v15.1	v16.0
1	3	87	90
2	0	82	82
3	-1	21	20

Summary of Changes

Level	Net Change	v15.1	v16.0
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 v16.0. 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	1
	Removed	2
	Modified	0
HLGT.ASC	Added	1
	Removed	2
	Modified	0
HLGT_HLT.ASC	Added	32
	Removed	28
	Modified	0
HLT.ASC	Added	16
	Removed	12
	Modified	0
HLT_PT.ASC	Added	1041

Summary of Changes

	Removed	463
	Modified	0
MDHIER.ASC	Added	1210
	Removed	594
	Modified	0
PT.ASC	Added	473
	Removed	153
	Modified	30
LLT.ASC	Added	692
	Removed	0
	Modified	1328
SMQ_LIST.ASC¹	Added ¹	3
	Removed	1
	Modified	203
SMQ_CONTENT.ASC	Added	4656
	Removed ²	69
	Modified	484

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>	1029	246	3911	888	87	17
<i>Cardiac disorders</i>	1302	292	2159	528	36	10
<i>Congenital, familial and genetic disorders</i>	3156	1174	3156	1174	98	19
<i>Ear and labyrinth disorders</i>	424	81	751	185	17	6
<i>Endocrine disorders</i>	592	163	1588	460	38	9
<i>Eye disorders</i>	2373	541	3417	884	64	13
<i>Gastrointestinal disorders</i>	3547	765	6995	1531	109	21
<i>General disorders and administration site conditions</i>	2290	727	2843	908	49	9
<i>Hepatobiliary disorders</i>	600	170	1331	380	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>	401	117	2236	574	25	4
<i>Infections and infestations</i>	6596	1738	6897	1816	147	12
<i>Injury, poisoning and procedural complications</i>	5891	872	7574	1533	65	7
<i>Investigations</i>	12728	5081	12728	5081	106	23
<i>Metabolism and nutrition disorders</i>	894	254	2412	671	63	14
<i>Musculoskeletal and connective tissue disorders</i>	2263	402	5870	1056	60	11
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	8144	1848	8730	2085	203	39
<i>Nervous system disorders</i>	3242	819	6360	1631	107	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1579	208	2644	510	48	8
<i>Psychiatric disorders</i>	2181	483	2964	680	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>	1138	317	2430	659	32	8
<i>Reproductive system and breast disorders</i>	1639	438	3871	1056	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1546	468	3779	1005	48	11
<i>Skin and subcutaneous tissue disorders</i>	1881	425	4051	1065	56	10
<i>Social circumstances</i>	588	244	588	244	20	7
<i>Surgical and medical procedures</i>	4130	1927	4130	1927	140	19
<i>Vascular disorders</i>	1172	257	5866	1309	68	11
Total	71326	20057				

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 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).

Summary of Changes

There are some HLTs that are counted in more than one SOC. For example, HLT *Connective tissue disorders congenital* and HLTG *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 HLTGs 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 terms renamed in MedDRA v16.0.

Code	Level	Term Name in v15.1	Term Name in v16.0
10062331	PT	Congenital eustachian tube anomaly	Congenital Eustachian tube anomaly
10018595	LLT	Gonococcal Salpingitis acute	Gonococcal salpingitis acute
10018626	LLT	Gougerot-Nulock-Houwer syndrome	Gougerot-Mulock-Houwer syndrome
10072824	LLT	Interphase dermatitis	Interface dermatitis
10051666	PT	Metastases to eustachian tube	Metastases to Eustachian tube
10030726	LLT	Open wound of eustachian tube, complicated	Open wound of Eustachian tube, complicated
10030727	LLT	Open wound of eustachian tube, uncomplicated	Open wound of Eustachian tube, uncomplicated
10072222	PT	Pyogenic Sterile Arthritis Pyoderma Gangrenosum and Acne syndrome	Pyogenic sterile arthritis pyoderma gangrenosum and acne syndrome

Table 4-7. Modified PT/LLT Names

4.5 LLT CURRENCY STATUS CHANGES

The following table reflects the 33 terms at the LLT level in MedDRA v16.0 that have a change in their currency status along with the rationale for that change. The relatively high number of currency changes is due to the changes implemented for SOC *Neoplasms benign, malignant and unspecified (incl cysts and polyps)*, changes to exposure terms and the number of requests submitted by MedDRA users.

Summary of Changes

Lowest Level Term	Currency Status Changed to	Rationale
Circulatory instability	Current	Circulatory instability is a general expression often used synonymously with cardiovascular instability in the medical literature. LLT <i>Instability cardiovascular</i> is a current MedDRA term under PT <i>Cardiovascular disorder</i> . Therefore, LLT <i>Circulatory instability</i> will change to a status of current.
Dilated stomach	Current	The adjective "dilated" in this context (i.e., dilated stomach) is interpreted as reflecting a recognized disorder and therefore represents a valid concept.
Female sex maturation retarded	Current	Although not widely used in medical literature, "Female sex maturation retarded" is a recognized concept and will be made current on that basis. The MSSO will add a more commonly used synonym LLT <i>Delayed female sexual development</i> under PT <i>Delayed puberty</i> .
Liquorrhea	Current	The decision to make LLT <i>Liquorrhea</i> current resulted from an approved request to promote the LLT <i>Cerebrospinal fluid leakage</i> from PT <i>Intracranial hypotension</i> . Once promoted, the synonyms and sub-concepts LLT <i>CSF leakage</i> , LLT <i>Leakage of cerebrospinal fluid</i> and LLT <i>Liquorrhea</i> were moved to new PT <i>Cerebrospinal fluid leakage</i> . The British English counterpart LLT <i>Liquorrhoea</i> was added under new PT <i>Cerebrospinal fluid leakage</i> . LLT <i>Liquorrhoea</i> was determined to be a relevant concept especially in non English speaking countries.
Male sex maturation retarded	Current	Although not widely used in medical literature, "Male sex maturation retarded" is a recognized concept and will be made current on that basis. The MSSO will add a more commonly used synonym LLT <i>Delayed male sexual development</i> under PT <i>Delayed puberty</i> .
Postmyocardial infarction syndrome	Current	Postmyocardial infarction syndrome is a recognized synonym of Dressler's syndrome. LLT <i>Postmyocardial infarction syndrome</i> resides under PT <i>Dressler's syndrome</i> .
Accidental exposure	Non-current	PT <i>Accidental exposure</i> was linked to HLT <i>Medication errors due to accidental exposures</i> prior to MedDRA v16.0. In v16.0, PT <i>Accidental exposure</i> was demoted to an LLT under new PT <i>Accidental exposure to product</i> and made non-current. The rationale is as follows: "accidental exposure" can relate to products (such as drugs, vaccines, etc.), but it can also relate to non-product agents (e.g., toxins, chemicals, etc.). To avoid

Summary of Changes

Lowest Level Term	Currency Status Changed to	Rationale
		confusion about the intent of LLT <i>Accidental exposure</i> , it has been made non-current. Note that this decision was made after consultation with MedDRA users and with a group of experts who assisted the MSSO with placement of several new “exposure” concepts.
Accidental ingestion	Non-current	LLT <i>Accidental ingestion</i> was linked to PT <i>Accidental exposure</i> prior to MedDRA v16.0. In v16.0, LLT <i>Accidental ingestion</i> was made non-current. The rationale is as follows: “accidental ingestion” can relate to products (such as drugs, vaccines, etc.), but it can also relate to non-product agents (e.g., toxins, chemicals, etc.). To avoid confusion about the intent of LLT <i>Accidental ingestion</i> , it has been made non-current. Note that this decision was made after consultation with MedDRA users and with a group of experts who assisted the MSSO with placement of several new “exposure” concepts.
ADMA	Non-current	The acronym ADMA is ambiguous and could refer to Acellular Dermal Matrix Allograft or Asymmetric dimethylarginine.
B-cell chronic lymphocytic leukaemia/prolymphocytic leukaemia/small lymphocytic lymphoma	Non-current	The latest WHO classification separates the chronic small cell lymphocytic leukemia/lymphoma from the B cell prolymphocytic leukemia. This is therefore a dual concept LLT. This request arose in the context of the MedDRA Blue Ribbon Panel recommendations on revisions to the SOC <i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i> which are being implemented for MedDRA Version 16.0.
B-cell chronic lymphocytic leukaemia/prolymphocytic leukaemia/small lymphocytic lymphoma recurrent	Non-current	Please see the rationale for LLT <i>B-cell chronic lymphocytic leukaemia/prolymphocytic leukaemia/small lymphocytic lymphoma</i> .
B-cell chronic lymphocytic leukaemia/prolymphocytic leukaemia/small lymphocytic lymphoma refractory	Non-current	Please see the rationale for LLT <i>B-cell chronic lymphocytic leukaemia/prolymphocytic leukaemia/small lymphocytic lymphoma</i> .
B-cell chronic lymphocytic leukaemia/prolymphocytic leukaemia/small lymphocytic lymphoma	Non-current	Please see the rationale for LLT <i>B-cell chronic lymphocytic leukaemia/prolymphocytic leukaemia/small lymphocytic lymphoma</i> .

Summary of Changes

Lowest Level Term	Currency Status Changed to	Rationale
stage I		
B-cell chronic lymphocytic leukaemia/prolymphocytic leukaemia/small lymphocytic lymphoma stage II	Non-current	Please see the rationale for LLT <i>B-cell chronic lymphocytic leukaemia/prolymphocytic leukaemia/small lymphocytic lymphoma</i> .
B-cell chronic lymphocytic leukaemia/prolymphocytic leukaemia/small lymphocytic lymphoma stage III	Non-current	Please see the rationale for LLT <i>B-cell chronic lymphocytic leukaemia/prolymphocytic leukaemia/small lymphocytic lymphoma</i> .
B-cell chronic lymphocytic leukaemia/prolymphocytic leukaemia/small lymphocytic lymphoma stage IV	Non-current	Please see the rationale for LLT <i>B-cell chronic lymphocytic leukaemia/prolymphocytic leukaemia/small lymphocytic lymphoma</i> .
B-cell chronic lymphocytic leukemia/prolymphocytic leukemia/small lymphocytic lymphoma	Non-current	Please see the rationale for LLT <i>B-cell chronic lymphocytic leukaemia/prolymphocytic leukaemia/small lymphocytic lymphoma</i> .
B-cell chronic lymphocytic leukemia/prolymphocytic leukemia/small lymphocytic lymphoma recurrent	Non-current	Please see the rationale for LLT <i>B-cell chronic lymphocytic leukaemia/prolymphocytic leukaemia/small lymphocytic lymphoma</i> .
B-cell chronic lymphocytic leukemia/prolymphocytic leukemia/small lymphocytic lymphoma refractory	Non-current	Please see the rationale for LLT <i>B-cell chronic lymphocytic leukaemia/prolymphocytic leukaemia/small lymphocytic lymphoma</i> .
B-cell chronic lymphocytic leukemia/prolymphocytic leukemia/small lymphocytic lymphoma stage I	Non-current	Please see the rationale for LLT <i>B-cell chronic lymphocytic leukaemia/prolymphocytic leukaemia/small lymphocytic lymphoma</i> .
B-cell chronic lymphocytic leukemia/prolymphocytic leukemia/small lymphocytic lymphoma stage II	Non-current	Please see the rationale for LLT <i>B-cell chronic lymphocytic leukaemia/prolymphocytic leukaemia/small lymphocytic lymphoma</i> .

Summary of Changes

Lowest Level Term	Currency Status Changed to	Rationale
B-cell chronic lymphocytic leukemia/prolymphocytic leukemia/small lymphocytic lymphoma stage III	Non-current	Please see the rationale for LLT <i>B-cell chronic lymphocytic leukaemia/prolymphocytic leukaemia/small lymphocytic lymphoma</i> .
B-cell chronic lymphocytic leukemia/prolymphocytic leukemia/small lymphocytic lymphoma stage IV	Non-current	Please see the rationale for LLT <i>B-cell chronic lymphocytic leukaemia/prolymphocytic leukaemia/small lymphocytic lymphoma</i> .
Dilation of stomach	Non-current	Section 5.1 of the MedDRA Introductory Guide - states "For purposes of distinction in MedDRA, the term 'dilation' is considered a procedure and the term 'dilatation' is considered a disorder. The word 'procedure' is normally added to 'dilation,' e.g., PT <i>Stomach dilation procedure</i> to make it self-explanatory. An exception to this convention is PT <i>Uterine dilation and curettage</i> , since it is recognized as a procedure without the addition of the qualifying word." Therefore, in keeping with the MedDRA convention to qualify "dilation" terms with "procedure", the LLT <i>Dilation of stomach</i> was made non-current.
Drainage from arteriovenous graft	Non-current	All drainage concepts not related to a procedure are flagged non-current. To facilitate coding a new LLT <i>Arteriovenous graft leakage</i> will be added to PT <i>Vascular graft complication</i> as a replacement of the non-current LLT <i>Drainage from arteriovenous graft</i> .
Generalised urticarial	Non-current	The submitter originally wanted to rename LLT <i>Generalised urticarial</i> to correctly spelled "Generalised urticaria". However, as LLT <i>Urticaria generalised</i> already exists the MSSO changed the status of the incorrectly spelled term instead.
Global hypokinesia	Non-current	A new LLT <i>Global ventricular hypokinesia</i> was added to PT <i>Ventricular hypokinesia</i> for MedDRA v16.0 to clarify that it is a cardiac event. In a related change, the status of LLT <i>Global hypokinesia</i> was made non-current to avoid confusion differentiating between a neuromuscular or a cardiac event.
Hereditary and idiopathic peripheral neuropathy, other	Non-current	LLT <i>Hereditary and idiopathic peripheral neuropathy, other</i> represents a multi-concept term and other similar concepts such as LLT <i>Other hereditary and idiopathic peripheral neuropathy</i> and LLT <i>Unspecified hereditary and idiopathic peripheral neuropathy</i> are already non-

Summary of Changes

Lowest Level Term	Currency Status Changed to	Rationale
		current.
LADA	Non-current	The acronym LADA is ambiguous and could stand for Latent Autoimmune Diabetes in Adults, Laboratory Animal Dander Allergy or Low-Affinity Dynein Atpase.
Radiography guided aspiration	Non-current	To clarify the difference between diagnostic and therapeutic aspiration in MedDRA, the MSSO took the following actions. New PT <i>Diagnostic aspiration</i> was added to HLT <i>Histopathology procedures NEC</i> . The following PTs were demoted to LLTs under the new PT <i>Diagnostic aspiration</i> - PT <i>Aspiration biopsy</i> and PT <i>Radiography guided aspiration</i> . Upon demotion of PT <i>Radiography guided aspiration</i> to an LLT, it was made non-current. Additionally, a new LLT <i>Radiography guided diagnostic aspiration</i> was added under new PT <i>Diagnostic aspiration</i> .
Vasodilation	Non-current	The status of LLT <i>Vasodilation</i> will be changed to non-current to avoid confusion between a procedure (PT <i>Vasodilation procedure</i>) and a disorder (PT <i>Vasodilatation</i>).
White blood cell analysis decreased	Non-current	Not all white blood cell "analyses" are quantitative; some analyses are related to morphology, function, etc. Therefore, the qualifiers of "increased" and "decreased" do not seem appropriate for "analysis" terms of this type.
White blood cell analysis increased	Non-current	Not all white blood cell "analyses" are quantitative; some analyses are related to morphology, function, etc. Therefore, the qualifiers of "increased" and "decreased" do not seem appropriate for "analysis" terms of this type.

Table 4-8. LLT Currency Changes