



What's New MedDRA Version 18.0

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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 17.1 and 18.0.

Section 2, Version 18.0 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 18.0, highlights changes in Version 18.0 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 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 18.0 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 and from special working group activities in which the MSSO participates.

MedDRA Version 18.0 is a complex change version which means that changes are made at all levels of the MedDRA hierarchy.

Change requests involve both MedDRA updates and SMQ changes. There were a total of 2,069 change requests processed for this version; 1,758 change requests were approved and implemented, and 280 change requests were not approved. There are, in addition, 31 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 Version 18.0 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 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 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 Version 18.0 (shown in Table 4-6) and the corresponding information for Version 17.1. 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 Version 18.0.

Version 18.0 Change Requests

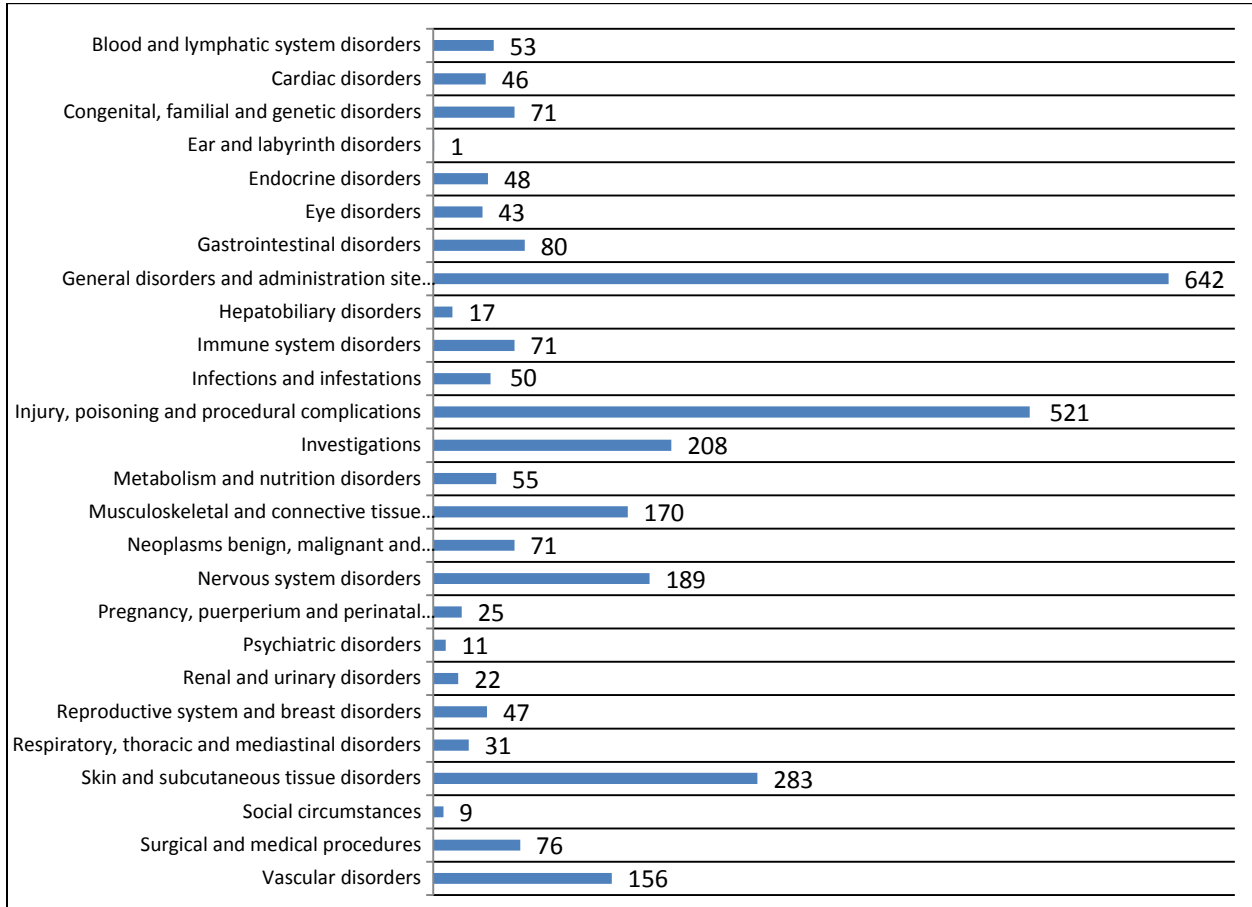


Figure 2-1. Net Changes of Terms per SOC

2.2 COMPLEX CHANGES

The proposals for complex changes considered during Version 18.0 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 MedDRA website for feedback from the MedDRA user community from 7 July 2014 to 1 August 2014. Complex changes were followed by further internal review and consensus discussions which resulted in the final approved set of 16 complex changes.

The complex changes implemented in Version 18.0 are summarized below. Please see the “Related Documents” on the [Change Request section](#) of the MedDRA website for specific details.

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

Version 18.0 Change Requests

At the HLGT level: One new High Level Grouping Term (HLGT) was added and no HLGTs were merged as a result of complex changes in Version 18.0. The changes are as follows:

New HLGTs

New HLGT	To SOC
Product use issues	Injury, poisoning and procedural complications

Table 2-1 New HLGTs

At the HLT level: There were eight new High Level Terms (HLTs) added and seven HLTs merged as a result of complex changes in Version 18.0. The changes are as follows:

New HLTs

New HLT	To SOC
Abdominal hernias NEC	Gastrointestinal disorders
Limb fractures	Musculoskeletal and connective tissue disorders
Limb fractures and dislocations	Injury, poisoning and procedural complications
Off label uses	Injury, poisoning and procedural complications
Overdoses NEC	Injury, poisoning and procedural complications
Patient positioning	Surgical and medical procedures
Product use issues NEC	Injury, poisoning and procedural complications
Underdoses NEC	Injury, poisoning and procedural complications

Table 2-2 New HLTs

Merged HLTs

Merged HLT	To HLT	SOC
Abdominal cavity hernias NEC	Abdominal hernias NEC	Gastrointestinal disorders
Abdominal hernias, site unspecified	Abdominal hernias NEC	Gastrointestinal disorders
Lower limb fractures	Limb fractures	Musculoskeletal and connective tissue disorders
Lower limb fractures and dislocations	Limb fractures and dislocations	Injury, poisoning and procedural complications
Overdoses	Overdoses NEC	Injury, poisoning and procedural complications

Version 18.0 Change Requests

Merged HLT	To HLT	SOC
Upper limb fractures	Limb fractures	Musculoskeletal and connective tissue disorders
Upper limb fractures and dislocations	Limb fractures and dislocations	Injury, poisoning and procedural complications

Table 2-3 Merged HLTs

2.3 TRANSLATION CHANGES

2.3.1 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 Version 18.0 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.

3. NEW DEVELOPMENTS IN VERSION 18.0

3.1 UPDATES TO PRODUCT USE CONCEPTS

A number of MedDRA users have requested complex and related changes, including new terms requests, to better organize the placement of product use concepts including medication error, overdose, and underdose concepts, as well as misuse concepts and off label use concepts. The MSSO reviewed the feedback received from these proposals and, in collaboration with the ICH M1 Points to Consider Working Group, developed a structure to better organize product use concepts. The following points briefly describe the approach taken. Please see the document “Implemented Complex Changes for Version 18.0” on the [Change Request](#) section of the MedDRA website for details.

- A new HLTG *Product use issues* has been added to SOC *Injury, poisoning and procedural complications* to group related product use concepts (medication errors, misuse, off label use, overdoses, and underdoses) in one location to facilitate coding and retrieval, without the need for extensive multi-axial links. New HLTG *Product use issues* contains four new HLTs:
 - HLT *Product use issues NEC* accommodates a mix of misuse, intentional use, and other non-specific use concepts. This new HLT will have two new PT concepts in addition to existing non-specific use PTs:
 - PT *Product use issue* accommodates non-specific product use concepts that are not specifically identified as medication errors, off label use, misuse etc.
 - PT *Intentional product use issue* accommodates use issue concepts that are known to be intentional but are not specifically identified as being misuse or off label use.
 - HLT *Overdoses NEC* accommodates overdose concepts that are not necessarily maladministrations and replaces HLT *Overdoses*.
 - HLT *Underdoses NEC* accommodates underdose concepts that are not necessarily maladministrations.
 - HLT *Off label uses* accommodates off label use concepts.

3.2 27TH SOC TO BE IMPLEMENTED IN MedDRA VERSION 19.0

The ICH MedDRA Management Board has endorsed the creation of an additional (27th) System Organ Class in MedDRA. The 27th SOC (which is yet to be named) is being created to accommodate non-clinical/non-patient related concepts. These terms cover issues related to medical products and are important from a regulatory perspective as they may have an indirect effect on patient safety.

Initially, the 27th SOC will include product quality issue terms which are defined as abnormalities that may be introduced during the manufacturing/labeling, packaging,

shipping, handling, or storage of medical products. The existing HLG *Product quality issues* will be moved from SOC *General disorders and administration site conditions* to the new SOC and will be supplemented by new terms related specifically to the manufacturing process. The impact on organizations which are not involved with product manufacturing or product quality is expected to be minimal.

The 27th SOC is expected to be implemented in March 2016 in MedDRA Version 19.0. The MSSO will provide more detailed information on the 27th SOC through documents, webinars, broadcast emails, and other communications well in advance of the planned implementation date in 2016. For questions on the 27th SOC, please contact the MSSO [Help Desk](#).

3.3 SCOPE OF MedDRA: REVISIONS TO INTRODUCTORY GUIDE

Revisions will be made to Section 1.5 (Scope of the Terminology) in the Introductory Guide for MedDRA Version 18.0. The revised wording pertains to the types of medical products and concepts that MedDRA supports and the potential for expansion of the terminology into new topic areas. These revisions are the result of the Blue Ribbon Panel recommendations on the scope of MedDRA which were endorsed by the MedDRA Management Board. The relevant wording is extracted and presented below.

“The MedDRA terminology applies to all phases of development of medical products for human use, excluding animal toxicology. The scope of MedDRA encompasses medical, health-related, and regulatory concepts pertaining to such products. The terminology also addresses the health effects and malfunction of devices (e.g., *PT Device related infection* and *PT Device failure*). Furthermore, the terminology may also support other types of products which are regulated in at least one region such as food or cosmetics.”

“In consultation with the MedDRA Management Board, the terminology may be expanded in scope to accommodate additional medical/health-related and regulatory concepts that are developed based on collaborative efforts involving relevant experts. The addition of new topic areas will undergo the usual MSSO change request process.”

3.4 NEW WEB-BASED BROWSER

The MSSO is pleased to announce that the new [MedDRA Web-Based Browser](#) (WBB) is available as of 1 December 2014. A MedDRA User ID and Password are required to use the application. The new WBB has features which are similar to the current MedDRA Desktop Browser plus a few new ones. Users will be able to:

- Browse the MedDRA hierarchy and SMQs
- Search for MedDRA terms or codes and SMQs
- View multiple supported languages simultaneously
- Use Research Bin to collect terms for analysis and research purposes
- View term history
- View term detail information
- Export search results to a spreadsheet
- Access the unique features of the MedDRA Japanese translation

The WBB is free to all MedDRA users as part of a MedDRA subscription. Please view or download a [videocast](#) from the Training Materials section of the MedDRA website located under “Tools” to learn how to log into and use the WBB. Additionally, there is a [user guide](#) available.

3.5 STANDARDISED MedDRA QUERIES (SMQs)

Two new level 1 SMQs were released into production in MedDRA Version 18.0: SMQ *Respiratory failure* and SMQ *Tendinopathies and ligament disorders*. There are now 98 level 1 SMQs in production as of this version. Please see the MedDRA Version 18.0 SMQ Introductory Guide for more information about the new SMQs including their inclusion and exclusion criteria.

In addition to new SMQs, four SMQs related to central nervous system vascular disorders or conditions were renamed in MedDRA Version 18.0. Terms related to the spinal cord are included in these SMQs in addition to terms related to the brain and, therefore, renaming these SMQs better reflects the anatomical areas covered. See the table below for the renamed SMQs.

Previous SMQ Name	New SMQ Name
Cerebrovascular disorders (SMQ)	Central nervous system vascular disorders (SMQ)
Cerebrovascular disorders, not specified as haemorrhagic or ischaemic (SMQ)	Central nervous system vascular disorders, not specified as haemorrhagic or ischaemic (SMQ)
Ischaemic cerebrovascular conditions (SMQ)	Ischaemic central nervous system vascular conditions (SMQ)
Haemorrhagic cerebrovascular conditions (SMQ)	Haemorrhagic central nervous system vascular conditions (SMQ)

Table 3-1 Renamed SMQs

3.6 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 18.0 change request processing period, the MSSO evaluated five proactivity proposals submitted by MedDRA users. Of the five proposals, four were implemented and one was 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.

3.6.1 Drug Utilization Terms

A MedDRA user requested a review of a set of drug utilization terms for potential inclusion into MedDRA. Based on a review by the MSSO, most of the requested concepts were already represented in MedDRA either as direct matches or close concepts. A total of three new terms were added (PT *Clinical trial participant*, PT *Planning to become pregnant*, and LLT *Drug supply chain interruption*), and the status of LLT *Out of medication* was changed to non-current because this ambiguous concept could refer to an individual patient running out of medication or a supply chain issue.

3.6.2 ‘Site’ Terms

In two separate requests, the MSSO was asked to consider adding more ‘site’ (e.g., administration site) concepts to MedDRA to provide more coding options for MedDRA users. Based on this review, a total of 224 new concepts were added mostly to SOC *General disorders and administration site conditions*. The MSSO’s approach was to add a set of administration site terms similar to existing injection site terms and fill in gaps to mirror injection site terms as appropriate for vaccination site, infusion site, application site, and medical device site terms. Appropriate secondary links were added for new terms based on MedDRA rules and conventions described in the MedDRA Introductory Guide. Please see the table below for examples of terms added.

PT	Primary HLT*
Application site phlebitis	Application and instillation site reactions
Infusion site hyperaesthesia	Infusion site reactions
Medical device site injury	Complications associated with device NEC
Vaccination site eczema	Vaccination site reactions
LLT	PT
Administration site joint redness	Administration site joint erythema
Application site joint redness	Application site joint erythema

Table 3-2 Examples of ‘site’ terms added to MedDRA

*SOC *General disorders and administration site conditions* is the primary SOC

3.6.3 Classification of spine/spinal and spinal/vertebral column terms

The MSSO was asked to review the specific choice of term or hierarchical placement of various MedDRA concepts relating to the anatomy of the back which are not always consistent with respect to bony structures or to nervous/soft tissues. Many of these terms are derivations of ‘vertebra,’ ‘spine’, and ‘back.’ Of the total 1,366 LLT, PT, HLT, and HLTG applicable MedDRA terms reviewed, 12 change requests were implemented to ensure the consistent use of these terms. The changes pertained to consistency of term definition, term status, and hierarchical relationships. See below for an example: LLT *Spinal hematoma* was made non-current because it is an ambiguous term; ‘spinal’ could refer to the spinal cord or to the bony structure/vertebra. (See also Section 4.5).

MedDRA v17.1		MedDRA v18.0	
LLT	Status	LLT	Status
Spinal hematoma	Current	Spinal hematoma	Non-current

Table 3-3 Example of changes to spine/spinal and spinal/vertebral terms

Section 5.1 of the Introductory Guide to MedDRA will be updated to include a statement explaining that, for purpose of MedDRA, spine/spinal terms are considered synonymous with vertebral and spinal column concepts rather than with the spinal cord, unless "spinal" clearly represents a neurological concept such as PT *Spinal claudication*.

3.6.4 Pharmacogenomic Biomarkers in Drug labeling

A MedDRA user requested the MSSO to consider adding additional medically relevant pharmacogenomics biomarker terms to MedDRA to provide more options for coding and analysis. After reviewing the proposal, the MSSO added 72 new medically relevant pharmacogenomic terms to MedDRA and made changes to four existing terms. Please see the table below for examples.

New PT	Primary HLT	Primary SOC
HLA-B*5701 assay positive	Cell marker analyses	Investigations
HER-2 protein overexpression	Acquired gene mutations and other alterations	General disorders and administration site conditions
New LLT	PT	Primary SOC
ESR1 positive	Oestrogen receptor assay positive	Investigations
PgR positive	Progesterone receptor assay positive	Investigations

Table 3-4 Examples of New Pharmacogenomic Biomarker 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 Version 18.0. These tables are intended only as a reference. For detailed information on the changes to Version 18.0, please see the MedDRA Version Report included within the English language download.

SOC, HLG T, HLT Changes

Level	Change Request Action	Net Change	v17.1	v18.0
SOC	Total SOCs	0	26	26
HLGT	New HLG Ts	1	0	1
	Merged HLG Ts	0	0	0
	Total HLG Ts ¹	1	334	335
HLT	New HLTs	8	0	8
	Merged HLTs	7	0	7
	Total HLTs ¹	1	1,720	1,721

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

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.

PT Changes

Level	Change Request Action	v17.1	v18.0
PT	New PTs	281	557
	Promoted LLTs	32	23

Summary of Changes

Level	Change Request Action	v17.1	v18.0
	Demoted PTs	64	43
	Net Change ¹	249	537
	Total PTs	20,808	21,345

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	v17.1	v18.0
LLT	Total LLTs ¹	1,008	73,221	74,229

Table 4-3 Summary of Impact on LLTs

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

New SMQs

Level	Net Change	v17.1	v18.0
1	2	96	98
2	0	82	82
3	0	20	20
4	0	12	12
5	0	2	2

Table 4-4 Summary of Impact on SMQs

Summary of Changes

4.2 SUMMARY OF IMPACT ON RECORDS IN MedDRA FILES

The table below summarizes the impact on MedDRA in Version 18.0. 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	0
	Modified	0
HLGT.ASC	Added	1
	Removed	0
	Modified	0
HLGT_HLT.ASC	Added	8
	Removed	7
	Modified	0
HLT.ASC	Added	8
	Removed	7
	Modified	0
HLT_PT.ASC	Added	1,059
	Removed	189
	Modified	0
MDHIER.ASC	Added	1,264
	Removed	228
	Modified	0
PT.ASC	Added	580
	Removed	43
	Modified	19
LLT.ASC	Added	1,008
	Removed	0

Summary of Changes

	Modified	254
SMQ_LIST.ASC¹	Added ¹	2
	Removed	0
	Modified	212
SMQ_CONTENT.ASC	Added	1,657
	Removed	0
	Modified	181

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	HLT ³	HLGT ³
<i>Blood and lymphatic system disorders</i>	1,101	271	4,072	940	87	17
<i>Cardiac disorders</i>	1,367	307	2,245	553	36	10
<i>Congenital, familial and genetic disorders</i>	3,282	1,227	3,282	1,227	98	19
<i>Ear and labyrinth disorders</i>	417	81	761	190	17	6
<i>Endocrine disorders</i>	631	176	1,675	489	38	9
<i>Eye disorders</i>	2,365	563	3,541	940	64	13

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>Gastrointestinal disorders</i>	3,680	813	7,206	1,613	108	21
<i>General disorders and administration site conditions</i>	2,815	1,065	3,542	1,315	49	9
<i>Hepatobiliary disorders</i>	617	179	1,377	398	19	4
<i>Immune system disorders</i>	414	122	2,398	624	26	4
<i>Infections and infestations</i>	6,866	1,822	7,177	1,903	149	12
<i>Injury, poisoning and procedural complications</i>	6,153	994	8,349	1,974	69	8
<i>Investigations</i>	13,121	5,305	13,121	5,305	106	23
<i>Metabolism and nutrition disorders</i>	925	267	2,489	699	63	14
<i>Musculoskeletal and connective tissue disorders</i>	2,348	414	6,111	1,161	59	11
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	8,344	1,880	8,995	2,144	201	39
<i>Nervous system disorders</i>	3,372	873	6,680	1,757	107	20

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>Pregnancy, puerperium and perinatal conditions</i>	1,602	212	2,786	546	48	8
<i>Psychiatric disorders</i>	2,199	488	2,996	698	78	23
<i>Renal and urinary disorders</i>	1,166	328	2,482	680	32	8
<i>Reproductive system and breast disorders</i>	1,682	459	4,020	1,107	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1,594	487	3,932	1,054	48	11
<i>Skin and subcutaneous tissue disorders</i>	1,949	457	4,458	1,264	56	10
<i>Social circumstances</i>	605	256	605	256	20	7
<i>Surgical and medical procedures</i>	4,367	2,015	4,367	2,015	141	19
<i>Vascular disorders</i>	1,247	284	6,217	1,461	68	11
Total	74,229	21,345				

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.

Summary of Changes

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 seven terms renamed in English MedDRA Version 18.0.

Code	Level	Term Name in v17.1	Term Name in v18.0
10074231	LLT	Biliocutaneous fistula	Biliocutaneous fistula
10075460	PT	Blastic plasmacytoid dendritic cell neoplasia	Blastic plasmacytoid dendritic cell neoplasia
10071595	PT	C-KIT receptor assay	C-kit receptor assay
10066835	PT	Eagles syndrome	Eagle's syndrome
10074991	LLT	Nipple alveolar complex resection	Nipple areolar complex resection
10059202	LLT	Peter's anomaly	Peters anomaly
10053780	LLT	Well's syndrome	Wells syndrome

Table 4-7 Modified PT/LLT Names

Summary of Changes

4.5 LLT CURRENCY STATUS CHANGES

The following table reflects the nine terms at the LLT level in MedDRA Version 18.0 that have a change in their currency status along with the rationale for the change.

Lowest Level Term	Currency Status Changed to	Rationale
Belly ache	Current	A change to current status adds this common colloquial term to enhance coding options in English and other languages.
Nonexudative senile macular degeneration of retina	Current	Both existing LLTs - LLT <i>Nonexudative senile macular degeneration of retina</i> and hyphenated LLT <i>Non-exudative senile macular degeneration of retina</i> are accepted as correct spellings of the expression.
Tummy ache	Current	A change to current status adds this common colloquial term to enhance coding options in English and other languages.
Adenomegaly	Non-current	The concept can be represented by one of the multiple existing LLTs under PT <i>Lymphadenopathy</i> such as LLT <i>Swollen lymph nodes</i> .
Breast excision	Non-current	Even though in clinical practice "breast excision" mainly refers to excision of a part of the breast, it may be also be interpreted as a synonym of mastectomy. Therefore, for clarification of the concept, LLT <i>Breast excision</i> will be made non-current and replaced by a new LLT <i>Breast lump excision</i> under PT <i>Breast lump removal</i> .
Open fracture of C5-C7 level with unspecified spinal cord injury	Non-current	This LLT represents a combination concept which does not conform to MedDRA conventions. This change was made as part of the proactivity request to review the classification of spinal terms versus conditions of vertebrae. See Section 3.6.3.
Out of medication	Non-current	"Out of medication" can be considered ambiguous as it could refer to an individual patient running out of medication or a supply chain issue.
Spinal haematoma	Non-current	Spinal haematoma is ambiguous because "Spinal" can refer to either spinal cord or the bony structure/vertebra. This change was made as part of the proactivity request to review the classification of spinal terms versus conditions of vertebrae. See Section 3.6.3.
Spinal hematoma	Non-current	Spinal hematoma is ambiguous because "Spinal" can refer to either spinal cord or the bony structure/vertebra. This change was made as part of the proactivity request to review the classification of spinal terms versus conditions of vertebrae. See Section 3.6.3.

Table 4-8 LLT Currency Changes