



What's New MedDRA Version 19.0

MSSO-DI-6001-19.0.0

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ACKNOWLEDGEMENTS

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Table of Contents

Table of Contents

1. DOCUMENT OVERVIEW	1
2. VERSION 19.0 CHANGE REQUESTS	2
2.1 TERMINOLOGY CHANGES	2
2.2 COMPLEX CHANGES	3
2.3 TRANSLATION CHANGES	7
2.3.1 French Translation Review	7
3. NEW DEVELOPMENTS IN VERSION 19.0	8
3.1 NEW SOC <i>PRODUCT ISSUES</i>	8
3.2 STANDARDISED MedDRA QUERIES (SMQS)	8
3.3 UPDATED MedDRA DESKTOP BROWSER	9
3.4 UPDATE TO MVAT DATA IMPACT REPORTS	9
3.5 PROACTIVITY REQUESTS	10
3.5.1 Changes in SOC <i>Psychiatric disorders</i>	10
3.5.2 Maternal, Fetal and Neonatal terms	11
3.5.3 Surgical shunts versus spontaneous shunts	11
3.5.4 Non- traumatic LLTs under HLTs implying trauma	12
4. SUMMARY OF CHANGES	13
4.1 SUMMARY OF IMPACT ON THE TERMINOLOGY	13
4.2 SUMMARY OF IMPACT ON RECORDS IN MedDRA FILES	15
4.3 MedDRA TERM COUNTS	16
4.4 MODIFIED PT AND LLT NAMES	19
4.5 LLT CURRENCY STATUS CHANGES	20

LIST OF FIGURES

Figure 2-1. Net Changes of Terms per SOC	3
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LIST OF TABLES

Table 2-1 New SOC	4
Table 2-2 New HLGTS	4
Table 2-3 Merged HLGTS	4
Table 2-4 Moved HLGTS	4
Table 2-5 New HLTs	5
Table 2-6 Merged HLTs	6
Table 2-7 Moved HLTs	6
Table 3-1 Example of changes in SOC <i>Psychiatric disorders</i>	10
Table 3-2 Example of fetal terms	11

Table of Contents

Table 3-3	Example of shunt term changes	11
Table 3-4	LLTs under HLTs implying trauma	12
Table 4-1	Summary of Impact on SOCs, HLGTS, HLTs.....	13
Table 4-2	Summary of Impact on PTs.....	14
Table 4-3	Summary of Impact on LLTs	14
Table 4-4	Summary of Impact on SMQs	15
Table 4-5	Summary of Impact on Records in MedDRA Files	16
Table 4-6	MedDRA Term Counts	19
Table 4-7	Modified PT/LLT Names.....	20
Table 4-8	LLT Currency Changes	21

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 18.1 and 19.0.

Section 2, Version 19.0 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 19.0, highlights changes in Version 19.0 related to change request submissions, new initiatives, information on Standardised MedDRA Queries (SMQs) and any recent updates to software tools provided by the MSSO.

Section 4, Summary of Changes, contains details on:

- 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 19.0 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 19.0 is a complex change version which means that changes may be made at all levels of the MedDRA hierarchy.

Change requests involve both MedDRA updates and SMQ changes. There were a total of 2,264 change requests processed for this version; 1,814 change requests were approved and implemented, and 419 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 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 19.0 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 HLGTS for Version 19.0 (shown in Table 4-6) and the corresponding information for Version 18.1. 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 19.0.

Version 19.0 Change Requests

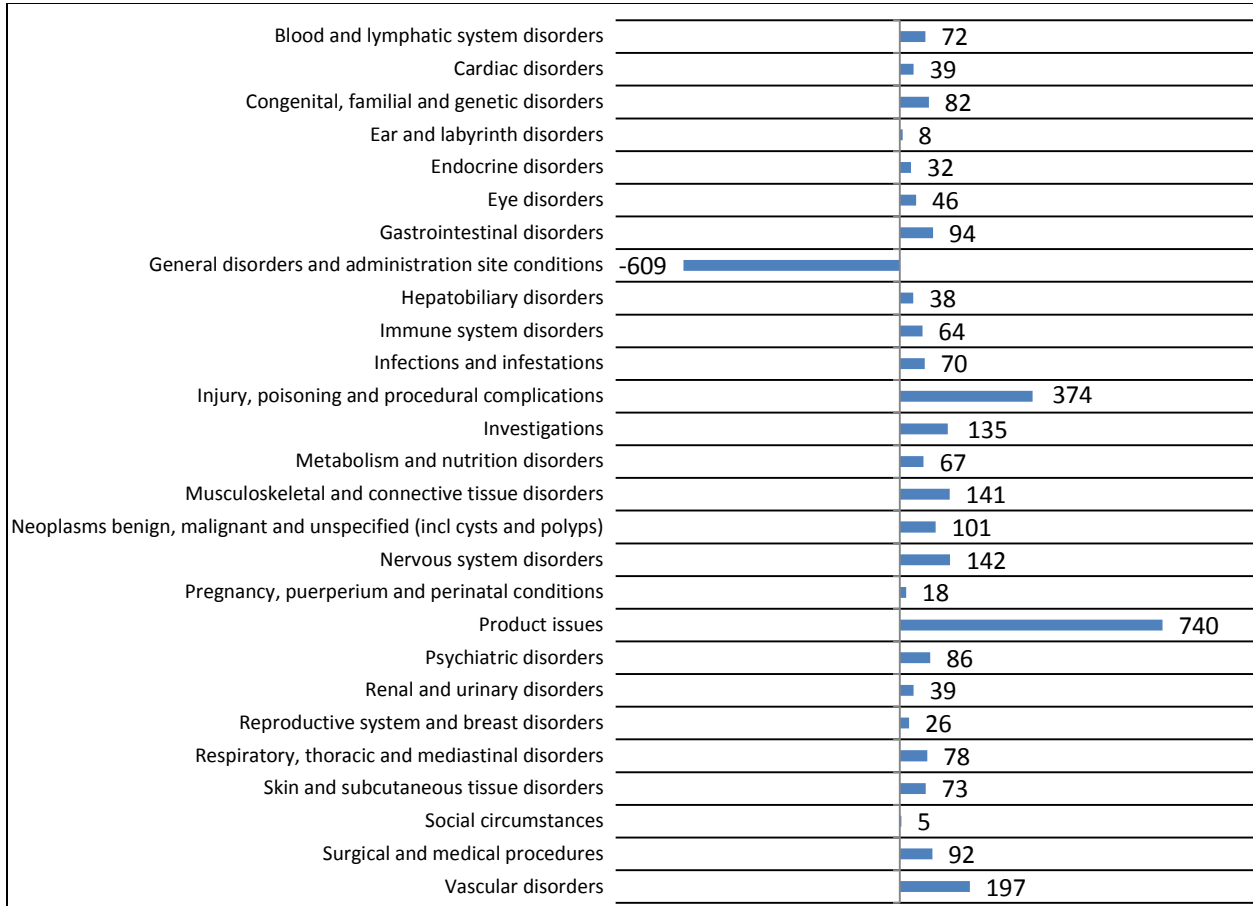


Figure 2-1. Net Changes of Terms per SOC

2.2 COMPLEX CHANGES

The proposals for complex changes considered during Version 19.0 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 6 August 2015 to 25 September 2015. Complex changes were followed by further internal review and consensus discussions which resulted in the final approved set of 32 complex changes.

The complex changes implemented in Version 19.0 are summarized below. Please see the “Related Documents” on the [Change Request section](#) of the MedDRA website for specific details.

Version 19.0 Change Requests

At the SOC level: One SOC was added. Please see section 3.1 for information on the new SOC *Product issues*.

New SOC

New SOC
Product issues

Table 2-1 New SOC

At the HLGT level: Two new High Level Grouping Terms (HLGTs) were added, two HLGTs were merged and one moved as a result of complex changes in Version 19.0. The changes are as follows:

New HLGTs

New HLGT	To SOC
Product quality, supply, distribution, manufacturing and quality system issues	Product issues
Somatic symptom and related disorders	Psychiatric disorders

Table 2-2 New HLGTs

Merged HLGTs

Merged HLGT	To HLGT	To SOC
Product quality issues	Product quality, supply, distribution, manufacturing and quality system issues	Product issues
Somatoform and factitious disorders	Somatic symptom and related disorders	Psychiatric disorders

Table 2-3 Merged HLGTs

HLGT Moves

HLGT	From SOC	To SOC
Device issues	General disorders and administration site conditions	Product issues

Table 2-4 Moved HLGTs

Version 19.0 Change Requests

At the HLT level: There were 16 new High Level Terms (HLTs) added, five HLTs merged, and five moved as a result of complex changes in Version 19.0. The changes are as follows:

New HLTs

New HLT	To SOC
Anaphylactic and anaphylactoid responses	Immune system disorders
Counterfeit, falsified and substandard products	Product issues
Device site reactions	Injury, poisoning and procedural complications
Intellectual disabilities	Psychiatric disorders Nervous system disorders
Intercepted medication errors	Injury, poisoning and procedural complications
Manufacturing facilities and equipment issues	Product issues
Manufacturing issues NEC	Product issues
Manufacturing laboratory controls issues	Product issues
Manufacturing materials issues	Product issues
Manufacturing production issues	Product issues
Marginal zone lymphomas NEC	Blood and lymphatic system disorders Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Paraphilias and paraphilic disorders	Psychiatric disorders
Product distribution and storage issues	Product issues
Product supply and availability issues	Product issues
Somatic symptom disorders	Psychiatric disorders
Varicose veins NEC	Vascular disorders

Table 2-5 New HLTs

Merged HLTs

Merged HLT	To HLT	SOC
Anaphylactic responses	Anaphylactic and anaphylactoid responses	Immune system disorders
Mental retardations	Intellectual disabilities	Psychiatric disorders Nervous system disorders

Version 19.0 Change Requests

Merged HLT	To HLT	SOC
Paraphilias	Paraphilias and paraphilic disorders	Psychiatric disorders
Somatoform disorders	Somatic symptom disorders	Psychiatric disorders
Varicose veins non-site specific	Varicose veins NEC	Vascular disorders

Table 2-6 Merged HLTs

HLT Moves

HLT	From SOC	To HLGT	In SOC
Product contamination and sterility issues	General disorders and administration site conditions	Product quality, supply, distribution, manufacturing and quality system issues	Product issues
Product label issues	General disorders and administration site conditions	Product quality, supply, distribution, manufacturing and quality system issues	Product issues
Product packaging issues	General disorders and administration site conditions	Product quality, supply, distribution, manufacturing and quality system issues	Product issues
Product physical issues	General disorders and administration site conditions	Product quality, supply, distribution, manufacturing and quality system issues	Product issues
Product quality issues NEC	General disorders and administration site conditions	Product quality, supply, distribution, manufacturing and quality system issues	Product issues

Table 2-7 Moved 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 until MedDRA Version 19.1. To assist MedDRA users to understand changes that have been implemented, the MSSO has included a spreadsheet in the French MedDRA Version 19.0 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 19.0

3.1 NEW SOC *PRODUCT ISSUES*

The ICH MedDRA Management Board confirmed the implementation of new SOC *Product issues* for MedDRA Version 19.0. This new SOC includes terms relevant for issues with product quality, devices, product manufacturing and quality systems, supply and distribution, and counterfeit products. One of the goals of incorporating product quality terms into MedDRA is to support the recording of product quality issues and any associated adverse events using a single terminology. It is envisaged that the product quality terms, including those relating to manufacturing and distribution, may be used to report product defects to regulatory authorities and may also be used in organizations' internal databases to track and trend quality issues or deviations.

As defined in the MedDRA Introductory Guide, for the purposes of MedDRA, a product can refer to various types of products intended for human use such as drugs (prescription and over the counter), biologics, vaccines, combination products, devices, nutraceuticals, dietary supplements, etc. Furthermore, the terminology may also support other types of products which are regulated in at least one region such as food or cosmetics.

The addition of SOC *Product issues* to MedDRA brings the total number of SOCs to 27. The new SOC has the same five level hierarchical structure as the existing SOCs and expresses multi-axiality where appropriate (e.g., PT *Transmission of an infectious agent via product* is represented in both in SOC *Product issues* and SOC *Infections and infestations*). For MedDRA Version 19.0, SOC *Product issues* contains two HLGTS: HLGT *Device issues* which moved from SOC *General disorders and administration site conditions* and new HLGT *Product quality, supply, distribution, manufacturing and quality system issues* which replaces HLGT *Product quality issues* and contains a mix of five existing product quality HLTs and eight new HLTs added in MedDRA Version 19.0. In addition, eight PTs were added to this new HLGT and new terms will continue to be added in future MedDRA releases based on input from users.

For additional information on the implementation of SOC *Product issues*, please see Section 2 of this document and the [27th SOC](#) page on the MedDRA website.

3.2 STANDARDISED MedDRA QUERIES (SMQs)

Three new level 1 SMQs were released into production in MedDRA Version 19.0:

- SMQ *Drug reaction with eosinophilia and systemic symptoms syndrome*
- SMQ *Hypoglycaemia*
- SMQ *Medication errors*

There are now 101 level 1 SMQs in production as of this version.

In addition to three new SMQs, SMQ *Pulmonary hypertension* has been revised due to the publication of an updated definition, classification, and revised diagnostic criteria for pulmonary hypertension. This new information impacted the original case identification parameters for the SMQ and, as a result, the CIOMS SMQ Working Group has extensively updated the documentation and term list based on testing in order to reflect the contemporary disease criteria of this condition.

Please see the MedDRA Version 19.0 SMQ Introductory Guide for more information, including inclusion and exclusion criteria, about the new SMQs and the revision of SMQ *Pulmonary hypertension*.

3.3 UPDATED MedDRA DESKTOP BROWSER

The MSSO is pleased to announce that an updated [MedDRA Desktop Browser \(MDB Version 4.0\)](#) was made available for download on 8 October 2015. The updated MDB has the following enhancements:

- User interface more closely resembles the Web-Based Browser (WBB)
- User interface can be displayed in all MedDRA languages
- Ability to export search results and Research Bin to local file system
- Option to filter search results by primary SOC
- Support for Japanese synonyms and J-Currency

The MDB is free to all MedDRA users and is part of your subscription. To download the new version of the desktop browser, click [here](#) (User ID and password required). To learn about the new features of MDB 4.0, please view or download the MDB 4.0 videocast from the [Training Materials](#) section of the MedDRA.org website located under “Tools.”

Please contact the [MSSO Help Desk](#) if you have any questions.

3.4 UPDATE TO MVAT DATA IMPACT REPORTS

Based on MedDRA user feedback, the MSSO made an update in November 2015 to the MVAT Data Impact reports. MVAT 2.0, which debuted in May 2015, included an enhanced “LLTs under different PTs” report to address user requests for more information about LLT changes.

While helpful to some, the enhanced report provided too much information for others and caused confusion. To address this situation, the MSSO has updated MVAT to include the original “LLTs under different PTs” Data Impact report while keeping the enhanced report for those users who find it helpful. The enhanced report has been renamed to “Comprehensive LLT Changes” to avoid confusion with the original report.

If you have any questions, please contact the [MSSO Help Desk](#).

3.5 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 19.0 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.

3.5.1 Changes in SOC *Psychiatric disorders*

The MSSO made changes in SOC *Psychiatric disorders* to better align MedDRA with the latest version of the Diagnostic and Statistical Manual of Mental Disorders (DSM-V) and the common use of mental disorder concepts among medical, educational, and other professionals. There were a total of 98 changes, including complex changes implemented which consisted of 35 new terms and 63 changes to existing terms. See the table below for examples of new terms and changes to existing terms.

New Term Examples		
New PT Name	Primary HLT	Primary SOC
Speech sound disorder	Communications disorders	Psychiatric disorders
Illness anxiety disorder	Somatic symptom disorders	Psychiatric disorders
Selective eating disorder	Eating disorders NEC	Psychiatric disorders
Term Move Examples		
Demoted PT	To New PT	HLT
Phonological disorder	Speech sound disorder	Communications disorders
Hypochondriasis	Illness anxiety disorder	Somatic symptom disorders
Feeding disorder of infancy or early childhood	Selective eating disorder	Eating disorders NEC

Table 3-1 Example of changes in SOC *Psychiatric disorders*

3.5.2 Maternal, Fetal and Neonatal terms

The MSSO was asked to consider adding a set of terms to MedDRA for use as a standardized international grading system being developed for maternal, fetal, and neonatal adverse events. The system will be used to support clinical trials and the terms will be based on MedDRA terms. While maternal and neonatal concepts are already well represented in MedDRA, certain recognized fetal concepts were not in the terminology and were needed for inclusion in the grading system. Based on this review, a total of 18 new terms were added. See below for examples.

New PT Name	Primary HLT	Primary SOC
Foetal compartment fluid collection	Foetal complications NEC	Pregnancy, puerperium and perinatal conditions
Foetal movement disorder	Dyskinesias and movement disorders NEC	Nervous system disorders
Foetal renal imaging abnormal	Foetal and neonatal imaging procedures	Investigations

Table 3-2 Example of fetal terms

3.5.3 Surgical shunts versus spontaneous shunts

The MSSO was asked to review the placement of surgical shunts versus spontaneous shunts for consistency in MedDRA. Shunt terms that can only refer to surgical procedures are placed in SOC *Surgical and medical procedures*; shunt terms that can only refer to anatomical/pathophysiologic conditions/disorders are placed in the appropriate "disorder" SOC. For other shunt concepts that could represent either a procedure or a condition/disorder, the unqualified shunt term is considered to represent the condition/disorder and a counterpart term qualified with the word "procedure" represents the surgical procedure concept. Based on this rationale, 2 new terms were added and changes were made to 11 existing "shunt" terms. See below for several examples.

LLT Move	From PT	To PT	Primary SOC
Mesocaval shunt	Portal shunt	Portal shunt procedure (new PT)	Surgical and medical procedures
Portacaval shunt	Portal shunt	Portal shunt procedure (new PT)	Surgical and medical procedures
Femoral-popliteal shunt	Vascular shunt	Peripheral artery bypass (existing PT)	Surgical and medical procedures

Table 3-3 Example of shunt term changes

3.5.4 Non-traumatic LLTs under HLTs implying trauma

A MedDRA user pointed out that there are terms at the LLT level which specify non-traumatic (or similar wording) under a PT concept which loses the non-traumatic aspect with a primary link to SOC *Injury, poisoning and procedural complications* or to HLTs implying trauma. Examples include:

LLT	PT	HLT	SOC
Non-traumatic extradural haemorrhage	Epidural haemorrhage	Primary - Cerebral injuries NEC; Secondary - Traumatic central nervous system haemorrhages, Nervous system haemorrhagic disorders	Primary - Injury, poisoning and procedural complications; Secondary – Nervous system disorders, Vascular disorders
Non-traumatic rupture of patellar tendon	Tendon rupture	Primary - Muscle, tendon and ligament injuries; Secondary - Tendon disorders	Primary - Injury, poisoning and procedural complications; Secondary - Musculoskeletal and connective tissue disorders

Table 3-4 LLTs under HLTs implying trauma

The MSSO determined that it is appropriate to keep the primary SOC allocation of SOC *Injury, poisoning and procedural complications* even for non-traumatic concepts because, in the case of tendon and muscle tissues for example, the broad concept of “injury” can apply to other damaging factors in addition to trauma such as changes due to aging, inflammation, fibrosis, and drug effects.

The MSSO noted that there were four non-traumatic LTTs under PT *Epidural haemorrhage* in HLT *Traumatic central nervous system haemorrhages* (see one example in the table above). This placement under a “trauma” HLT is not appropriate; however, to move them would require the creation of a new, qualified non-traumatic PT for epidural hemorrhage with the possibility of setting a precedent for the addition of unqualified and qualified (traumatic and non-traumatic) terms for multiple hemorrhage terms at various anatomical sites. It is not practical from a pharmacovigilance perspective to create combination hemorrhage terms reflecting both etiology and anatomical location therefore the best solution with a minimal impact on legacy data was to change the status of the LLT *Non-traumatic extradural haemorrhage* and LLT *Non-traumatic extradural hemorrhage* to non-current. The two other non-traumatic LLTs, LLT *Nontraumatic extradural haemorrhage* and LLT *Nontraumatic extradural hemorrhage*, were already non-current. See section 4.5 LLT Currency Status Changes.

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 19.0. These tables are intended only as a reference. For detailed information on the changes to Version 19.0, please see the MedDRA Version Report included within the MedDRA download.

SOC, HLG T, HLT Changes

Level	Change Request Action	Net Change	v18.1	v19.0
SOC	Total SOCs	1	26	27
HLGT	New HLG Ts	2	0	2
	Merged HLG Ts	2	0	2
	Total HLG Ts ¹	0	335	335
HLT	New HLTs	16	0	16
	Merged HLTs	5	0	5
	Total HLTs ¹	11	1,721	1,732

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.

Summary of Changes

PT Changes

Level	Change Request Action	v18.1	v19.0
PT	New PTs	296	367
	Promoted LLTs	21	25
	Demoted PTs	50	84
	Net Change ¹	267	308
	Total PTs	21,612	21,920

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	v18.1	v19.0
LLT	Current Terms	831	65,838	66,669
LLT	Non-current Terms	7	9,142	9,149
LLT	Total LLTs ¹	838	74,980	75,818

Table 4-3 Summary of Impact on LLTs

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

New SMQs

Level	Net Change	v18.1	v19.0
1	3	98	101
2	0	82	82

Summary of Changes

Level	Net Change	v18.1	v19.0
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 Version 19.0. The table is intended only as a reference.

INTL_ORD.ASC	Added	1
	Removed	0
	Modified	0
SOC.ASC	Added	1
	Removed	0
	Modified	0
SOC_HLGT.ASC	Added	3
	Removed	3
	Modified	0
HLGT.ASC	Added	2
	Removed	2
	Modified	0
HLGT_HLT.ASC	Added	23
	Removed	12
	Modified	0
HLT.ASC	Added	16
	Removed	5
	Modified	0
HLT_PT.ASC	Added	854
	Removed	248
	Modified	0

Summary of Changes

MDHIER.ASC	Added	1070
	Removed	435
	Modified	0
PT.ASC	Added	392
	Removed	84
	Modified	142
LLT.ASC	Added	838
	Removed	0
	Modified	518
SMQ_LIST.ASC¹	Added ¹	3
	Removed	0
	Modified	214
SMQ_CONTENT.ASC	Added	4112
	Removed	0
	Modified	234

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>	1,125	278	4,152	971	88	17
<i>Cardiac disorders</i>	1,395	316	2,289	574	36	10
<i>Congenital, familial and genetic disorders</i>	3,360	1,269	3,360	1,269	98	19

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>Ear and labyrinth disorders</i>	422	84	771	196	17	6
<i>Endocrine disorders</i>	650	179	1,711	504	38	9
<i>Eye disorders</i>	2,402	575	3,626	964	64	13
<i>Gastrointestinal disorders</i>	3,738	828	7,340	1,656	108	21
<i>General disorders and administration site conditions</i>	2,363	957	3,125	1,227	36	7
<i>Hepatobiliary disorders</i>	631	188	1,441	417	19	4
<i>Immune system disorders</i>	447	135	2,495	658	26	4
<i>Infections and infestations</i>	6,992	1,860	7,315	1,948	149	12
<i>Injury, poisoning and procedural complications</i>	6,266	1,044	8,716	2,141	71	8
<i>Investigations</i>	13,305	5,390	13,305	5,390	106	23
<i>Metabolism and nutrition disorders</i>	922	271	2,563	724	63	14

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>Musculoskeletal and connective tissue disorders</i>	2,452	440	6,272	1,204	59	11
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	8,426	1,919	9,098	2,198	202	39
<i>Nervous system disorders</i>	3,495	906	6,893	1,825	107	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1,620	216	2,820	558	48	8
<i>Product issues</i>	557	144	566	150	21	2
<i>Psychiatric disorders</i>	2,301	504	3,109	720	78	23
<i>Renal and urinary disorders</i>	1,182	340	2,525	703	32	8
<i>Reproductive system and breast disorders</i>	1,701	468	4,058	1,123	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1,660	506	4,037	1,086	48	11
<i>Skin and subcutaneous tissue disorders</i>	1,996	473	4,552	1,301	56	10
<i>Social circumstances</i>	617	261	617	261	20	7

Summary of Changes

SOC	LLTs* (Primary) ¹	PTs (Primary) ¹	LLTs* (Primary and Secondary) ²	PTs (Primary and Secondary) ²	HLTs ³	HLGTs ³
<i>Surgical and medical procedures</i>	4,498	2,072	4,498	2,072	141	19
<i>Vascular disorders</i>	1,295	297	6,514	1,555	68	11
Total	75,818	21,920				

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). 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.

Summary of Changes

The table below lists the one term modified in English MedDRA Version 19.0.

Code	Level	Term Name in v18.1	Term Name in v19.0
10065413	PT	PaO2/FiO2 ratio decreased	PaO2/FiO2 ratio decreased

Table 4-7 Modified PT/LLT Names

4.5 LLT CURRENCY STATUS CHANGES

The following table reflects the 9 terms at the LLT level in MedDRA Version 19.0 that have a change in their currency status along with the rationale for the change.

Lowest Level Term	Currency Status Changed to	Rationale
Subaortic stenosis, congenital	Current	The status of non-current LLT <i>Subaortic stenosis, congenital</i> was made current and moved from PT <i>Congenital aortic valve stenosis</i> under a more appropriate - PT <i>Hypertrophic cardiomyopathy</i> . Subaortic stenosis, congenital it is not a valvular issue, but is a hypertrophy of the subaortic myocardium and a synonym of idiopathic hypertrophic subaortic stenosis.
Catheter thrombosis	Non-current	Since catheter thrombosis can be interpreted in two ways (thrombosis in catheter or related to catheter), the MSSO changed the status of LLT <i>Catheter thrombosis</i> to non-current. A new LLT <i>Catheter related thrombosis</i> was added under the new PT <i>Device related thrombosis</i> .
Device misuse	Non-current	Device misuse can be interpreted as a term for coding circumstances other than those described in the MedDRA concept description of misuse, therefore, it was made non-current because of its potential ambiguity.
LE rash	Non-current	The status of LLT <i>LE rash</i> was made non-current because of its potential ambiguity and uncommon use.
Non-traumatic extradural haemorrhage	Non-current	For consistency with similar already non-current LLTs, e.g., LLT <i>Nontraumatic extradural haemorrhage</i> , the status of LLT <i>Non-traumatic extradural haemorrhage</i> was changed to non-current.
Non-traumatic extradural hemorrhage	Non-current	For consistency with similar already non-current LLTs, e.g., LLT <i>Nontraumatic extradural haemorrhage</i> , the status of LLT <i>Non-traumatic extradural hemorrhage</i> was changed to non-current.
Panic disorder with agoraphobia	Non-current	PT <i>Panic disorder with agoraphobia</i> was demoted under new PT <i>Panic disorder</i> and was made non-current as it

Summary of Changes

Lowest Level Term	Currency Status Changed to	Rationale
		represents a combination between two separate concepts.
Solvent administered without active ingredient	Non-current	LLT <i>Solvent administered without active ingredient</i> combines two concepts: a drug administration error and a preparation error. Placement either under PT <i>Product preparation error</i> or under PT <i>Wrong technique in product usage process</i> does not represent the additional concept of an administration error. A single term cannot represent both important concepts and so instead, the concepts can be represented by LLT <i>Product preparation error</i> and LLT <i>Drug administration error</i> and/or LLT <i>Missed dose</i> .
Suffering	Non-current	A new LLT <i>Emotional suffering</i> was added under PT <i>Emotional distress</i> for clarification of the nature of the concept of "suffering".

Table 4-8 LLT Currency Changes