



What's New MedDRA Version 19.1

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ACKNOWLEDGEMENTS

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Table of Contents

Table of Contents

1. DOCUMENT OVERVIEW	1
2. VERSION 19.1 CHANGE REQUESTS	2
2.1 TERMINOLOGY CHANGES	2
2.2 TRANSLATION CHANGES	3
2.2.1 Translation Review	3
3. NEW DEVELOPMENTS IN VERSION 19.1	4
3.1 PROPOSAL TO REASSIGN PRIMARY SOC OF VASCULAR TERMS	4
3.2 PAEDIATRIC AND GENDER ADVERSE EVENT TERM LISTS.....	4
3.3 STANDARDISED MedDRA QUERIES (SMQS)	4
3.4 PROACTIVITY REQUESTS	5
3.4.1 Review of “Device type” and “Device Event” Terms in MedDRA	5
3.4.2 Representation of Organ/Body Site Enlargement versus Hypertrophy.....	6
3.4.3 Review Inconsistency in the Mapping of Specific “Wound” Terms	7
4. SUMMARY OF CHANGES.....	9
4.1 SUMMARY OF IMPACT ON THE TERMINOLOGY	9
4.2 SUMMARY OF IMPACT ON RECORDS IN MedDRA FILES	11
4.3 MedDRA TERM COUNTS	12
4.4 MODIFIED PT AND LLT NAMES	15
4.5 LLT CURRENCY STATUS CHANGES.....	17

LIST OF FIGURES

Figure 2-1 Net Changes of Terms per SOC	3
Figure 3-1 LLTs Under PT Wound as of v19.1	8

LIST OF TABLES

Table 3-1 Promoted and Moved Organ/body Site Enlargement Terms.....	6
Table 3-2 New Injury / Wound PTs.....	7
Table 4-1 Summary of Impact on SOC, HLGTS, HLTs.....	9
Table 4-2 Summary of Impact on PTs.....	10
Table 4-3 Summary of Impact on LLTs	10
Table 4-4 Summary of Impact on SMQs	11
Table 4-5 Summary of Impact on Records in MedDRA Files	12
Table 4-6 MedDRA Term Counts	15
Table 4-7 Modified PT/LLT Names.....	16
Table 4-8 LLT Currency Changes	17

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 19.0 and 19.1.

Section 2, Version 19.1 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 19.1, highlights changes in Version 19.1 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 19.1 CHANGE REQUESTS

2.1 TERMINOLOGY CHANGES

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

MedDRA Version 19.1 is a simple change version which means that changes may be made only at the PT and LLT levels of the MedDRA hierarchy.

Change requests involve both MedDRA updates and SMQ changes. There were a total of 1,672 change requests processed for this version; 1,362 change requests were approved and implemented, and 266 change requests were not approved. There are, in addition, 44 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 19.1 is accessible as a cumulative Detail Report included in the MedDRA English version download. Users may review all change requests considered by the MSSO from MedDRA 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 19.1 (shown in Table 4-6) and the corresponding information for Version 19.0. Additionally, term name changes and LLT currency status changes are included in Figure 2-1.

Please see Section 4 for a summary of the changes in MedDRA Version 19.1.

Version 19.1 Change Requests

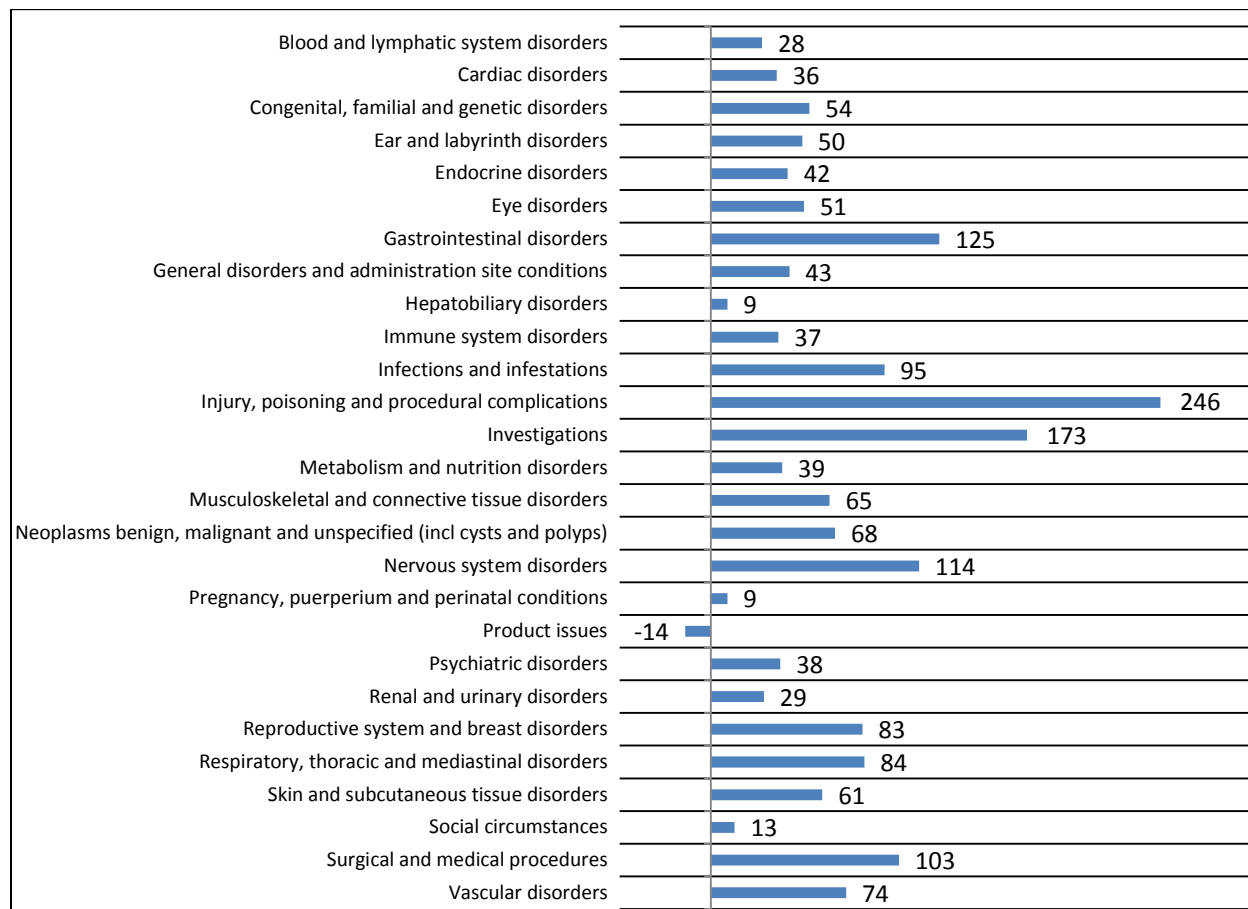


Figure 2-1 Net Changes of Terms per SOC

2.2 TRANSLATION CHANGES

2.2.1 Translation Review

As part of our regular quality process, the MSSO is conducting a review of terms translated from English into the supported MedDRA languages, except Japanese. This will be an ongoing effort that is expected to last several MedDRA releases and will result in updates to term names in the respective translations of MedDRA. The list of terms updated will be available in the associated version reports included in the MedDRA download for each language. 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 or non-Japanese translation of MedDRA.

3. NEW DEVELOPMENTS IN VERSION 19.1

3.1 PROPOSAL TO REASSIGN PRIMARY SOC OF VASCULAR TERMS

Periodically the MSSO has received requests from MedDRA users to consider reassigning the primary SOC of vascular terms from the site of manifestation to SOC *Vascular disorders* for consistency and data retrieval purposes. The MSSO consulted with the MedDRA Expert Panel to review recent proposals to reassign the primary SOC of certain vascular terms, including those relating to the carotid artery. After reviewing these proposals, the Expert Panel recommended adhering to the established MedDRA rule which is that PTs relating to diseases or signs and symptoms are assigned to the prime manifestation site SOC as the primary SOC. At its meeting in Lisbon, Portugal in June 2016, the MedDRA Management Board supported the Expert Panel's recommendation not to change the primary SOC assignment for vascular terms.

There are other approaches to retrieval of vascular concepts instead of changing the primary SOC allocation. Vascular terms can be retrieved and viewed by means of secondary SOC analyses as described in the MedDRA Data Retrieval and Presentation: Points to Consider document. In addition, there are SMQs focusing on vascular events to aid in identification of potential cases independent of the hierarchy or primary SOC allocation including SMQ *Embolic and thrombotic events*, SMQ *Haemorrhages*, and SMQ *Vasculitis*, etc.

3.2 PAEDIATRIC AND GENDER ADVERSE EVENT TERM LISTS

In April 2016, the MSSO conducted a survey on the utility and extent of use of the MSSO Best Practice documents and Paediatric and Gender Adverse Event Term Lists. The results of the survey indicated a low level of use of the Paediatric and Gender Lists; they did not meet users' needs as paediatric and gender related adverse events are best identified by demographic data fields rather than specific adverse event terms.

The MedDRA Management Board supported that the MSSO discontinue maintenance of the Paediatric and Gender Lists as of MedDRA Version 19.0. The last versions of the lists (MedDRA Version 19.0) and their supporting documentation are archived on the MedDRA website for reference.

3.3 STANDARDISED MedDRA QUERIES (SMQs)

No new SMQs were introduced into MedDRA v19.1, but there were 187 approved changes to existing SMQs. Only minor changes were made to the SMQ Introductory Guide.

3.4 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 19.1 change request processing period, the MSSO evaluated six proactivity proposals submitted by MedDRA users. Three of the six proposals were implemented in this release. 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.

3.4.1 Review of “Device type” and “Device Event” Terms in MedDRA

The MSSO was requested to review inconsistencies against the general convention that events/findings concepts are placed at the PT level and devices causing event/findings are placed on the LLT level (e.g., *Pump reservoir issue*, *Lead dislodgement*, and *Device lead damage* are represented at the PT level).

The MSSO performed a review of the PTs and LLTs under HLG *Device issues* and HLG *Complications associated with device* and concluded that, in general, device type terms are subordinate LLTs under the appropriate device event term PTs. There are justifiable exceptions such as certain stent complications (e.g., endo-leaks, where the event and device type are linked), and the representation at the PT level of certain device components which are present in many devices, such as batteries, leads, syringes, or needles.

However, two PTs were identified which did not warrant PT status and, to be consistent with similar device type terms, are better placed as LLTs under a more general device term. The MSSO implemented the following changes:

- PT *Pump reservoir issue* was demoted under PT *Device issue*
- PT *Feeding tube complication* was demoted under PT *Complications associated with device*

The general convention has been to place device type terms as LLTs to device event PTs. However, MedDRA has evolved in response to users’ requests to add certain device type terms when these devices are widely used or have a particular clinical relevance. Therefore, the MSSO will update section 6.8.2 and 6.19.2 of the MedDRA Introductory Guide to describe the general conventions for representing device events

and types, and the relevant exceptions that are made reflecting the evolution of users' needs in device reporting.

3.4.2 Representation of Organ/Body Site Enlargement versus Hypertrophy

A MedDRA user requested the MSSO review the current representation of organ/body site enlargement versus hypertrophy of the same organ/site for more consistent placement. For the liver and kidney, hypertrophy and enlargement/-megaly are separated on the PT level, whereas for other body sites such breast, salivary and parotid glands, clitoris, genital labia and uterus, these concepts are grouped as PTs/LLTs. For example, PT *Salivary gland enlargement* has subordinate to it LLT *Salivary gland hypertrophy*, LLT *Salivary gland hyperplasia*, and LLT *Salivary gland swelling*.

The MSSO reviewed the both the correctness of PT/LLT subordination, and possible concept duplication (over-representation) at the PT level. A total of 15 changes were made including 9 LLT promotions, 1 PT demotion, 4 LLT moves and 1 term rename. See below for examples.

Promoted LLTs				
Term name	Level in v19.0	Level in v19.1	Primary HLT	Primary SOC
Aortic valve thickening	LLT	PT	Aortic valvular disorders	Cardiac disorders
Left ventricular enlargement	LLT	PT	Myocardial disorders NEC	Cardiac disorders
Right ventricular enlargement	LLT	PT	Myocardial disorders NEC	Cardiac disorders
Moved LLTs				
LLT	PT v19.0		PT v19.1	
Gallbladder wall thickening	Gallbladder disorder		Gallbladder enlargement	
Tumor enlargement	Neoplasm		Neoplasm progression	

Table 3-1 Promoted and Moved Organ/body Site Enlargement Terms

3.4.3 Review Inconsistency in the Mapping of Specific “Wound” Terms

A MedDRA user requested the MSSO move site specific LLT terms under PT *Wound* (e.g., LLT *Lower limb wound*; LLT *Open wound of back*; LLT *Open wound of ear*) to site specific PTs under HLT *Site specific injuries NEC* for improved reporting and analysis.

The MSSO implemented a total of 258 changes including changing the status of 94 LLTs under PT *Wound* to non-current because these terms represent combinations of two or more concepts, many of which were incorporated into the initial version of MedDRA. Examples include LLT *Open wound of auricle, uncomplicated* and LLT *Open wound of cheek, complicated*. All of the LLTs under PT *Wound* which pertain to anatomically-specific wound sites (e.g., LLT *Lower limb wound*), including those with a non-current status, were moved to a respective PT that corresponds to a site of injury. In situations where no appropriate PT was available a new site specific PT was added. See the table below for examples.

PT	Primary HLT	Primary SOC
Abdominal wall wound	Abdominal injuries NEC	Injury, poisoning and procedural complications
Nasal injury	Site specific injuries NEC	Injury, poisoning and procedural complications
Paranasal sinus injury	Site specific injuries NEC	Injury, poisoning and procedural complications
Thyroid gland injury	Site specific injuries NEC	Injury, poisoning and procedural complications
Trunk injury	Site specific injuries NEC	Injury, poisoning and procedural complications

Table 3-2 New Injury / Wound PTs

The graphic below shows how PT *Wound* and its revised group of subordinate LLTs appear in MedDRA Version 19.1.

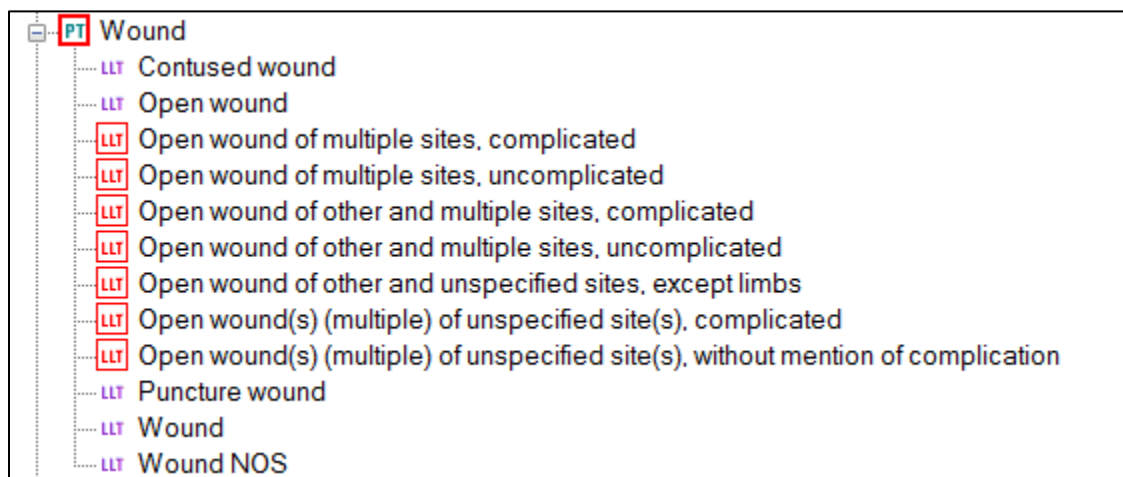


Figure 3-1 LLTs under PT Wound as of v19.1

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 19.1. These tables are intended only as a reference. For detailed information on the changes to Version 19.1, please see the MedDRA Version Report included within the MedDRA download.

SOC, HLGT, HLT Changes

Level	Change Request Action	Net Change	v19.0	v19.1
SOC	Total SOCs	0	27	27
HLGT	New HLGTs	0	0	0
	Merged HLGTs	0	0	0
	Total HLGTs ¹	0	335	335
HLT	New HLTs	0	0	0
	Merged HLTs	0	0	0
	Total HLTs ¹	0	1,732	1,732

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

MedDRA v19.1 is a simple change version which means changes are only made at the PT and LLT levels of the MedDRA hierarchy; hence there are no changes in the number of HLTs and HLGTs.

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

Summary of Changes

PT Changes

Level	Change Request Action	v19.0	v19.1
PT	New PTs	367	298
	Promoted LLTs	25	34
	Demoted PTs	84	42
	Net Change ¹	308	290
	Total PTs	21,920	22,210

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	v19.0	v19.1
LLT	Current Terms	553	66,669	67,222
LLT	Non-current Terms	97	9,149	9,246
LLT	Total LLTs ¹	650	75,818	76,468

Table 4-3 Summary of Impact on LLTs

¹Total LLTs include PTs as they are included together in the LLT distribution file.

New SMQs

Level	Net Change	v19.0	v19.1
1	0	101	101
2	0	82	82
3	0	20	20

Summary of Changes

Level	Net Change	v19.0	v19.1
4	0	12	12
5	0	2	2

Table 4-4 Summary of Impact on SMQs

4.2 SUMMARY OF IMPACT ON RECORDS IN MedDRA FILES

The table below summarizes the impact on the MedDRA files in Version 19.1.

INTL_ORD.ASC	Added	0
	Removed	0
	Modified	0
SOC.ASC	Added	0
	Removed	0
	Modified	0
SOC_HLGT.ASC	Added	0
	Removed	0
	Modified	0
HLGT.ASC	Added	0
	Removed	0
	Modified	0
HLGT_HLT.ASC	Added	0
	Removed	0
	Modified	0
HLT.ASC	Added	0
	Removed	0
	Modified	0
HLT_PT.ASC	Added	542
	Removed	92
	Modified	0
MDHIER.ASC	Added	572

Summary of Changes

	Removed	114
	Modified	0
PT.ASC	Added	332
	Removed	42
	Modified	22
LLT.ASC	Added	650
	Removed	0
	Modified	375
SMQ_LIST.ASC¹	Added ¹	0
	Removed	0
	Modified	217
SMQ_CONTENT.ASC	Added	534
	Removed	0
	Modified	267

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	HLT³	HLGT³
<i>Blood and lymphatic system disorders</i>	1,130	281	4,166	978	88	17
<i>Cardiac disorders</i>	1,406	325	2,312	587	36	10
<i>Congenital, familial and genetic disorders</i>	3,395	1,287	3,395	1,287	98	19

Summary of Changes

SOC	LLTs* (Primary)¹	PTs (Primary)¹	LLTs* (Primary and Secondary)²	PTs (Primary and Secondary)²	HLTs³	HLGTs³
<i>Ear and labyrinth disorders</i>	424	84	800	199	17	6
<i>Endocrine disorders</i>	659	183	1,739	514	38	9
<i>Eye disorders</i>	2,414	583	3,660	981	64	13
<i>Gastrointestinal disorders</i>	3,785	838	7,428	1,676	108	21
<i>General disorders and administration site conditions</i>	2,385	965	3,156	1,240	36	7
<i>Hepatobiliary disorders</i>	645	190	1,448	419	19	4
<i>Immune system disorders</i>	448	136	2,522	669	26	4
<i>Infections and infestations</i>	7,051	1,887	7,379	1,977	149	12
<i>Injury, poisoning and procedural complications</i>	6,375	1,085	8,822	2,191	71	8
<i>Investigations</i>	13,410	5,460	13,410	5,460	106	23
<i>Metabolism and nutrition disorders</i>	932	274	2,593	733	63	14

Summary of Changes

SOC	LLTs* (Primary)¹	PTs (Primary)¹	LLTs* (Primary and Secondary)²	PTs (Primary and Secondary)²	HLTs³	HLGTs³
<i>Musculoskeletal and connective tissue disorders</i>	2,472	443	6,317	1,222	59	11
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	8,456	1,932	9,139	2,218	202	39
<i>Nervous system disorders</i>	3,501	922	6,971	1,860	107	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1,623	218	2,826	561	48	8
<i>Product issues</i>	549	139	558	145	21	2
<i>Psychiatric disorders</i>	2,312	506	3,138	728	78	23
<i>Renal and urinary disorders</i>	1,185	343	2,541	716	32	8
<i>Reproductive system and breast disorders</i>	1,710	471	4,122	1,136	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1,676	512	4,089	1,099	48	11
<i>Skin and subcutaneous tissue disorders</i>	2,022	483	4,597	1,316	56	10
<i>Social circumstances</i>	625	266	625	266	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>	4,576	2,097	4,576	2,097	141	19
<i>Vascular disorders</i>	1,302	300	6,568	1,578	68	11
Total	76,468	22,210				

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.

The table below lists the eleven terms modified in English MedDRA Version 19.1.

Summary of Changes

Code	Level	Term Name in v19.0	Term Name in v19.1
10054205	PT	Aeromona infection	Aeromonas infection
10002464	LLT	Angiomimmunoblastic (AILD, LgX (Kiel Classification))	Angioimmunoblastic (AILD, LgX (Kiel Classification))
10002465	LLT	Angiomimmunoblastic (AILD, LgX (Kiel Classification)) recurrent	Angioimmunoblastic (AILD, LgX (Kiel Classification)) recurrent
10002466	LLT	Angiomimmunoblastic (AILD, LgX (Kiel Classification)) refractory	Angioimmunoblastic (AILD, LgX (Kiel Classification)) refractory
10002467	LLT	Angiomimmunoblastic (AILD, LgX (Kiel Classification)) stage I	Angioimmunoblastic (AILD, LgX (Kiel Classification)) stage I
10002468	LLT	Angiomimmunoblastic (AILD, LgX (Kiel Classification)) stage II	Angioimmunoblastic (AILD, LgX (Kiel Classification)) stage II
10002469	LLT	Angiomimmunoblastic (AILD, LgX (Kiel Classification)) stage III	Angioimmunoblastic (AILD, LgX (Kiel Classification)) stage III
10002470	LLT	Angiomimmunoblastic (AILD, LgX (Kiel Classification)) stage IV	Angioimmunoblastic (AILD, LgX (Kiel Classification)) stage IV
10077707	PT	Cornelia de-Lange syndrome	Cornelia de Lange syndrome
10016690	LLT	Finger top hypertrophy	Finger tip hypertrophy
10071084	PT	Follicle-stimulating hormone deficiency	Follicle stimulating hormone deficiency

Table 4-7 Modified PT/LLT Names

4.5 LLT CURRENCY STATUS CHANGES

The following table reflects the 97 terms at the LLT level in MedDRA Version 19.1 that have a change in their currency status along with the rationale for the change.

Lowest Level Term	Currency Status Changed to	Rationale
Agoraphobia with panic attacks	Non-current	The concept of Panic disorder with agoraphobia in DSM-5 is now represented by two separate terms and the combination concept LLT <i>Agoraphobia with panic attacks</i> will be changed to non-current.
Bilateral recurrent paralysis	Non-current	Due to its ambiguity LLT <i>Bilateral recurrent paralysis</i> was made non-current and replaced with LLT <i>Bilateral recurrent laryngeal nerve paralysis</i> to more fully represent this concept.
Tongue red swollen pain	Non-current	LLT Tongue red swollen pain warranted a change in status from current to non-current, because the term represents a combination of three individual concepts, and MedDRA generally avoids such combination terms. The concepts of this term can be represented by split coding, for example: LLT <i>Tongue redness</i> plus LLT <i>Swollen tongue</i> plus LLT <i>Tongue pain</i> .
Set of 94 Wound LLTs	Non-current	A total of 94 LLTs under PT Wound were changed to a status of non-current because these terms represent combinations of two or more concepts, most of which were incorporated into the initial versions of MedDRA. Examples include LLT <i>Open wound of auricle, uncomplicated</i> and LLT <i>Open wound of cheek, complicated</i> . Such terms can be represented in MedDRA by one or more single concepts These changes were part of a proactivity request to review an inconsistency in the placement of site specific “Wound” terms under PT Wound. See section 3. The specific list of terms can be obtained from MVAT or the Version Report included in the MedDRA release package.

Table 4-8 LLT Currency Changes