



**MedDRA**

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# **What's New MedDRA Version 16.1**

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**MSSO-DI-6001-16.1.0**

**September 2013**



### 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 16.0 and 16.1.

Section 2, Version 16.1 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 16.1, highlights changes in v16.1 related to change request submissions, new initiatives, and information on Standardised MedDRA Queries (SMQs).

Section 4, Summary of Changes, contains details on:

- Term history
- The impact of this version on the terminology (in tables)
- Impact on the records in MedDRA files
- MedDRA term 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](mailto:mssohelp@meddra.org).

## 2. VERSION 16.1 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 as well as special working group activities in which the MSSO participates.

MedDRA v16.1 is a simple change version which means changes are only made at the PT and LLT levels of the MedDRA hierarchy. (Complex changes, which entail modifications pertaining to levels HLT and above, are not included in MedDRA v16.1.)

Change requests involve both MedDRA updates and SMQ changes. There were a total of 1813 change requests processed for this version; 1356 change requests were approved and implemented, and 320 change requests were not approved. There are, in addition, 137 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.

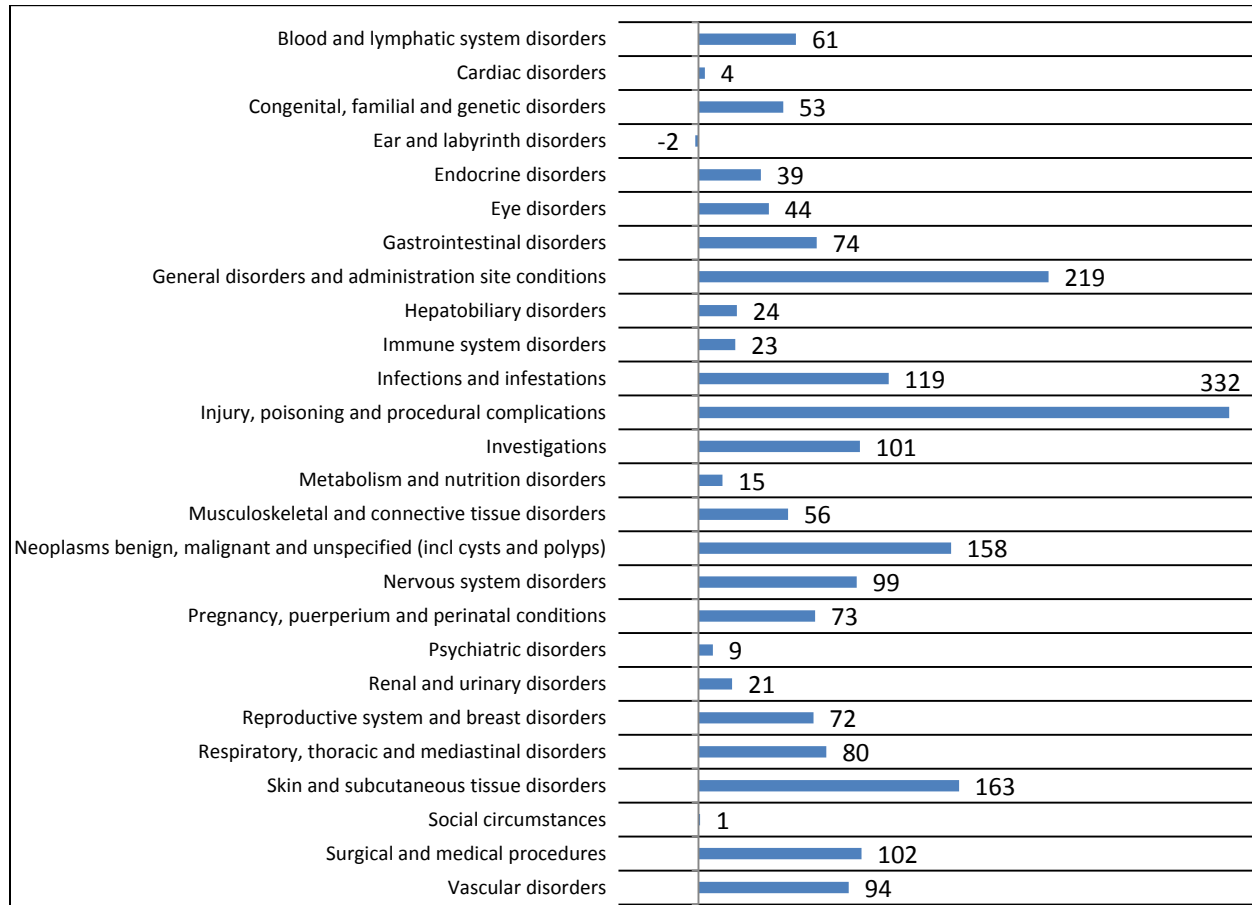
Between MedDRA releases, the MSSO makes available [weekly supplemental update](#) files which are approved changes that will be implemented for the next MedDRA version. The supplemental files may be helpful for users to understand what changes will be implemented in the next release.

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

## Version 16.1 Change Requests



**Figure 2-1. Net Changes of Terms per SOC**

## 2.2 TRANSLATION CHANGES

In addition to terminology changes, there were 311 translation correction requests considered and 307 approved changes implemented to the non-English versions of MedDRA. Below is a summary of the number of changes implemented and the language affected.

- 12 Chinese
- 4 Dutch
- 32 French
- 13 German
- 20 Italian
- 226 Spanish

The large number of changes to Spanish MedDRA v16.1 is due to 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 16.1

#### 3.1 STANDARDISED MedDRA QUERIES (SMQs)

Four new level 1 SMQs were released into production in MedDRA v16.1: SMQ *Arthritis*, SMQ *Myelodysplastic syndrome*, SMQ *Noninfectious diarrhoea* and SMQ *Tumour lysis syndrome*. There are now 94 level 1 SMQs in production as of this version. Please see the MedDRA v16.1 SMQ Introductory Guide for more information about the new SMQs including their inclusion and exclusion criteria.

Over the years, the structure of some SMQs were expanded to form hierarchical SMQs which are SMQs with one or more sub-search SMQs that could be combined to create a superordinate, more inclusive SMQ. When modifying the structure of these SMQs, the PTs directly under the parent SMQ were made inactive and added as active PTs under respective sub-search SMQs. The inactive PTs directly under the parent hierarchical SMQs have been removed in MedDRA v16.1 to reduce potential confusion. The figures below show an example of inactive PTs directly under the parent hierarchical SMQ *Cerebrovascular disorders* which have been removed and how the SMQ appears in v16.1.

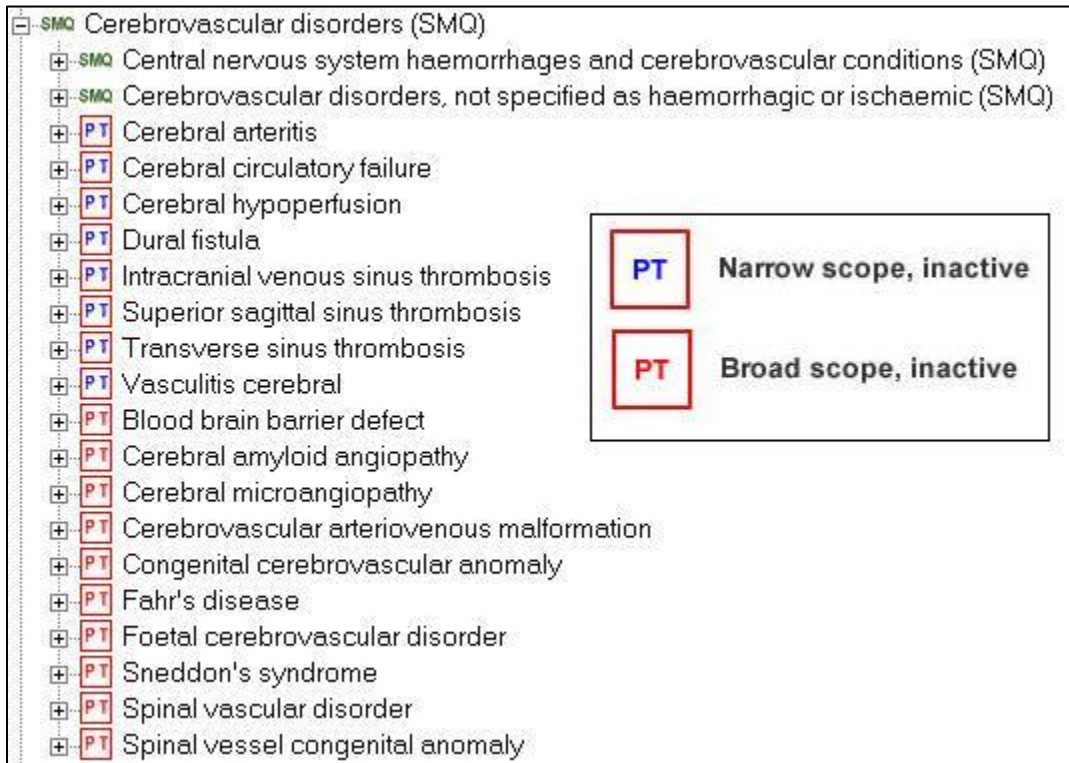
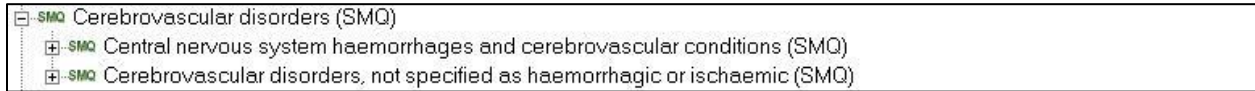


Figure 3-1. Inactive PTs in Parent Hierarchical SMQs Version 16.0



**Figure 3-2. Inactive PTs Removed from Hierarchical SMQs in Version 16.1**

### 3.2 PROACTIVITY REQUESTS

The proactive maintenance 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 proactive maintenance proposals from MedDRA users and has implemented three specific suggestions in MedDRA v16.1. See below for details.

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.

#### 3.2.1 Terms with Missing American or British Spelling Counterparts

In MedDRA v15.1 the MSSO added a small set of missing American English or British English spelling counterparts to existing esophageal terms to improve MedDRA for coding and consistency. After implementing these missing counterparts, a more extensive review was conducted to identify additional missing American or British spellings of existing terms throughout MedDRA. This review was completed for MedDRA v16.1 and resulted in 216 new terms being added. See the table below for examples. In addition, several terms with mixed American or British spellings were identified and renamed or, in some cases, made non-current. See sections 4.4 and 4.5 for details.

Existing term	Missing American or British Spelling Counterpart
PT Hospitalisation	LLT Hospitalization
LLT Intracranial hemorrhage	LLT Intracranial haemorrhage
LLT Liver tumor	LLT Liver tumour

**Table 3-1. Missing American or British Spelling Counterpart Terms**



### 3.2.2 Catheter Site Terms

As part of a proactivity request submitted by a MedDRA user to consider a set of catheter and stoma site terms, the MSSO added 37 catheter site PTs and LLTs in MedDRA v16.1 to improve coding and data analysis. Most of these terms were added under primary HLT *Implant and catheter site reactions* in SOC *General disorders and administration site conditions*. See below for examples.

Term name	Level	Primary HLT	Primary SOC
Catheter site hypertrophy	PT	Implant and catheter site reactions	General disorders and administration site conditions
Catheter site injury	PT	Implant and catheter site reactions	General disorders and administration site conditions
Catheter site itching	LLT	Implant and catheter site reactions	General disorders and administration site conditions
Catheter site pustule	PT	Skin structures and soft tissue infections	Infections and infestations

**Table 3-2. Catheter site terms**

In addition to catheter site terms, the submitter requested that the MSSO review a potential set of stoma site terms for inclusion in MedDRA. Based on the MSSO review, the current MedDRA hierarchy does not have an appropriate high level grouping term to add "stoma site" terms in MedDRA. For this reason, the MSSO has proposed new HLT *Stoma site reactions* under HLT *Procedural related injuries and complications NEC* in SOC *Injury, poisoning and procedural complications* for MedDRA v17.0. The proposed list of stoma site terms will be reviewed for potential inclusion in this new HLT should it be implemented in MedDRA v17.0.

### 3.2.3 Neonatal Term Changes

The MSSO was asked to review the placement of terms relating to the neonatal period such as "neonatal", "neonatorum", "perinatal", "newborn", "due to birth trauma" in order to better support coding and analysis. The MSSO identified neonatal terms that were subordinated to terms that were not specific to the neonatal period and also identified terms that could be better aligned in the hierarchy. As a result of this review, a total of 37 changes, including the addition of 4 new terms were implemented. See below for examples.

<b>Term Moves</b>		
<b>LLT Name</b>	<b>Version 16.0 PT</b>	<b>Version 16.1 PT</b>
Perinatal intestinal perforation	Intestinal perforation	Neonatal intestinal perforation
<b>PT Name</b>	<b>Version 16.0 HLT</b>	<b>Version 16.1 HLT</b>
Phenylalanine screen	Protein analyses NEC	Foetal and neonatal diagnostic procedures
<b>Promoted LLT</b>	<b>Primary HLT</b>	<b>Primary SOC</b>
Polycythaemia neonatorum	Polycythaemia (excl rubra vera)	Blood and lymphatic system disorders
<b>New Term Examples</b>		
<b>New PT Name</b>	<b>Primary HLT</b>	<b>Primary SOC</b>
Neonatal gastrointestinal haemorrhage	Non-site specific gastrointestinal haemorrhages	Gastrointestinal disorders
Neonatal intestinal perforation	Intestinal ulcers and perforation NEC	Gastrointestinal disorders

**Table 3-3. Neonatal term changes**

## 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 v16.1. These tables are intended only as a reference. For detailed information on the changes to v16.1, please see the MedDRA Version Report included within the [English language download](#).

#### SOC, HLGTT, HLT Changes

Level	Change Request Action	Net Change	v16.0	v16.1
<b>SOC</b>	Total SOCs	0	26	26
<b>HLGTT</b>	New HLGTTs	0	0	0
	Merged HLGTTs	0	0	0
	Total HLGTTs <sup>1</sup>	0	334	334
<b>HLT</b>	New HLTs	0	0	0
	Merged HLTs	0	0	0
	Total HLTs <sup>1</sup>	0	1717	1717

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

MedDRA v16.1 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 HLGTTs.

<sup>1</sup> Total net change of HLGTTs/HLT equals the number of new HLGTTs/HLT minus the number of merged HLGTTs/HLT.

**Summary of Changes**

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**PT Changes**

<b>Level</b>	<b>Change Request Action</b>	<b>v16.0</b>	<b>v16.1</b>
<b>PT</b>	New PTs	360	269
	Promoted LLTs	113	24
	Demoted PTs	153	43
	Net Change <sup>1</sup>	320	250
	Total PTs	20057	20307

**Table 4-2. Summary of Impact on PTs**

<sup>1</sup>Net change of PTs equals the number of new PTs plus the number of promoted LLTs minus the number of demoted PTs.

**LLT Changes**

<b>Level</b>	<b>Change Request Action</b>	<b>Net Change</b>	<b>v16.0</b>	<b>v16.1</b>
<b>LLT</b>	Total LLTs <sup>1</sup>	746	71326	72072

**Table 4-3. Summary of Impact on LLTs**

<sup>1</sup>Total LLTs include PTs.

**New SMQs**

<b>Level</b>	<b>Net Change</b>	<b>v16.0</b>	<b>v16.1</b>
<b>1</b>	4	90	94
<b>2</b>	0	82	82

## Summary of Changes

Level	Net Change	v16.0	v16.1
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 v16.1. The table is intended only as a reference.

<b>INTL_ORD.ASC</b>	Added	0
	Removed	0
	Modified	0
<b>SOC.ASC</b>	Added	0
	Removed	0
	Modified	0
<b>SOC_HLGT.ASC</b>	Added	0
	Removed	0
	Modified	0
<b>HLGT.ASC</b>	Added	0
	Removed	0
	Modified	0
<b>HLGT_HLT.ASC</b>	Added	0
	Removed	0
	Modified	0
<b>HLT.ASC</b>	Added	0
	Removed	0
	Modified	0

## Summary of Changes

<b>HLT_PT.ASC</b>	Added	535
	Removed	79
	Modified	0
<b>MDHIER.ASC</b>	Added	622
	Removed	92
	Modified	0
<b>PT.ASC</b>	Added	293
	Removed	43
	Modified	7
<b>LLT.ASC</b>	Added	746
	Removed	0
	Modified	358
<b>SMQ_LIST.ASC<sup>1</sup></b>	Added <sup>1</sup>	4
	Removed	0
	Modified	206
<b>SMQ_CONTENT.ASC</b>	Added	2471
	Removed <sup>2</sup>	1195
	Modified	367

**Table 4-5. Summary of Impact on Records in MedDRA Files**

<sup>1</sup> The number of SMQs added includes both top level (Level 1) and sub-search SMQs.

<sup>2</sup> The number of removed PTs represents terms moved from one SMQ to another or inactive PTs removed. See section 3.1 for details.

## 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) <sup>1</sup>	PTs (Primary) <sup>1</sup>	LLTs* (Primary and Secondary) <sup>2</sup>	PTs (Primary and Secondary) <sup>2</sup>	HLT <sup>3</sup>	HLGT <sup>3</sup>
<i>Blood and lymphatic system disorders</i>	1048	250	3975	899	87	17
<i>Cardiac disorders</i>	1310	295	2158	534	36	10
<i>Congenital, familial and genetic disorders</i>	3195	1192	3195	1192	98	19
<i>Ear and labyrinth disorders</i>	425	82	752	186	17	6
<i>Endocrine disorders</i>	599	164	1623	465	38	9
<i>Eye disorders</i>	2385	545	3451	895	64	13
<i>Gastrointestinal disorders</i>	3564	771	7050	1547	109	21
<i>General disorders and administration site conditions</i>	2409	789	2989	979	49	9
<i>Hepatobiliary disorders</i>	603	171	1349	385	19	4

### Summary of Changes

SOC	LLTs* (Primary) <sup>1</sup>	PTs (Primary) <sup>1</sup>	LLTs* (Primary and Secondary) <sup>2</sup>	PTs (Primary and Secondary) <sup>2</sup>	HLTs <sup>3</sup>	HLGTs <sup>3</sup>
<i>Immune system disorders</i>	404	119	2255	583	25	4
<i>Infections and infestations</i>	6674	1763	6973	1842	147	12
<i>Injury, poisoning and procedural complications</i>	5928	895	7806	1634	65	7
<i>Investigations</i>	12799	5115	12799	5115	106	23
<i>Metabolism and nutrition disorders</i>	906	258	2422	677	63	14
<i>Musculoskeletal and connective tissue disorders</i>	2281	403	5914	1070	60	11
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	8272	1857	8888	2098	203	39
<i>Nervous system disorders</i>	3271	831	6427	1663	107	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1587	210	2699	526	48	8
<i>Psychiatric disorders</i>	2180	485	2968	685	78	23
<i>Renal and urinary disorders</i>	1144	319	2447	663	32	8



### Summary of Changes

SOC	LLTs* (Primary) <sup>1</sup>	PTs (Primary) <sup>1</sup>	LLTs* (Primary and Secondary) <sup>2</sup>	PTs (Primary and Secondary) <sup>2</sup>	HLTs <sup>3</sup>	HLGTs <sup>3</sup>
<i>Reproductive system and breast disorders</i>	1652	443	3937	1063	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1566	471	3842	1022	48	11
<i>Skin and subcutaneous tissue disorders</i>	1887	430	4160	1120	56	10
<i>Social circumstances</i>	589	244	589	244	20	7
<i>Surgical and medical procedures</i>	4213	1946	4213	1946	140	19
<i>Vascular disorders</i>	1181	259	5933	1337	68	11
<b>Total</b>	<b>72072</b>	<b>20307</b>				

**Table 4-6. MedDRA Term Counts**

<sup>1</sup>Primary 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.

<sup>2</sup>Total 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.

<sup>3</sup>The 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

## Summary of Changes

HLTs and HLGs 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 v16.1.

Code	Level	Term Name in v16.0	Term Name in v16.1
10064153	LLT	Antibiotic resistant staphylococcal aureus infection	Antibiotic resistant Staphylococcus aureus infection
10064389	PT	Disbacteriosis	Dysbacteriosis
10072937	LLT	Drug-induced hepatotoxicity	Drug-induced hepatotoxicity
10057963	LLT	Enterocolitis methicillin-resistant staphylococcal aureus	Enterocolitis methicillin-resistant Staphylococcus aureus
10016259	LLT	Fatigueability	Fatiguability
10053426	LLT	Gastroenteritis methicillin-resistant staphylococcal aureus	Gastroenteritis methicillin-resistant Staphylococcus aureus
10052101	LLT	Glycopeptide antibiotic resistant staphylococcal aureus infection	Glycopeptide antibiotic resistant Staphylococcus aureus infection
10060607	LLT	Hemodialysed	Hemodialyzed
10072965	LLT	Methicillin-resistant staphylococcal aureus cellulitis	Methicillin-resistant Staphylococcus aureus cellulitis
10027508	LLT	Methicillin-resistant staphylococcal aureus infection	Methicillin-resistant Staphylococcus aureus infection
10058931	LLT	Methicillin-resistant staphylococcal aureus pneumonia	Methicillin-resistant Staphylococcus aureus pneumonia
10058867	LLT	Methicillin-resistant staphylococcal aureus sepsis	Methicillin-resistant Staphylococcus aureus sepsis
10056081	LLT	Oesophageal tumor benign	Oesophageal tumour benign
10069145	LLT	Oxacillin-resistant staphylococcal aureus infection	Oxacillin-resistant Staphylococcus aureus infection
10069210	LLT	Prostatic greenlight laser vaporisation	Prostatic greenlight laser vapourisation
10058214	LLT	Septicaemia due to haemophilus influenzae (H. influenzae)	Septicaemia due to Haemophilus influenzae (H. influenzae)
10040093	LLT	Septicemia due to hemophilus influenzae (H. influenzae)	Septicemia due to Hemophilus influenzae (H. influenzae)

## Summary of Changes

Code	Level	Term Name in v16.0	Term Name in v16.1
10066412	LLT	Staphylococcal aureus skin infection	Staphylococcus aureus skin infection
10069778	LLT	Vancomycin intermediate staphylococcus aureus infection	Vancomycin intermediate Staphylococcus aureus infection
10047041	LLT	Vasa previa complicating labour and delivery	Vasa praevia complicating labour and delivery
10054091	LLT	Wound infection due to staphylococcus aureus	Wound infection due to Staphylococcus aureus

**Table 4-7. Modified PT/LLT Names**

### 4.5 LLT CURRENCY STATUS CHANGES

The following table reflects the 12 terms at the LLT level in MedDRA v16.1 that have a change in their currency status along with the rationale for the change.

Lowest Level Term	Currency Status Changed to	Rationale
Enterococcus fecalis endocarditis	Current	This American English spelling LLT is a recognized counterpart to the current British English LLT <i>Enterococcus faecalis endocarditis</i> .
Injury to brachial plexus due to birth trauma	Current	Based upon a proactivity request submitted by a MedDRA user, the MSSO is adding, moving, changing currency or promoting a small number of terms related to the neonatal period to facilitate coding and data analysis. LLT <i>Injury to brachial plexus due to birth trauma</i> was made current and promoted to a PT from under PT <i>Brachial plexus injury</i> because, as a frequent obstetric injury, it represents a valid medical concept. Representation at the PT level allows a secondary link to HLT <i>Neonatal disorders due to birth trauma (excl intracranial haemorrhages)</i>
Streptococcus fecalis endocarditis	Current	This American English spelling LLT is a recognized counterpart to the British English LLT <i>Streptococcus faecalis endocarditis</i> which has a status of current.
Apoplactic thyroid cancer	Non-current	The word "apoplactic" has no apparent recognized medical meaning, and thus will be made non-current.
Fatigueability generalised	Non-current	The correct British spelling is "Fatiguability" which has been added to MedDRA in version 16.1 as LLT <i>Fatiguability generalised</i> . Therefore, the incorrect spelling will be made non-current.

## Summary of Changes

Lowest Level Term	Currency Status Changed to	Rationale
Generalized infection during labour	Non-current	LLT <i>Generalized infection during labour</i> is a mixture of British and American English spelling. Both British and American counterparts exist as current LLTs.
Hypoestrogenaemia	Non-current	LLT <i>Hypoestrogenaemia</i> is a mixture of British and American English spelling. Both British and American counterparts exist as current LLTs.
Intracranial tumour hemorrhage	Non-current	LLT <i>Intracranial tumour hemorrhage</i> is a mixture of British and American English spelling. Both British and American counterparts exist as current LLTs
Maternal anaesthesia and analgesia affecting fetus or newborn	Non-current	LLT <i>Maternal anaesthesia and analgesia affecting fetus or newborn</i> is a mixture of British and American English spelling and will be made non-current.
PID	Non-current	Although commonly used to convey pelvic inflammatory disease, PID may also be an abbreviation of multiple other concepts such as: Prolapsed Intervertebral Disc, Pain Intensity Difference [score], Phosphotyrosine Interaction Domain, Photoionization Detector, etc.
Sore roof of mouth	Non-current	LLT <i>Sore roof of mouth</i> was made non-current because of its ambiguity in that it can be interpreted as a lesion or as pain. LLT <i>Soreness roof of mouth</i> was added to PT <i>Oral pain</i> to remove potential ambiguity.
White spot disease	Non-current	In light of the variety of different pathologic conditions that are associated with white skin spots, or "white spot disease", it is appropriate to change the status of the term to non-current.

**Table 4-8. LLT Currency Changes**