

# What's New MedDRA Version 22.0

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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 21.1 and 22.0.

Section 2, Version 22.0 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 22.0, highlights changes in Version 22.0 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:

- 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
- 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 22.0 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 22.0 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 was a total of 1,541 change requests processed for this version; 1,333 change requests were approved and implemented, and 207 change requests were not approved. There is, in addition, one change request 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 <u>weekly supplemental update</u> files, which are approved changes that will be implemented for the next MedDRA version. Additionally, supplemental changes may be viewed in MedDRA Web-Based Browser via the "supplemental view" feature. Supplemental information 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 22.0 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 <u>WebCR</u>.

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 22.0 (shown in Table 4-6) and the corresponding information for Version 21.1. 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 22.0.

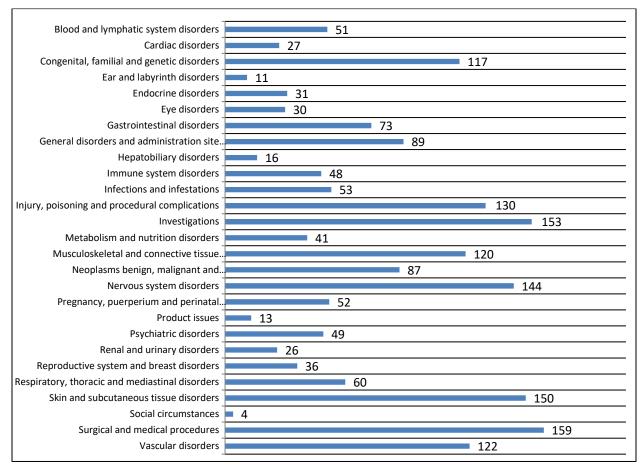


Figure 2-1 Net Changes of Terms per SOC

#### 2.2 COMPLEX CHANGES

The proposals for complex changes considered during Version 22.0 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 30 July 2018 to 21 September 2018. 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 22.0 are summarized below. Please see the "Related Documents" on the <u>Change Request section</u> of the MedDRA website for specific details.

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

**At the HLGT level:** There were two High Level Group Terms (HLGTs) added and two merged as a result of complex changes in Version 22.0. The changes are as follows:

#### **New HLGTs**

New HLGT	To SOC
Cardiac disorders, signs and symptoms NEC	Cardiac disorders
Vascular infections and inflammations	Vascular disorders

Table 2-1 New HLGTs

#### Merged HLGTs

HLGT	To HLGT	soc
Cardiac disorder signs and symptoms	Cardiac disorders, signs and symptoms NEC	Cardiac disorders
Vascular inflammations	Vascular infections and inflammations	Vascular disorders

**Table 2-2 Merged HLGTs** 

**At the HLT level:** There were six High Level Terms (HLTs) added and six merged as a result of complex changes in Version 22.0. The changes are as follows:

#### **New HLTs**

New HLT	To SOC
Aortic infections and inflammations	Vascular disorders
Arterial infections and inflammations	Vascular disorders
Gingival disorders, signs and symptoms NEC	Gastrointestinal disorders
Hallucinations (excl sleep-related)	Psychiatric disorders
Perception disturbances NEC	Psychiatric disorders

# **Version 22.0 Change Requests**

New HLT	To SOC
Thoracic spinal cord and nerve root disorders	Nervous system disorders

Table 2-3 New HLTs

# Merged HLTs

HLT	To HLT	soc	
Aortic inflammatory disorders	Aortic infections and inflammations	Vascular disorders	
Arterial inflammations	Arterial infections and inflammations	Vascular disorders	
Gingival discolourations	Gingival disorders, signs and symptoms NEC	Gastrointestinal disorders	
Gingival disorders NEC	Gingival disorders, signs and symptoms NEC	Gastrointestinal disorders	
Gingival pains	Gingival disorders, signs and symptoms NEC	Gastrointestinal disorders	
Perception disturbances	Perception disturbances NEC	Psychiatric disorders	

Table 2-4 Merged HLTs

#### 3. NEW DEVELOPMENTS IN VERSION 22.0

#### 3.1 RUSSIAN MedDRA

The MSSO is pleased to announce that as of Version 22.0, Russian MedDRA will be available to MedDRA users. Russian MedDRA is provided to all users at no additional cost and includes the MedDRA term files, availability in the MedDRA Web-Based Browser and all the related documentation that is provided in other supported languages. Users may access Russian MedDRA from the MedDRA website in the same manner as other languages. Note that a Russian version report and accessibility of Russian term information in MVAT will be available in September 2019 when Version 22.1 debuts as there are not yet two Russian versions to generate a comparison. For any specific questions about Russian MedDRA and how to access it, please contact the MSSO Help Desk.

#### 3.2 STANDARDISED MedDRA QUERIES (SMQs)

New SMQ *Hypokalaemia* was added in MedDRA Version 22.0. There are now 104 level 1 SMQs in production as of this version. Additionally, there were 389 approved changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA Version 22.0 Version Report.

Please see the MedDRA Version 22.0 SMQ Introductory Guide for detailed information on new SMQ *Hypokalaemia*.

#### 3.2.1 Update to the SMQ Spreadsheet

The MSSO provides an SMQ spreadsheet in the English MedDRA download package for the purpose of offering SMQ information to users that may not have the resources or tools to work with the SMQ files (i.e., smq\_list.asc and smq\_content.asc). The SMQ spreadsheet is updated for each MedDRA Version and includes SMQ hierarchical information, a list of narrow and broad scope PTs in each SMQ, a summary of the level 1 SMQs and list of active and inactive PT counts for each SMQ.

As of MedDRA Version 22.0, an additional report will be included in the SMQ spreadsheet that lists the active PT codes for both narrow and broad scope searches for each SMQ. This new report will allow users to quickly copy the PT codes for the purposes of inserting them directly into a query. Hierarchical SMQs will include the PT codes of all subordinate SMQs. For algorithmic SMQs, the broad scope search includes all active PTs from all categories; if users wish to use the algorithmic search approach, they will need to apply the specific algorithm based on categories that is described in the SMQ Introductory Guide to their query. See the example below. Users may also extract SMQ information via the "SMQ Export" feature of the MedDRA Web-Based Browser and Desktop Browser.

SMQ Code	SMQ	Scope	Active PT Codes
20000135	Accidents and injuries (SMQ)	Narrow	'10000044','10000369','10000370','10000372','10000397','10001356','10002544'
20000135	Accidents and injuries (SMQ)	Broad+Narrow	'10000044','10000369','10000370','10000372','10000397','10001356','10002515'
20000116	Acute central respiratory depression (SMQ)	Narrow	'10001053','10002974','10002977','10006102','10006322','10007982','10021079'
20000116	Acute central respiratory depression (SMQ)	Broad+Narrow	'10001053','10002660','10002974','10002977','10003497','10005539','10005705'
20000022	Acute pancreatitis (SMQ)	Narrow	'10033625','10033635','10033636','10033645','10033647','10033650','10033654'

Figure 3-1 SMQ PT Codes

Note that the PT Codes shown in the figure above are not a complete listing and would extend further out to the right in the SMQ PT Codes report.

#### 3.3 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 22.0 change request processing period, the MSSO received and implemented two requests from MedDRA users. See below for details. The MSSO publishes and updates a list of all proposals received and their status on the <a href="Change Request">Change Request</a> 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.

#### 3.3.1 Placement of Anesthesia terms

Based on a request by a MedDRA user, the MSSO reviewed anesthesia terms to consider more optimal placement in MedDRA. As a result of this review, new PT *Anaesthesia oral* was added to primary HLT *Oral soft tissue signs and symptoms* in SOC *Gastrointestinal disorders* with a secondary link to HLT *Paraesthesias and dysaesthesias* in SOC *Nervous system disorders* to represent anesthesia terms separately from hypoesthesia terms. As a result, nine existing LLTs were moved from PT *Hypoaesthesia oral* to new PT *Anaesthesia oral*. See the table below for examples.

#### **New Developments in Version 22.0**

LLT Name	PT v21.1	PT v22.0
Anaesthesia lip	Hypoaesthesia oral	Anaesthesia oral
Anaesthesia oral mucosa	Hypoaesthesia oral	Anaesthesia oral
Anaesthesia tongue	Hypoaesthesia oral	Anaesthesia oral

**Table 3-1 Moved Anesthesia Terms** 

Additionally, for consistency of placement, the following PTs were moved from HLT Sensory abnormalities NEC to HLT Paraesthesias and dysaesthesias: PT Anaesthesia dolorosa, PT Anaesthesia, PT Hemianaesthesia, and PT Thermoanaesthesia.

#### 3.3.2 Review of Chemical burns and corrosive injuries

The MSSO reviewed a proactivity request to consider modifications to the placement of existing chemical burn and corrosive injury terms. Based in this review, a total of six changes were made to existing terms for more consistent placement in MedDRA. For example, two PTs were demoted to reduce over-granulation of anatomically closely related concepts. See below for details:

PT Demoted to LLT	Under PT	In SOC
Chemical iritis	Chemical burns of eye	Injury, poisoning and procedural complications
Chemical eye injury	Chemical burns of eye	Injury, poisoning and procedural complications

Table 3-2 Modifications to Chemical burn terms

#### 3.4 MedDRA WEB-BASED BROWSER 3.0

An update to the MedDRA Web-Based Browser (WBB) is available as of October 2018. The update includes the following enhancements:

- An option to view supplemental updates
- SMQ analysis
- Hierarchy analysis
- More advanced searching via additional Boolean and string operators
- An option to include the secondary SOC path in exports of search results, the research bin, and hierarchy analysis reports

The MSSO has developed a <u>videocast</u> that focuses on the new features of the WBB. The videocast is available for download or for direct viewing under the Tools

#### **New Developments in Version 22.0**

section/MedDRA Web-Based Browser section on the <u>Training Materials page</u> with the title "WBB 3.0 Enhancements."

To access the <u>WBB</u>, simply login using your MedDRA ID and Password. This password is the same password used to access the MedDRA website. If you don't know your User ID and Password, please use the <u>MedDRA Self-Service Application</u>.

#### 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 22.0. These tables are intended only as a reference. For detailed information on the changes to Version 22.0, please see the MedDRA Version Report included within the MedDRA download.

SOC, HLGT, HLT Changes

Level	Change Request Action	Net Change	v21.1	v22.0
soc	Total SOCs	0	27	27
	New HLGTs	2	0	2
HLGT	Merged HLGTs	2	0	2
	Total HLGTs <sup>1</sup>	0	337	337
	New HLTs	6	0	6
HLT	Merged HLTs	6	0	6
	Total HLTs <sup>1</sup>	0	1,737	1,737

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

<sup>&</sup>lt;sup>1</sup> Total net change of HLGTs or HLTs equals the number of new HLGTs or HLTs minus the number of respective merged HLGTs or HLTs.

## PT Changes

Level	Change Request Action	v21.1	v22.0
	New PTs	347	327
	Promoted LLTs	19	42
PT	Demoted PTs	65	50
	Net Change <sup>1</sup>	301	319
	Total PTs	23,389	23,708

Table 4-2 Summary of Impact on PTs

## **LLT Changes**

Level	Currency Status	Net Change	v21.1	v22.0
LLT	Current Terms	748	70,229	70,977
LLT	Non-current Terms	7	9,278	9,285
LLT	Total LLTs <sup>1</sup>	755	79,507	80,262

Table 4-3 Summary of Impact on LLTs

<sup>&</sup>lt;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.

<sup>&</sup>lt;sup>1</sup>Total LLTs include PTs as they are also in the LLT distribution file.

#### **New SMQs**

Level	Net Change	v21.1	v22.0
1	1	103	104
2	0	82	82
3	0	20	20
4	0	16	16
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 22.0. The table is intended only as a reference.

	Added	0
INTL_ORD.ASC	Removed	0
	Modified	0
	Added	0
SOC.ASC	Removed	0
	Modified	0
	Added	2
SOC_HLGT.ASC	Removed	2
	Modified	0
	Added	2
HLGT.ASC	Removed	2
	Modified	0
	Added	13
HLGT_HLT.ASC	Removed	13
	Modified	0
	Added	6
HLT.ASC	Removed	6
	Modified	0

	Added	658
HLT_PT.ASC	Removed	158
	Modified	0
	Added	856
MDHIER.ASC	Removed	320
	Modified	0
	Added	369
PT.ASC	Removed	50
	Modified	4
	Added	755
LLT.ASC	Removed	0
	Modified	339
	Added <sup>1</sup>	1
SMQ_LIST.ASC <sup>1</sup>	Removed	0
	Modified	223
	Added	1,062
SMQ_CONTENT.ASC	Removed	0
	Modified	145

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

#### 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. Note that the number of LLTs also includes PTs.

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>
Blood and lymphatic system disorders	1,155	293	4,343	1,036	88	17
Cardiac disorders	1,481	357	2,418	633	36	10

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

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>
Congenital, familial and genetic disorders	3,714	1,441	3,714	1,441	98	19
Ear and labyrinth disorders	442	93	844	218	17	6
Endocrine disorders	680	193	1,849	566	38	9
Eye disorders	2,501	623	3,824	1,051	63	13
Gastrointestinal disorders	3,926	881	7,700	1,750	106	21
General disorders and administration site conditions	2,538	1,030	3,439	1,361	36	7
Hepatobiliary disorders	673	203	1,504	443	19	4
Immune system disorders	498	144	2,723	742	26	4
Infections and infestations	7,289	1,984	7,652	2,085	149	12
Injury, poisoning and procedural complications	6,800	1,242	9,522	2,429	78	9
Investigations	13,921	5,785	13,921	5,785	106	23
Metabolism and nutrition disorders	977	287	2,755	798	63	14

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>
Musculoskeletal and connective tissue disorders	2,636	479	6,727	1,357	59	11
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8,669	1,990	9,462	2,312	202	39
Nervous system disorders	3,730	987	7,430	2,024	108	20
Pregnancy, puerperium and perinatal conditions	1,641	229	2,953	623	48	8
Product issues	664	159	681	167	21	2
Psychiatric disorders	2,382	536	3,274	806	77	23
Renal and urinary disorders	1,240	361	2,653	756	32	8
Reproductive system and breast disorders	1,769	498	4,282	1,201	52	16
Respiratory, thoracic and mediastinal disorders	1,755	544	4,327	1,177	49	12
Skin and subcutaneous tissue disorders	2,146	518	4,988	1,425	56	10
Social circumstances	642	275	642	275	20	7

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>
Surgical and medical procedures	5,037	2,258	5,037	2,258	141	19
Vascular disorders	1,356	318	6,882	1,688	68	11
Total	80,262	23,708				

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 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.

The table below summarizes terms modified in English MedDRA Version 22.0.

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Code	Level	Term Name in v21.1	Term Name in v22.0
10066910	PT	Lumbar syndrome	LUMBAR syndrome
10047372	LLT	Vesicouretral reflux unspecified or without reflux nephropathy	Vesicoureteral reflux unspecified or without reflux nephropathy
10047373	LLT	Vesicouretral reflux with reflux nephropathy NOS	Vesicoureteral reflux with reflux nephropathy NOS
10047374	LLT	Vesicouretral reflux with reflux nephropathy, bilateral	Vesicoureteral reflux with reflux nephropathy, bilateral
10047375	LLT	Vesicouretral reflux with reflux nephropathy, unilateral	Vesicoureteral reflux with reflux nephropathy, unilateral

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

#### 4.5 LLT CURRENCY STATUS CHANGES

The following table reflects 11 terms at the LLT level in MedDRA Version 22.0 that had a change in currency status along with the rationale for the change.

Lowest Level Term	Currency Status Changed to	Rationale
LUMBAR syndrome	Current	LUMBAR syndrome was changed to a status of current as it is a recognized concept often characterized by a large infantile hemangioma on the lower back often extending down to the leg. Other features are urogenital tract malformations, spinal cord defects, bone deformities, anorectal malformations, and arterial anomalies. In MedDRA Version 22.0, LLT <i>LUMBAR</i> syndrome was promoted to a PT and linked to primary HLT Vascular anomalies congenital NEC in SOC Congenital, familial and genetic disorders, secondary HLT Cardiovascular neoplasms benign in SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps).
PET scan	Current	LLT <i>PET scan</i> was changed to a status of current because it is a commonly used and non-ambiguous concept.

Lowest Level Term	Currency Status Changed to	Rationale
Acute renal failure with lesion of tubular necrosis	Non-current	Although acute renal failure can result from tubular necrosis secondary to exposure to a toxin or ischemic damage to the tubules, the concepts combined in LLT <i>Acute renal failure with lesion of tubular necrosis</i> can be coded separately. All of the other combination terms of this type presently subordinate to PT <i>Acute kidney injury</i> have been changed to a non-current status.
Aspiration bronchial	Non-current	LLT Aspiration bronchial was changed to a status of non- current and replaced with LLT Aspiration into bronchus to clarify the concept and to provide a term that is distinct from the investigation term represented by LLT Bronchial aspiration procedure.
Aspiration tracheal	Non-current	LLT Aspiration tracheal was changed to a status of non- current and replaced with LLT Aspiration into trachea to clarify the concept and to provide a term that is distinct from the investigation term represented by LLT Tracheal aspiration procedure.
Cardialgia	Non-current	LLT Cardialgia was changed to a status of non-current because it is ambiguous as it is defined as pain in and around the heart and has been used to represent heartburn in addition to heart pain.
Loss of thoracic lordosis	Non-current	The vertebral column is constituted by a succession of three physiological curves: lumbar lordosis, dorsal kyphosis, cervical lordosis. LLT <i>Loss of thoracic lordosis</i> , which is intended to represent the loss of a physiologic thoracic lordosis, does not exist in normal spine curvatures.
Raised TG	Non-current	LLT Raised TG was changed to a status of non-current due to its ambiguity as it may represent many medical concepts such as: triglyceride; tendon graft; testosterone glucuronide; tocogram; total gastrectomy; toxic goiter; transmissible gastroenteritis; treated group; tricuspid gradient; trigeminal ganglion; tumor growth, etc.
Tracheal aspiration	Non-current	LLT <i>Tracheal aspiration</i> was changed to a status of non- current and replaced by new LLT <i>Aspiration into trachea</i> which was added for clarification of the concept.
Transient hypogammaglobulinaemia	Non-current	The status of LLT <i>Transient hypogammaglobulinaemia</i> was changed to non-current because "Transient" can refer to unspecified transient hypogammaglobulinaemia in adults or to transient hypogammaglobulinemia of infancy.

Lowest Level Term	Currency Status Changed to	Rationale
Transient hypogammaglobulinemia	Non-current	The status of LLT <i>Transient hypogammaglobulinemia</i> was changed to non-current because "transient" can refer to unspecified transient hypogammaglobulinemia in adults or to transient hypogammaglobulinemia of infancy.

**Table 4-8 LLT Currency Changes**