



What's New MedDRA Version 27.0

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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 26.1 and 27.0.

Section 2, Version 27.0 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 27.0, highlights changes in Version 27.0 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
- 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 mssohelp@meddra.org.

2. VERSION 27.0 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 27.0 is a complex change version which means changes may be made at any level of the MedDRA hierarchy.

Change requests involve both MedDRA updates and SMQ changes. There was a total of 1,582 change requests processed for this version; 1,206 change requests were approved and implemented, and 310 change requests were not approved. There are, in addition, 66 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 which compares MedDRA Version 26.1 to Version 27.0 is identical to the Version Report provided in the MedDRA zip file download. MVAT is provided free of charge to MedDRA users as part of their subscription.

Between MedDRA releases, the MSSO makes available English [weekly supplemental update](#) files, which are approved changes that will be implemented for the next MedDRA version. Additionally, supplemental changes may be viewed in the MedDRA Web-Based Browser or MVAT 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 27.0 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 measure 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 27.0 (shown in Table 4-5) and the corresponding information for Version 26.1. Additionally, LLT currency status changes are included in Figure 2-1.

Please see Section 4 for a summary of the changes in MedDRA Version 27.0.

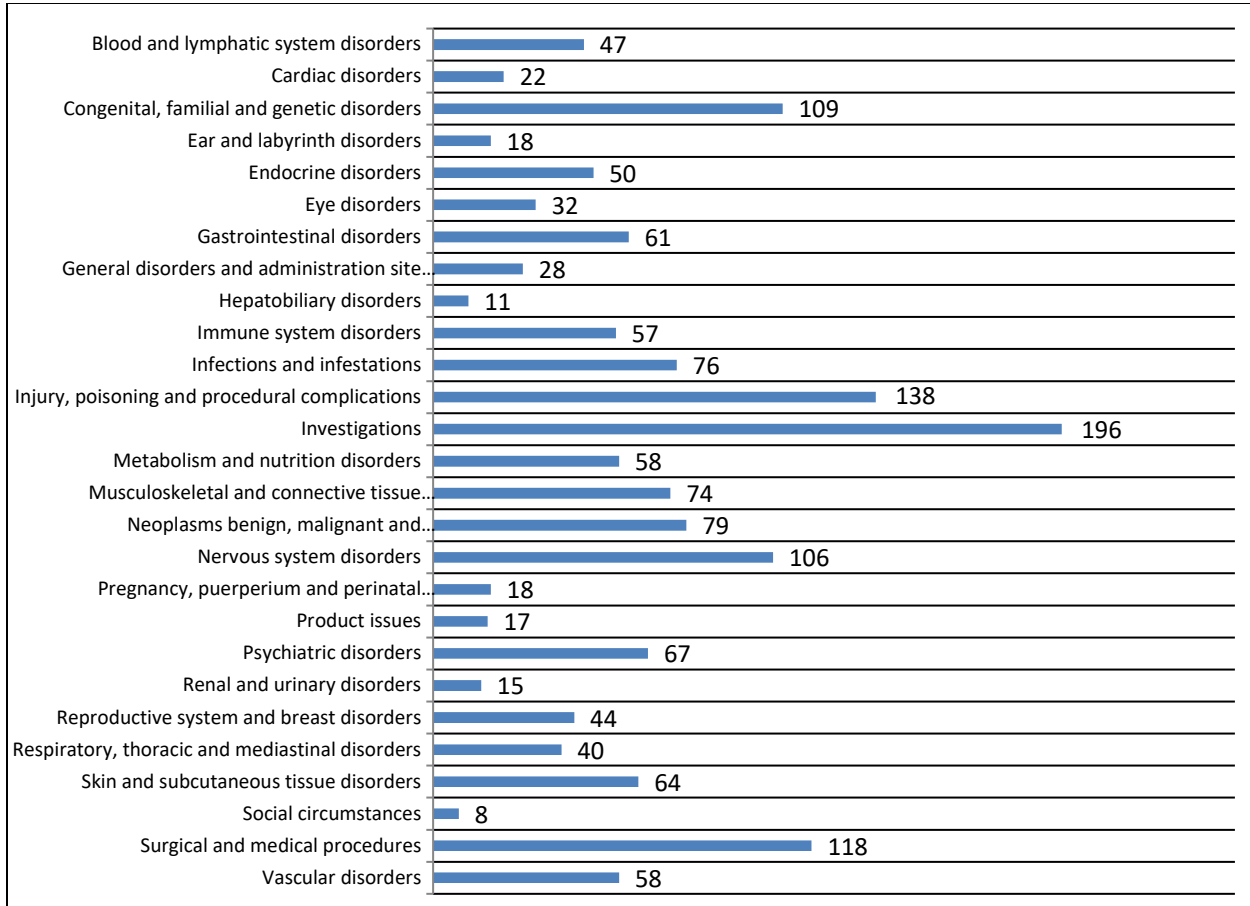


Figure 2-1 Net Changes of Terms per SOC

2.2 COMPLEX CHANGES

The proposals for complex changes considered during Version 27.0 included those submitted by users 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 1 August 2023 to 22 September 2023. Complex changes were followed by further internal review and consensus discussions which resulted in the final approved set of 2 complex changes.

The complex changes implemented in Version 27.0 are summarized below. Please see the “Related Documents” on the [Change Request section](#) of the MedDRA website for specific details.

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

At the HLGT level: No changes were made to existing HLGTs.

At the HLT level: There was one High Level Term (HLT) added and an existing HLT renamed as a result of complex changes in Version 27.0.

The changes are as follows:

New HLTs

New HLT	To SOC
Instillation site reactions ¹	General disorders and administration site conditions
	Injury, poisoning and procedural complications

Table 2-1 New HLT

Renamed HLTs

Old HLT Name	New HLT Name	To SOC
Application and instillation site reactions	Application site reactions ¹	General disorders and administration site conditions
		Injury, poisoning and procedural complications

Table 2-2 Renamed HLT

HLT *Application and instillation site reactions* was split into two separate HLTs – HLT *Application site reactions* and HLT *Instillation site reactions* to improve analysis and assist with the differentiation between products which are applied, such as ointments, from those being instilled, such as eye drops. HLT *Application and instillation site reactions* (code 10003057) was renamed to HLT *Application site reactions* which was the original name of this term from MedDRA Version 2.1 to Version 3.3.

¹There is a multi-axial link between parent HLGT *Administration site reactions* and SOC *General disorders and administration site conditions* and SOC *Injury, poisoning and procedural complications*.

3. NEW DEVELOPMENTS IN VERSION 27.0

3.1 STANDARDISED MedDRA QUERIES (SMQs)

No new SMQs have been added for MedDRA Version 27.0. There were 248 approved PT changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA Version 27.0.

3.2 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 27.0 change request processing period, the MSSO reviewed two requests and implemented one proactivity proposal. See below for details. 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.

3.2.1 Primary SOC placement of PTs under HLT *Oncologic complications and emergencies*

In MedDRA 26.0, the primary SOC of PT *Malignant ascites* was changed from SOC *Neoplasms benign, malignant and unspecified (incl cysts and polyps)* to SOC *Gastrointestinal disorders*. The justification for this change was that some, but not all, PTs in the HLT *Neoplasm related morbidities* that are specific to sites of manifestation have a primary link to the SOC representative of that site and a secondary link to the SOC *Neoplasms benign, malignant and unspecified (incl cysts and polyps)*. Based on this change, a MedDRA user asked the MSSO to review other PTs under HLT *Oncologic complications and emergencies* for consistency of placement per the site of manifestation rule described above. As a result of this review, the primary SOC of five PTs were changed. See the table below for details.

Summary of Changes

PT Name	Primary SOC V26.1	Primary SOC V27.0
Intracranial tumour haemorrhage	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Nervous system disorders
Malignant pleural effusion	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Respiratory, thoracic and mediastinal disorders
Metastatic pulmonary embolism	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Respiratory, thoracic and mediastinal disorders
Pericardial effusion malignant	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Cardiac disorders
Pulmonary tumour thrombotic microangiopathy	Neoplasms benign, malignant and unspecified (incl cysts and polyps)	Respiratory, thoracic and mediastinal disorder

Table 3-1 Primary SOC change of PTs under HLT *Oncologic complications and emergencies*

3.3 NEW MedDRA LANGUAGES DEPLOYED AND UNDER DEVELOPMENT

The MSSO continues to work on new languages to enable more users to apply MedDRA in their native language and facilitate global communication of MedDRA coded data. The newest available language is Finnish.

Finnish is part of the 17 European Economic Area (EEA) official languages, approved for translation by the MedDRA Management Committee in 2020, which are needed to support the electronic product information initiative. Note that this initiative includes the translation of MedDRA terms only and does not include MedDRA user documentation.

Presently, Bulgarian, Croatian, Icelandic, Lithuanian, Maltese, Norwegian, Romanian, Slovak and Slovenian translations are EEA languages in development. These languages will be translated and made available in 2024 or 2025. Please see the multilingual access section of the [MedDRA Home page](#) for the list of currently supported languages. The MSSO will provide estimated release dates for these languages as they become available.

3.4 UPDATE TO APOSTROPHE IN MAINTAINED LANGUAGES

The MSSO discovered that several languages under maintenance had an inconsistency with how the apostrophe character ' was applied to terms. Some terms used the apostrophe ' (ascii code 039) and others within the same language contained the single quote ´ (ascii code 0146). Many of these languages use the apostrophe as a diacritical mark or to indicate the possessive form of a singular noun or a plural noun such as LLT *Gibert's dandruff*. For consistency, the MSSO updated all terms which contained the

Summary of Changes

single quote ' (ascii code 0146) to the apostrophe ' (ascii code 039) for MedDRA 27.0 and will apply the apostrophe going forward. This update will improve consistency of searching in these languages. See the table below for examples and the total number of terms from all affected languages.

English Term Name	Language	Term in V26.1	Update in V27.0	Number of Terms Updated in V27.0
Cortical visual impairment	Arabic	إعاقة بصرية قشرية	ضعف بصري قشري	1
Stahl's ear	Dutch	Stahl's oor	Stahl's oor	5
Proteus test positive	Estonian	Proteus'e test positiivne	Proteus'e test positiivne	782
Injection site lump	French	Grosseur au site d'injection	Grosseur au site d'injection	3032
Hy's law case	German	Fall von Hy's Law	Fall von Hy's Law	1
Home quarantine	Greek	Κατ' οίκον καραντίνα	Κατ' οίκον καραντίνα	11
Deafness right ear	Italian	Sordità dell'orecchio destro	Sordità dell'orecchio destro	1128
Tourette's syndrome	Polish	Zespół Tourette'a	Zespół Tourette'a	29
5'nucleotidase increased	Russian	Повышение уровня 5'-нуклеотидазы	Повышение уровня 5'-нуклеотидазы	3

Table 3-2 Examples of Updated Translated Terms

For a detailed list of impacted terms for a specific language, please review the respective MedDRA Version Report in MVAT or the zip file download from the MedDRA website.

3.5 UPDATED WebCR

WebCR is the web based tool used to submit term changes, SMQ changes and translation update requests to the MSSO for consideration in the next MedDRA release.

In November of 2023, the MSSO deployed an updated [WebCR](#) application to a modern software platform with an improved user interface. The updated WebCR performs all of the same functions as the previous application and includes improved tool tips, error and warning messages to assist and guide users as they enter and submit changes. In addition, the color scheme and layout of the updated application will match our Self-Service and MapCR applications for consistency across these platforms. Users familiar with the previous version of WebCR should not have any issues using the updated

Summary of Changes

version. Please see the [Change requests](#) section of the MedDRA website for the WebCR quick start guide.

[Home](#) [Term Changes](#) [SMQ Changes](#) [Translation Changes](#) [Batch Review & Submit](#) [Reconsider](#) [Search CR History](#) [Account](#) [Support](#) [TM Utilities](#) [Logout](#)

Term Changes

☒ Add a New Term ☐ Move Term / Change Term Link ☐ Other Changes

Change Action *

Add New LLT

 Change Action *

Choose CR Action

 Change Action *

Choose CR Action

Proposed LLT * (Maximum 100 characters)

PT to Link to (Optional)

Enter Proposed LLT

Rationale for this Request * (Maximum 2000 characters)

Characters remaining: 2000

**Please do not include any company or product name information.

Attach Supporting Document (optional)
(For multiple attachments, please zip files and submit.)

Choose File

 No file chosen

Save CR to Batch

Cancel

To send requests to the MSSO, please review and submit the batch on the "Batch Review & Submit" page.

0 Unsubmitted Term CR(s)

0 Unsubmitted SMQ CR(s)

0 Unsubmitted Translation CR(s)

Figure 3-1 New LLT request in the updated WebCR application

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 27.0. For detailed information on the changes to Version 27.0, please see the MedDRA Version Report in MVAT.

File Name	Number of Records in V26.1	Number of Records in V27.0	Change
hlgt.asc	337	337	0
hlgt_hlt.asc	1,755	1,756	1
hlt.asc	1,737	1,738	1
hlt_pt.asc	38,380	38,749	369
llt.asc	87,592	88,345	753
meddra_history_english.asc	136,994	138,081	1,087
meddra_release.asc	1	1	0
mdhier.asc	40,613	40,994	381
pt.asc	26,180	26,409	229
soc.asc	27	27	0
soc_hlgt.asc	354	354	0
intl_ord.asc	27	27	0
smq_list.asc	230	230	0
smq_content.asc	94,737	95,501	764

Table 4-1 MedDRA Term File Counts

The MedDRA history and release files are optional files for use with the MedDRA Desktop Browser (MDB) release 3.0.2 Beta and up. These files are not part of the MedDRA schema.

Summary of Changes

The table below identifies the number of current vs. non-current terms.

LLT Changes

Level	Currency Status	v26.1	v27.0
LLT	Current Terms	78,283	79,026
LLT	Non-current Terms	9,309	9,319
LLT	Total LLTs ¹	87,592	88,345

Table 4-2 Summary of Impact on LLTs

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

New SMQs

Level	Net Change	v26.1	v27.0
1	0	110	110
2	0	82	82
3	0	20	20
4	0	16	16
5	0	2	2

Table 4-3 Summary of Impact on SMQs

4.2 SUMMARY OF IMPACT ON RECORDS IN MedDRA FILES

The table below lists the consecutive files, associated MedDRA tables and the number of records contained in each consecutive file. A zero indicates that the file has not changed since the prior consolidated MedDRA release. The table below summarizes the impact on MedDRA in Version 27.0. Please see the MedDRA Version Report in MVAT for details.

Summary of Changes

File Name	Number of Records in Table
hlgt.seq	0
hlgt_hlt.seq	1
hlt.seq	2
hlt_pt.seq	611
llt.seq	918
mdhier.seq	1,115
pt.seq	333
soc.seq	0
soc_hlgt.seq	0
intl_ord.seq	0

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

4.3 MedDRA TERM COUNTS BY SOC

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) ¹	PTs (Primary) ¹	LLTs (Primary and Secondary) ²	PTs (Primary and Secondary) ²	HLTs ³	HLGTs ³
<i>Blood and lymphatic system disorders</i>	1,273	337	4,680	1,160	87	17
<i>Cardiac disorders</i>	1,609	393	2,677	710	36	10

Summary of Changes

SOC	LLTs (Primary)¹	PTs (Primary)¹	LLTs (Primary and Secondary)²	PTs (Primary and Secondary)²	HLTs³	HLGTs³
<i>Congenital, familial and genetic disorders</i>	4,591	1,841	4,591	1,841	100	19
<i>Ear and labyrinth disorders</i>	464	104	949	250	17	6
<i>Endocrine disorders</i>	757	213	2,070	634	38	9
<i>Eye disorders</i>	2,728	685	4,189	1,183	63	13
<i>Gastrointestinal disorders</i>	4,260	988	8,286	1,958	105	21
<i>General disorders and administration site conditions</i>	2,595	1,032	3,639	1,423	36	7
<i>Hepatobiliary disorders</i>	750	228	1,644	487	19	4
<i>Immune system disorders</i>	603	173	3,276	928	26	4
<i>Infections and infestations</i>	7,821	2,195	8,295	2,330	150	12
<i>Injury, poisoning and procedural complications</i>	7,376	1,415	10,585	2,790	79	9
<i>Investigations</i>	15,186	6,350	15,186	6,350	106	23
<i>Metabolism and nutrition disorders</i>	1,064	313	3,147	915	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>	2,859	532	7,314	1,549	59	11
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	9,113	2,122	10,040	2,489	201	39
<i>Nervous system disorders</i>	4,137	1,132	8,303	2,335	108	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1,729	254	3,135	695	48	8
<i>Product issues</i>	933	180	968	197	21	2
<i>Psychiatric disorders</i>	2,505	576	3,581	898	77	23
<i>Renal and urinary disorders</i>	1,317	387	2,843	821	32	8
<i>Reproductive system and breast disorders</i>	1,903	550	4,634	1,339	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1,963	606	4,748	1,318	49	12
<i>Skin and subcutaneous tissue disorders</i>	2,404	577	6,087	1,615	56	10
<i>Social circumstances</i>	689	300	689	300	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>	6,240	2,578	6,240	2,578	141	19
<i>Vascular disorders</i>	1,476	348	7,589	1,901	68	11
Total	88,345	26,409				

Table 4-5 MedDRA Term Counts by SOC

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 4-1 and 4-2.

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 4-1 and 4-2.

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 LLT CURRENCY STATUS CHANGES

The following table reflects 10 terms at the LLT level in MedDRA Version 27.0 that had a change in currency status along with the rationale for the changes.

Lowest Level Term	Currency Status Changed to	Rationale
Aplasia	Non-current	PT <i>Aplasia</i> was demoted to an LLT under the new PT <i>Congenital aplasia</i> added in MedDRA 27.0 and then changed to a status of non-current to avoid confusion with bone marrow aplasia.
Benign melanoma	Non-current	The expression "benign melanoma" is misleading, potentially causing confusion and is not well recognized in medical literature.
Gordon syndrome	Non-current	Gordon syndrome is an eponymous term used for both distal arthrogryposis type 3 and for pseudohypoaldosteronism type 2, also known as, familial hyperkalaemic hypertension, which are two distinct medical conditions. As a result, LLT <i>Gordon syndrome</i> was changed to a status of non-current due to the ambiguity of the eponym.
His disease	Non-current	"His disease" is ambiguous and may lead to confusion. The eponym term LLT <i>Werner-His disease</i> was added to represent the concept.
Infected socket	Non-current	As "socket" does not only refer to teeth but can also refer to other locations, e.g. eye socket, the LLT <i>Infected socket</i> was changed to a status of non-current. New LLT <i>Tooth socket infection</i> was added under PT <i>Alveolar osteitis</i> to represent the intended concept.
RCL infection	Non-current	RCL infection stands for replication competent lentivirus infection in the context of PT <i>Lentivirus infection</i> . RCL can have numerous meanings as a medical abbreviation such as "recurrent cutaneous leishmaniasis". Therefore, the MSSO changed the status of LLT <i>RCL infection</i> to non-current to avoid confusion.
TLC	Non-current	"TLC" could represent total lung capacity, total leukocyte count or total lymphocyte count. Due to this

Summary of Changes

Lowest Level Term	Currency Status Changed to	Rationale
		ambiguity, this term was changed to a status of non-current.
TLC abnormal	Non-current	"TLC" could represent total lung capacity, total leukocyte count or total lymphocyte count. Due to this ambiguity, this term was changed to a status of non-current.
TLC decreased	Non-current	"TLC" could represent total lung capacity, total leukocyte count or total lymphocyte count. Due to this ambiguity, this term was changed to a status of non-current.
TLC normal	Non-current	"TLC" could represent total lung capacity, total leukocyte count or total lymphocyte count. Due to this ambiguity, this term was changed to a status of non-current.

Table 4-6 LLT Currency Changes