What's New
MedDRA Version 29.0

ACKNOWLEDGEMENTS

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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 28.1 and 29.0.

Section 2, Version 29.0 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 29.0, highlights changes in Version 29.0 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 29.0 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 29.0 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 1,380 change requests processed for this version; 1,042 change requests were approved and implemented, and 333 change requests were not approved. There are, in addition, 5 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 28.1 to Version 29.0 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 29.0 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 HLGTs for Version 29.0 (shown in Table 4-5) and the corresponding information for Version 28.1. Additionally, LLT currency status changes are calculated in Figure 2-1.

Please see Section 4 for a summary of the changes in MedDRA Version 29.0.
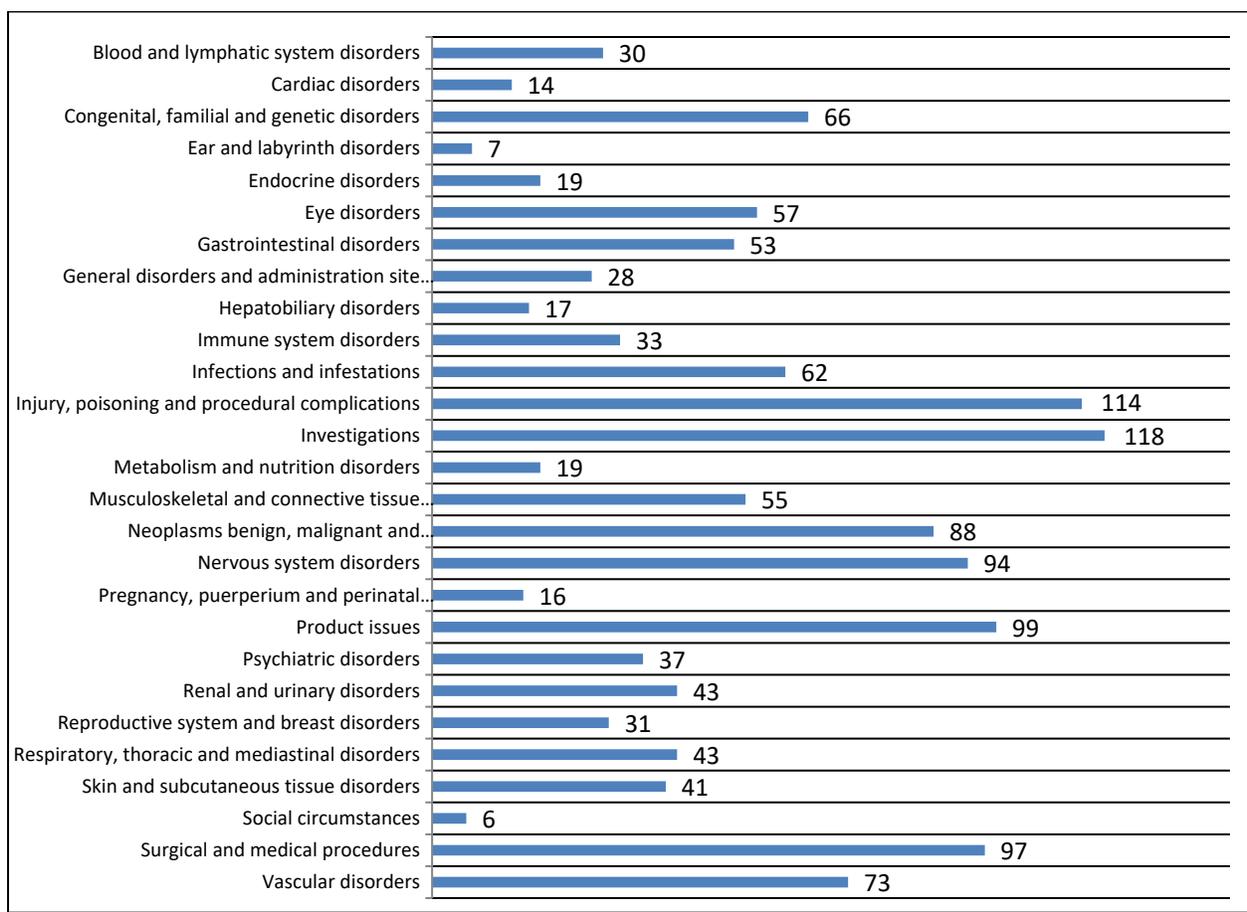
Figure 2-1 Net Changes of Terms per SOC

2.2 COMPLEX CHANGES

The proposals for complex changes considered during Version 29.0 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 8 September 2025 to 31 October 2025. Complex changes were followed by further internal review and consensus discussions which resulted in the final approved 2 complex changes.

The complex changes implemented in Version 29.0 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 SOCs.

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 merged because of complex changes in Version 29.0.

The changes are as follows:

New HLTs

New HLT	To SOC
Poliovirus infections	Infections and infestations

Table 2-1 New HLTs

Merged HLTs

HLT	To HLT	To SOC
Poliomyelitis viral infections	Poliovirus infections	Infections and infestations

Table 2-2 Merged HLT

Replacing HLT *Poliomyelitis viral infections* with new HLT *Poliovirus infections* conforms to the MedDRA term naming conventions and reflects the taxonomic classification as well as standard medical usage. Polio viruses are a group of viruses that cause poliomyelitis, a highly infectious disease that can affect the nervous system and lead to paralysis.

3.   NEW DEVELOPMENTS IN VERSION 29.0

3.1   STANDARDISED MedDRA QUERIES (SMQs)

No new SMQs have been added for MedDRA Version 29.0. There were 255 approved PT changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA 29.0 Version Report. With the release of MedDRA 29.0, there are 110 Level 1 SMQ topics (i.e., main topics) with a total of 230 SMQs which includes sub-SMQs under the Level 1 SMQs.

3.2   MOVED MEDICATION ERROR / ISSUE TERMS

Based on MedDRA user requests, the MSSO rearranged LLTs in the HLGT *Medication errors and other product use errors and issues*. These changes included LLT moves which aligned the LLTs with the PTs for the adequate scenario as described below. Terms only indicating a 'wrong' or 'incorrect' outcome without clearly indicating that the reason was an error or accidental, where aligned with 'issue' PTs to improve the representation of these concepts in MedDRA. Additionally, moves of LLTs to clear 'error' PTs were also performed. This included addition of new PTs. See below for examples.

LLT Name	From PT	To PT
Accidental dose decrease	Wrong dose	Dosing error
Drug maladministration	Product administration error	Product administration issue
Expired drug dispensed	Product dispensing error	Product dispensing issue
Incorrect storage of drug	Product storage error	Product storage issue
Wrong drug product dispensed	Product dispensing error	Product dispensing issue

Table 3-1 Examples of Moved Medication Error / Issue Terms

For the entire list of moved LLTs which occurred in MedDRA 29.0, including the moved LLTs explained above, please see the MedDRA 29.0 Version report or use MVAT.

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 MedDRA 29.0 change request processing period, one proactivity proposal was implemented. See the section 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.

3.3.1   "Secondary malignancy" LLT currency status changes

A MedDRA user asked the MSSO to review a set of LLTs containing the words "secondary malignancy" (e.g., LLT *Secondary carcinoma*) as the meaning of these terms has changed and is a potential source of confusion. Although "secondary malignancy" has traditionally been used as a synonym for metastases in definitions such as those from the National Cancer Institute, its contemporary use increasingly refers to a new, distinct primary cancer unrelated to any previous cancer diagnosis. This ambiguity in relation to a shift in usage reflects a need for greater clinical precision, as equating metastases with a further primary cancer can lead to diagnostic and therapeutic misunderstandings. Recognizing this evolving distinction helps ensure clearer communication in both clinical and research settings and avoids ambiguity. Therefore, to address this issue, a total of 24 "secondary malignancy" LLTs in the context of "metastasis" PTs were changed to a status of non-current. Below are several examples of LLTs which changed their currency status. See the MedDRA 29.0 Version report for the specific list of terms.

LLT Name	V28.1 Currency Status	V29.0 Currency Status	Linked PT Name
Brain secondaries	Current	Non-current	Metastases to central nervous system
Secondary carcinoma	Current	Non-current	Metastasis
Secondary malignant neoplasm of lung	Current	Non-current	Metastases to lung
Secondary malignant neoplasm of skin	Current	Non-current	Metastases to skin

Table 3-2 Examples of "Secondary malignancy" LLTs

3.4   MedDRA RENAMED TERMS

MedDRA terms in English are renamed to correct spelling, capitalization, spacing, and punctuation. These changes ensure the accuracy of represented concepts. For MedDRA 29.0, a total of 8 term names changed. See the table below for the specific terms changed. These changes are also listed in the Version Report included with the MedDRA download zip file or may be viewed using the MVAT application. The MedDRA code associated with renamed terms remains the same.

Code	V28.1 Term name	V29.0 Term name	Level
10092556	Intraventricular septum leftward shift	Interventricular septum leftward shift	PT
10085549	Parainfluenzae viral bronchitis	Parainfluenza viral bronchitis	PT
10033796	Parainfluenzae viral infections	Parainfluenza viral infections	HLT
10033797	Parainfluenzae viral laryngotracheobronchitis	Parainfluenza viral laryngotracheobronchitis	PT
10061907	Parainfluenzae virus infection	Parainfluenza virus infection	PT
10049650	Parainfluenzae virus infection NOS	Parainfluenza virus infection NOS	LLT
10035727	Pneumonia parainfluenzae viral	Pneumonia parainfluenza viral	PT
10092783	Videothoracosopy	Videothoracoscopy	LLT

Table 3-3 English Renamed Terms

Of note, 6 terms with "Parainfluenzae" in their name were renamed to "Parainfluenza" to update the spelling of these concepts. Existing HLT *Parainfluenzae viral infections* was updated to HLT *Parainfluenza viral infections* as part of this effort. While the rename of HLT *Parainfluenza viral infections* is technically a complex change, due to the nature of the change, the MSSO opted not to include this minor modification in the list of proposed complex changes provided to MedDRA users for MedDRA 29.0.

3.5   NEW MedDRA TRANSLATIONS DEPLOYED AND UNDER DEVELOPMENT

The MSSO continues to work on new MedDRA translations to enable more users to apply MedDRA in their native language and facilitate global communication of MedDRA coded data. The MSSO expects to release Danish after deployment of the MedDRA

29.0 translations on 15 March. With the release of Danish, there will be 28 MedDRA languages available to users.

Danish is part of the 17 European Economic Area (EEA) official languages, approved for translation by the MedDRA Steering 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, Maltese, and Romanian translations are EEA MedDRA translations in development.

Additionally, ICH approved a MedDRA Uzbek translation which has just started development.

These languages will be translated and made available when completed. Please see the multilingual access section (i.e., middle of the page) 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.

3.6   REPLACEMENT OF NONBREAKING SPACES

The MSSO has identified instances of nonbreaking spaces in MedDRA terms within certain supported languages. These have been replaced with standard spaces. A nonbreaking space is a special character that looks like a regular space but prevents words or characters from splitting across lines. It is commonly used in document and webpage formatting and is not visually distinguishable from regular space characters.

Nonbreaking spaces do not affect the use of MedDRA; however, to maintain consistency across all supported translations of MedDRA, they were removed starting with MedDRA Version 29.0. English was not impacted by this update.

Because the difference between nonbreaking and standard spaces is not visible, changes shown in sequence files and version reports for affected translations may appear as if no modification occurred. If you have any questions about this update, please contact the MSSO Helpdesk at mssohelp@meddra.org.

3.7   MedDRA DOWNLOAD API

In October 2025, the MSSO released a new API for MedDRA users to use – the Download API. The Download API provides an additional method to obtain the MedDRA data files such as the LLT, PT, MDHIER files, so they can be more easily uploaded into pharmacovigilance and related systems.

The specific features of the Download API include:

- MedDRA data files are available in all versions and supported languages

- Two formats are provided – JavaScript Object Notation (JSON) and dollar sign '$' delimited ASCII format (the same format as provided in the current Zip file download)
- Three mappings are available via the Download API – SNOMED CT to MedDRA, MedDRA to SNOMED CT, and ICD-10 to MedDRA

The current method of obtaining MedDRA files via Zip files posted on the Download Page of the MedDRA website is unchanged and will continue to be supported.

In addition to the Download API, the MSSO has enhanced the capability of two APIs, the Details and the Type API which provide term detail and hierarchy information. The updates to these two APIs are summarized as follows:

- Details API – updated with an option to include mapping information in term details
- Type API – the Type API has three enhancements:

  - An option to output underlying terms in a "stacked view" to facilitate browsing in multiple languages at the same time
  - The ability to export an SMQ and its underlying PTs
  - A 'research bin' functionality to export a term or underlying terms

The Download API and the updates to the Details and Type API are available in the MSSO's Production API environment and will be available in the GxP-assessed Production environment in the first half of this year.

4. SUMMARY OF CHANGES

4.1 SUMMARY OF IMPACT ON THE TERMINOLOGY

The tables below (Table*s* 4-1 through 4-5) summarize the impact on MedDRA in Version 29.0. For detailed information on the changes to Version 29.0, please see the MedDRA Version Report in MVAT.

File Name	Number of Records in V28.1	Number of Records in V29.0	Change
hlgt.asc	337	337	0
hlgt_hlt.asc	1,757	1,757	0
hlt.asc	1,739	1,739	0
hlt_pt.asc	39,916	40,213	297
llt.asc	90,471	91,082	611
meddra_history_english.asc	141,148	142,087	939
meddra_release.asc	1	1	0
mdhier.asc	42,221	42,530	309
pt.asc	27,163	27,361	198
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	97,480	98,140	660

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.

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

LLT Changes

Level	Currency Status	v28.1	v29.0
LLT	Current Terms	81,143	81,719
LLT	Non-current Terms	9,328	9,363
LLT	Total LLTs[1]	90,471	91,082

Table 4-2 Summary of Impact on LLTs

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

New SMQs

Level	Net Change	v28.1	v29.0
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 29.0. Please see the MedDRA Version Report in MVAT for details.

File Name	Number of Records in Table
hlgt.seq	0
hlgt_hlt.seq	2
hlt.seq	3
hlt_pt.seq	435
llt.seq	887
mdhier.seq	473
pt.seq	287
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]
Blood and lymphatic system disorders	1,303	345	4,766	1,187	87	17
Cardiac disorders	1,665	412	2,770	740	36	10

Summary of Changes

SOC	LLTs (Primary)[1]	PTs (Primary)[1]	LLTs (Primary and Secondary)[2]	PTs (Primary and Secondary)[2]	HLTs[3]	HLGTs[3]
Congenital, familial and genetic disorders	4,824	1,953	4,824	1,953	100	19
Ear and labyrinth disorders	479	106	962	256	17	6
Endocrine disorders	766	215	2,153	653	38	9
Eye disorders	2,827	721	4,376	1,250	63	13
Gastrointestinal disorders	4,360	1,014	8,518	2,030	105	21
General disorders and administration site conditions	2,642	1,045	3,718	1,446	36	7
Hepatobiliary disorders	775	236	1,698	503	19	4
Immune system disorders	618	176	3,385	956	26	4
Infections and infestations	7,989	2,256	8,493	2,399	150	12
Injury, poisoning and procedural complications	7,553	1,466	10,859	2,890	79	9
Investigations	15,675	6,573	15,675	6,573	106	23
Metabolism and nutrition disorders	1,093	317	3,249	942	63	14

Summary of Changes

SOC	LLTs (Primary)[1]	PTs (Primary)[1]	LLTs (Primary and Secondary)[2]	PTs (Primary and Secondary)[2]	HLTs[3]	HLGTs[3]
Musculoskeletal and connective tissue disorders	2,956	554	7,519	1,606	59	11
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	9,308	2,189	10,279	2,573	201	39
Nervous system disorders	4,298	1,181	8,645	2,452	108	20
Pregnancy, puerperium and perinatal conditions	1,744	261	3,194	720	48	8
Product issues	1,038	212	1,088	234	22	2
Psychiatric disorders	2,546	588	3,682	942	77	23
Renal and urinary disorders	1,350	396	2,931	852	32	8
Reproductive system and breast disorders	1,938	563	4,720	1,381	52	16
Respiratory, thoracic and mediastinal disorders	2,025	638	4,878	1,375	49	12
Skin and subcutaneous tissue disorders	2,454	586	6,246	1,654	56	10
Social circumstances	707	306	707	306	20	7

SOC	LLTs (Primary)[1]	PTs (Primary)[1]	LLTs (Primary and Secondary)[2]	PTs (Primary and Secondary)[2]	HLTs[3]	HLGTs[3]
Surgical and medical procedures	6,637	2,693	6,637	2,693	141	19
Vascular disorders	1,512	359	7,800	1,964	68	11
Total	**91,082**	**27,361**				

Table 4-5 MedDRA Term Counts by SOC

[1]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 4-1 and 4-2.

[2]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 4-1 and 4-2.

[3]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   LLT CURRENCY STATUS CHANGES

The following table reflects 35 terms at the LLT level in MedDRA Version 29.0 that had a change in currency status along with the rationale for the changes.

Lowest Level Term	Currency Status Changed to	Rationale
Brucella abortus	Non-current	Brucella abortus only represents the name of the bacterium and therefore this unqualified term was changed to a non-current statis. Note LLT *Brucella abortus infection* is an existing term.
Brucella canis	Non-current	Brucella canis only represents the name of the bacterium and therefore this unqualified term was changed to a non-current statis. New LLT *Brucella canis infection* was added to PT *Brucellosis* in MedDRA 29.0.
Brucella melitensis	Non-current	Brucella melitensis only represents the name of the bacterium and therefore this unqualified term was changed to a non-current status. Note LLT *Brucella melitensis infection* is an existing term.
Brucella suis	Non-current	Brucella suis only represents the name of the bacterium and therefore this unqualified term was changed to a non-current status. Note LLT *Brucella suis infection* is an existing term.
Cough decreased	Non-current	The LLT *Cough decreased* describes a change in symptom severity, reflecting disease improvement in the course of the symptom. MedDRA does not usually include severity or course of disease qualifiers in the MedDRA term name, as these can be captured in other database fields. Therefore, this term was changed to a non-current status.
Influenza (epidemic)	Non-current	LLT *Influenza (epidemic)* was changed to a non-current status because population qualifiers and epidemiology terms are usually not added to MedDRA.
Manufacturing process control procedure media fill issue	Non-current	LLT *Manufacturing process control procedure media fill issue* was made non-current due to its imprecise nature and ambiguity. It was substituted with new LLT *Media fill issue* under new PT *Aseptic process simulation issue*.

Lowest Level Term	Currency Status Changed to	Rationale
Painful letdown	Non-current	To avoid ambiguity of the concept, the status of LLT *Painful letdown* was made non-current. New LLT *Painful milk letdown* was added to PT *Painful lactation* to represent the intended concept.
Pyoderma gangenosum	Non-current	LLT *Pyoderma gangenosum* was made non-current due to its misspelling. The concept is represented by correctly spelled LLT *Pyoderma gangrenosum*.
"Secondary malignancy" LLTs	Non-current	As explained in section 3.2.1, the MSSO changed the status of 24 "secondary malignancy" LLTs in the context of "metastasis" PTs based on a proactivity request to avoid ambiguity. The clinical and scientific use of these concepts shifted from being used as a synonym of metastases to refer to a new, distinct primary cancer in unrelated to any previous cancer diagnosis. Please see the MedDRA 29.0 Version report for the specific list of terms.
Risk of stigmatisation	Non-current	LLT *Risk of stigmatisation* was changed to a non-current status to avoid confusion with new PT *Concern of disease stigma*. Concern of disease stigma refers to the fear or anticipation of social judgment or discrimination due to a medical condition, which can prevent individuals from consistently following prescribed treatments..
Risk of stigmatization	Non-current	The U.S. spelling variant LLT *Risk of stigmatization,* under new PT *Concern of disease stigma,* was changed to a non-current status in line with British spelled LLT *Risk of stigmatisation*. See above justification.

Table 4-6 LLT Currency Changes