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# **What's New MedDRA Version 29.1**

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**September 2026**

**001434**



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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 29.0 and 29.1.

Section 2, Version 29.1 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 29.1, highlights changes in Version 29.1 related to change request submissions, new initiatives, information on Standardised MedDRA Queries (SMQs), and any recent updates to software tools provided by the MSSO.

Section 4, Summary of Changes, contains details on:

- 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](mailto:mssohelp@meddra.org).

## 2. VERSION 29.1 CHANGE REQUESTS

### 2.1 TERMINOLOGY CHANGES

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

MedDRA Version 29.1 is a simple change version which means changes are made only at the PT and LLT level.

Change requests involve both MedDRA updates and SMQ changes. There was a total of 1,065 change requests processed for this version; 753 change requests were approved and implemented, and 300 change requests were not approved. There are, in addition, 12 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 29.0 to Version 29.1 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.

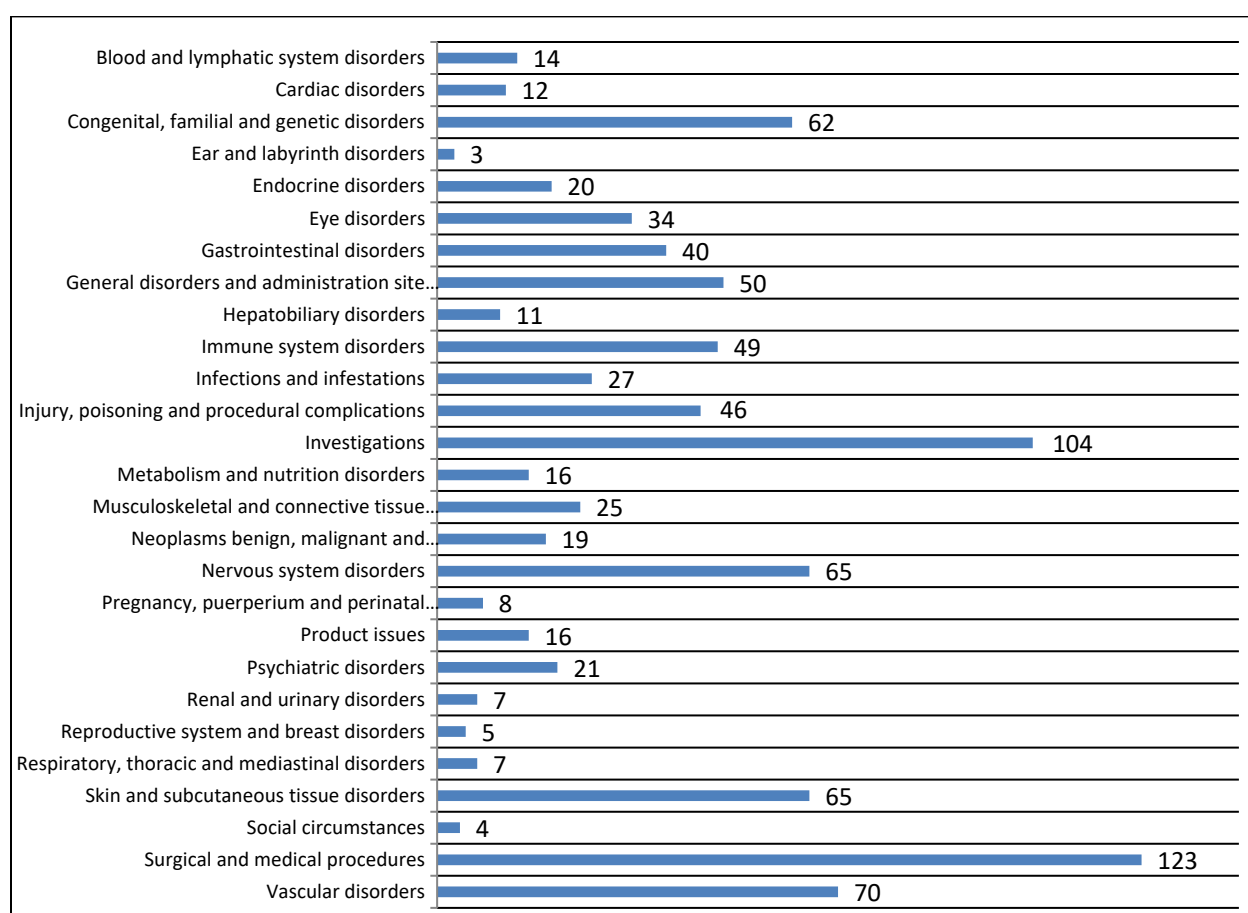
Between MedDRA releases, the MSSO makes available English [weekly supplemental update](#) files, which are approved changes that will be implemented for the next MedDRA version. Additionally, supplemental changes may be viewed in the MedDRA Web-Based Browser or MVAT via the “supplemental view” feature. 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 29.1 is accessible as a cumulative Detail Report included in the MedDRA English version download. Users may review all change requests considered by the MSSO from MedDRA Version 5.1 to the present in [WebCR](#).

Figure 2-1 (shown below) summarizes all changes made per System Organ Class (SOC) and may be useful to 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 29.1 (shown in Table 4-5) and the corresponding information for Version 29.0. Additionally, LLT currency status changes are calculated in Figure 2-1.

Please see Section 4 for a summary of the changes in MedDRA Version 29.1.

## Version 29.1 Change Requests



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

### 3. NEW DEVELOPMENTS IN VERSION 29.1

#### 3.1 STANDARDISED MedDRA QUERIES (SMQs)

No new SMQs have been added for MedDRA Version 29.1. There were 177 approved PT changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA 29.1 Version Report. With the release of MedDRA 29.1, 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

In MedDRA Version 29.0, several LLTs containing descriptive qualifiers such as “wrong” and “incorrect,” as well as certain descriptive LLTs without qualifiers, were moved from “error” PTs to “issue” PTs based upon MedDRA user requests. Following a detailed review by a group of medication error experts from industry and regulatory agencies across ICH regions, these LLT changes were reversed in Version 29.1. The expert group determined that these concepts—including terms with the word “wrong” within the HLT *Medication errors and other product use errors and issues*—are considered errors when reported in pharmacovigilance single case reports. This conclusion was further supported by a data driven understanding of the use of the terms in cases coded to these LLTs.. See below for examples.

| LLT Name                                 | From PT                      | To PT                        |
|------------------------------------------|------------------------------|------------------------------|
| Accidental dose decrease                 | Dosing error                 | Wrong dose                   |
| Drug maladministration                   | Product administration issue | Product administration error |
| Expired drug dispensed                   | Product dispensing issue     | Product dispensing error     |
| Drug not dispensed in original container | Product dispensing issue     | Product dispensing error     |
| Incorrect storage of drug                | Product storage issue        | Product storage error        |
| Drug stored in wrong location            | Product storage issue        | Product storage error        |

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

For the entire list of moved LLTs which occurred in MedDRA 29.1, including the moved LLTs explained above, please see the MedDRA 29.1 Version report or use MVAT.

The MSSO and the ICH M1 Points to Consider Working Group are currently reviewing the whole HLGT *Medication errors and other product use errors and issues* which might result in further changes to medication error/issue terms and possible addition of new or adapted concept descriptions to clarify term interpretation.

### 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 29.1 change request processing period, no proactivity proposals were implemented. The MSSO publishes and updates a list of all proposals received and their status on the [Change Request](#) section of the MedDRA website.

The MSSO is interested in learning about any ideas that users may have about proactive improvements to MedDRA. Please email your ideas for “proactive” MedDRA improvements to the MSSO [Help Desk](#). Be as specific as possible in describing your suggestion(s) and include a justification which explains why you think your proposal should be implemented.

### 3.4 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 two languages before the end of 2026 – Bulgarian and Romanian. With the release of two languages, there will be 29 MedDRA languages available to users.

Bulgarian and Romanian are 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, there are three other translations in development – Danish, Maltese and Uzbek.

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.

## 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 29.1. For detailed information on the changes to Version 29.1, please see the MedDRA Version Report in MVAT.

| File Name                  | Number of Records in V29.0 | Number of Records in V29.1 | Change |
|----------------------------|----------------------------|----------------------------|--------|
| hlgt.asc                   | 337                        | 337                        | 0      |
| hlgt_hlt.asc               | 1,757                      | 1,757                      | 0      |
| hlt.asc                    | 1,739                      | 1,739                      | 0      |
| hlt_pt.asc                 | 40,213                     | 40,455                     | 242    |
| llt.asc                    | 91,082                     | 91,499                     | 417    |
| meddra_history_english.asc | 142,087                    | 142,768                    | 681    |
| meddra_release.asc         | 1                          | 1                          | 0      |
| mdhier.asc                 | 42,530                     | 42,778                     | 248    |
| pt.asc                     | 27,361                     | 27,504                     | 143    |
| 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            | 98,140                     | 98,554                     | 414    |

**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.

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## Summary of Changes

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

### LLT Changes

| Level | Currency Status         | v29.0  | v29.1  |
|-------|-------------------------|--------|--------|
| LLT   | Current Terms           | 81,719 | 82,124 |
| LLT   | Non-current Terms       | 9,363  | 9,375  |
| LLT   | Total LLTs <sup>1</sup> | 91,082 | 91,499 |

**Table 4-2 Summary of Impact on LLTs**

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

### New SMQs

| Level | Net Change | v29.0 | v29.1 |
|-------|------------|-------|-------|
| 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 29.1. 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 | 0                          |
| hlt.seq      | 0                          |
| hlt_pt.seq   | 398                        |
| llt.seq      | 672                        |
| mdhier.seq   | 430                        |
| pt.seq       | 253                        |
| 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) <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>Blood and lymphatic system disorders</i> | 1,308                       | 347                        | 4,776                                     | 1,191                                    | 87                | 17                 |
| <i>Cardiac disorders</i>                    | 1,668                       | 411                        | 2,780                                     | 744                                      | 36                | 10                 |

## Summary of Changes

| <b>SOC</b>                                                              | <b>LLTs<br/>(Primary)<sup>1</sup></b> | <b>PTs<br/>(Primary)<sup>1</sup></b> | <b>LLTs<br/>(Primary and<br/>Secondary)<sup>2</sup></b> | <b>PTs<br/>(Primary and<br/>Secondary)<sup>2</sup></b> | <b>HLTs<sup>3</sup></b> | <b>HLGTs<sup>3</sup></b> |
|-------------------------------------------------------------------------|---------------------------------------|--------------------------------------|---------------------------------------------------------|--------------------------------------------------------|-------------------------|--------------------------|
| <i>Congenital,<br/>familial and<br/>genetic disorders</i>               | 4,866                                 | 1,971                                | 4,866                                                   | 1,971                                                  | 100                     | 19                       |
| <i>Ear and labyrinth<br/>disorders</i>                                  | 482                                   | 106                                  | 965                                                     | 256                                                    | 17                      | 6                        |
| <i>Endocrine<br/>disorders</i>                                          | 774                                   | 218                                  | 2,169                                                   | 660                                                    | 38                      | 9                        |
| <i>Eye disorders</i>                                                    | 2,838                                 | 729                                  | 4,397                                                   | 1,262                                                  | 63                      | 13                       |
| <i>Gastrointestinal<br/>disorders</i>                                   | 4,362                                 | 1,015                                | 8,550                                                   | 2,040                                                  | 105                     | 21                       |
| <i>General disorders<br/>and<br/>administration site<br/>conditions</i> | 2,666                                 | 1,051                                | 3,761                                                   | 1,453                                                  | 36                      | 7                        |
| <i>Hepatobiliary<br/>disorders</i>                                      | 781                                   | 237                                  | 1,707                                                   | 506                                                    | 19                      | 4                        |
| <i>Immune system<br/>disorders</i>                                      | 620                                   | 176                                  | 3,424                                                   | 965                                                    | 26                      | 4                        |
| <i>Infections and<br/>infestations</i>                                  | 8,018                                 | 2,267                                | 8,522                                                   | 2,410                                                  | 150                     | 12                       |
| <i>Injury, poisoning<br/>and procedural<br/>complications</i>           | 7,560                                 | 1,472                                | 10,890                                                  | 2,902                                                  | 79                      | 9                        |
| <i>Investigations</i>                                                   | 15,748                                | 6,600                                | 15,748                                                  | 6,600                                                  | 106                     | 23                       |
| <i>Metabolism and<br/>nutrition disorders</i>                           | 1,096                                 | 318                                  | 3,261                                                   | 946                                                    | 63                      | 14                       |

### Summary of Changes

| <b>SOC</b>                                                                                 | <b>LLTs<br/>(Primary)<sup>1</sup></b> | <b>PTs<br/>(Primary)<sup>1</sup></b> | <b>LLTs<br/>(Primary and<br/>Secondary)<sup>2</sup></b> | <b>PTs<br/>(Primary and<br/>Secondary)<sup>2</sup></b> | <b>HLTs<sup>3</sup></b> | <b>HLGTs<sup>3</sup></b> |
|--------------------------------------------------------------------------------------------|---------------------------------------|--------------------------------------|---------------------------------------------------------|--------------------------------------------------------|-------------------------|--------------------------|
| <i>Musculoskeletal<br/>and connective<br/>tissue disorders</i>                             | 2,976                                 | 558                                  | 7,539                                                   | 1,613                                                  | 59                      | 11                       |
| <i>Neoplasms<br/>benign, malignant<br/>and unspecified<br/>(incl cysts and<br/>polyps)</i> | 9,327                                 | 2,198                                | 10,311                                                  | 2,584                                                  | 201                     | 39                       |
| <i>Nervous system<br/>disorders</i>                                                        | 4,319                                 | 1,189                                | 8,689                                                   | 2,470                                                  | 108                     | 20                       |
| <i>Pregnancy,<br/>puerperium and<br/>perinatal<br/>conditions</i>                          | 1,747                                 | 262                                  | 3,201                                                   | 722                                                    | 48                      | 8                        |
| <i>Product issues</i>                                                                      | 1,038                                 | 212                                  | 1,103                                                   | 236                                                    | 22                      | 2                        |
| <i>Psychiatric<br/>disorders</i>                                                           | 2,553                                 | 590                                  | 3,697                                                   | 947                                                    | 77                      | 23                       |
| <i>Renal and urinary<br/>disorders</i>                                                     | 1,346                                 | 395                                  | 2,936                                                   | 855                                                    | 32                      | 8                        |
| <i>Reproductive<br/>system and<br/>breast disorders</i>                                    | 1,947                                 | 565                                  | 4,728                                                   | 1,382                                                  | 52                      | 16                       |
| <i>Respiratory,<br/>thoracic and<br/>mediastinal<br/>disorders</i>                         | 2,032                                 | 640                                  | 4,894                                                   | 1,381                                                  | 49                      | 12                       |
| <i>Skin and<br/>subcutaneous<br/>tissue disorders</i>                                      | 2,473                                 | 588                                  | 6,295                                                   | 1,672                                                  | 56                      | 10                       |
| <i>Social<br/>circumstances</i>                                                            | 714                                   | 305                                  | 714                                                     | 305                                                    | 20                      | 7                        |

### 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>Surgical and medical procedures</i> | 6,726                       | 2,725                      | 6,726                                     | 2,725                                    | 141               | 19                 |
| <i>Vascular disorders</i>              | 1,514                       | 359                        | 7,853                                     | 1,980                                    | 68                | 11                 |
| <b>Total</b>                           | <b>91,499</b>               | <b>27,504</b>              |                                           |                                          |                   |                    |

**Table 4-5 MedDRA Term Counts by SOC**

<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 4-1 and 4-2.

<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 4-1 and 4-2.

<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 LLT CURRENCY STATUS CHANGES

The following table reflects 13 terms at the LLT level in MedDRA Version 29.1 that had a change in currency status along with the rationale for the changes.

| Lowest Level Term             | Currency Status Changed to | Rationale                                                                                                                                                                                                                                                                                                                                                                                                                    |
|-------------------------------|----------------------------|------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Acetaminophen                 | Non-current                | Acetaminophen is a drug name which is not within the scope of MedDRA. LLT <i>Acetaminophen drug level</i> was added to PT <i>Analgesic drug level</i> as a substitute for LLT <i>Acetaminophen</i> .                                                                                                                                                                                                                         |
| Cervical stricture            | Non-current                | Cervical stricture is an ambiguous term. LLT <i>Cervical stricture</i> does not follow naming conventions based on section 5.1 of the MedDRA introductory guide: The word “cervical” is used to identify the neck location whereas “cervix” is used to identify the uterine location. When a “cervical” term refers to the uterus, it carries the qualifier of “uterine” to differentiate it from cervical spine conditions. |
| Closed capsulotomy            | Non-current                | LLT <i>Closed capsulotomy</i> is an anatomically imprecise and misleading concept. New term LLT <i>Closed breast capsulotomy</i> was added to provide anatomically clarity.                                                                                                                                                                                                                                                  |
| Coloboma of optic disc        | Current                    | LLT <i>Coloboma of optic disc</i> was changed from non-current to current. Optic disc coloboma is a valid concept and represents a congenital structural anomaly of the optic nerve resulting from incomplete closure of the embryonic fissure, with variable functional impact depending on its extent and associated macular involvement.                                                                                  |
| Congenital intrahepatic shunt | Non-current                | LLT <i>Congenital intrahepatic shunt</i> was changed to non-current as it is an imprecise term. New PT <i>Congenital intrahepatic portosystemic shunt</i> was added as a coding option.                                                                                                                                                                                                                                      |
| Encephalitis post measles     | Non-current                | LLT <i>Encephalitis post measles</i> represents a temporal relationship and may represent various forms of measles related encephalitis and is therefore an imprecise diagnosis. Placement under PT <i>Subacute sclerosing panencephalitis</i> , which refers specifically to a very late measles related brain inflammation, was inappropriately narrow.                                                                    |

## Summary of Changes

| Lowest Level Term                                           | Currency Status Changed to | Rationale                                                                                                                                                                                                                                                                                                                                                 |
|-------------------------------------------------------------|----------------------------|-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Fever malignant                                             | Non-current                | Malignant fever is an ambiguous term, as it can refer to different scenarios. For example, in oncology, malignant fever is frequently used to describe neoplastic or cancer-related fever, and it has historically been used in medical literature to refer to dangerous or life-threatening fevers.                                                      |
| Paracetamol                                                 | Non-current                | Paracetamol is a drug name which is not within the scope of MedDRA. LLT <i>Paracetamol drug level</i> was added to PT <i>Analgesic drug level</i> as a substitute for the LLT <i>Paracetamol</i> .                                                                                                                                                        |
| Post measles encephalitis                                   | Non-current                | LLT <i>Post measles encephalitis</i> represents a temporal relationship and may represent various forms of measles related encephalitis and is therefore an imprecise diagnosis. Placement under PT <i>Subacute sclerosing panencephalitis</i> , which refers specifically to a very late measles related brain inflammation, was inappropriately narrow. |
| Salicylate                                                  | Non-current                | Salicylate is a drug name which is not within the scope of MedDRA. LLT <i>Salicylate drug level</i> was added to PT <i>Analgesic drug level</i> as a substitute for the LLT <i>Salicylate</i> .                                                                                                                                                           |
| Spiritual experience                                        | Non-current                | LLT <i>Spiritual experience</i> was changed to a status of non-current as the concept is a broad and ambiguous concept without additional context.                                                                                                                                                                                                        |
| Walking aid support                                         | Non-current                | LLT <i>Walking aid support</i> was made non-current because of ambiguity of the concept. New LLT <i>Therapeutic use of walking aid</i> was added to PT <i>Mobility support</i> to represent the intended concept.                                                                                                                                         |
| Wrong technique in product usage process performed in error | Non-current                | Wrong technique in product usage process performed in error is a pleonasm as it includes both “wrong” and “performed in error” in the term name. To avoid confusion and over granularity the term was made non-current.                                                                                                                                   |

**Table 4-6 LLT Currency Changes**