# What's New
# MedDRA Version 25.0

**ACKNOWLEDGEMENTS**

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## Table of Contents

## 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 24.1 and 25.0.

Section 2, Version 25.0 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 25.0, highlights changes in Version 25.0 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 25.0 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 25.0 is a complex change version which means changes may made at any level of the MedDRA hierarchy.

Change requests involve both MedDRA updates and SMQ changes. There was a total of 1,832 change requests processed for this version; 1,508 change requests were approved and implemented, and 299 change requests were not approved. There are, in addition, 25 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 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 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 25.0 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 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 25.0 (shown in Table 4-5) and the corresponding information for Version 24.1. Additionally, LLT currency status changes are included in Figure 2-1.

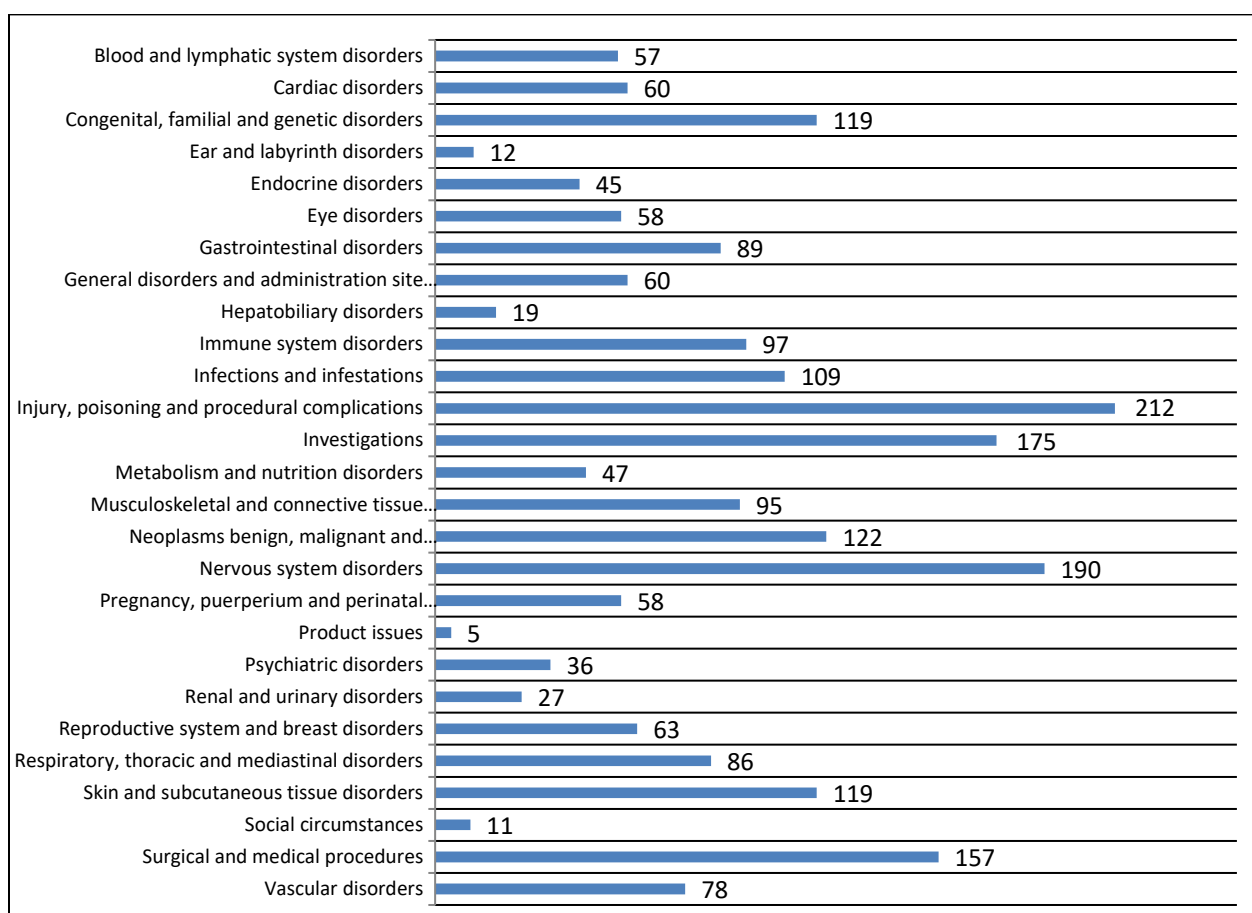Please see Section 4 for a summary of the changes in MedDRA Version 25.0.

Figure 2-1 Net Changes of Terms per SOC

## 2.2 COMPLEX CHANGES

The proposals for complex changes considered during Version 25.0 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 29 July 2021 to 24 September 2021. Complex changes were followed by further internal review and consensus discussions which resulted in the final approved set of 8 complex changes.

The complex changes implemented in Version 25.0 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:** There were two High Level Group Terms (HLGTs) added and two HLGTs merged as a result of complex changes in Version 25.0. The changes are as follows:

| New HLGT | To SOC |
|---|---|
| Cytogenetic investigations and genetic analyses | Investigations |
| Skin and subcutaneous tissue infections and infestations NEC | Skin and subcutaneous tissue disorders |

**Table 2-1  New HLGTs**

**Merged HLGTs**

| HLGT | To HLGT | SOC |
|---|---|---|
| Cytogenetic investigations | Cytogenetic investigations and genetic analyses | Investigations |
| Skin and subcutaneous tissue infections and infestations | Skin and subcutaneous tissue infections and infestations NEC | Skin and subcutaneous tissue disorders |

**Table 2-2  Merged HLGTs**

**At the HLT level:** There were two High Level Terms (HLTs) added and two HLTs merged as a result of complex changes in Version 25.0. The changes are as follows:

**New HLTs**

| New HLT | To SOC |
|---|---|
| Hepatobiliary function diagnostic procedures | Investigations |
| Skin histopathology and skin investigations NEC | Investigations |

**Table 2-3  New HLTs**

**Merged HLTs**

| HLT | To HLT | SOC |
|---|---|---|
| Liver function analyses | Hepatobiliary function diagnostic procedures | Investigations |
| Skin histopathology procedures | Skin histopathology and skin investigations NEC | Investigations |

**Table 2-4  Merged HLTs**

## 3.   NEW DEVELOPMENTS IN VERSION 25.0

### 3.1   ADDITIONAL COVID-19 RELATED TERMS

The MSSO continued to add COVID-19 related terms in MedDRA Version 25.0 based upon MedDRA user requests. A total of 54 new COVID-19 related LLTs/PTs were added including terms related to vaccines which may be applicable in the context of COVID-19. See the table below for several examples:

| LLT | PT | HLT | Primary SOC |
|---|---|---|---|
| SARS-CoV-2 infection post vaccine | Breakthrough COVID-19 | Coronavirus infections | Infections and infestations |
| SARS-CoV-2 Omicron variant infection | COVID-19 | Coronavirus infections | Infections and infestations |
| Vaccine preparation error | Product preparation error | Product preparation errors and issues | Injury, poisoning and procedural complications |
| Vaccination hesitancy | Refusal of vaccination | Social issues NEC | Social circumstances |
| Heterologous prime-boost vaccination | Immunisation | Immunisations | Surgical and medical procedures |

**Table 3-1  COVID-19 Term Examples**

### 3.2   STANDARDISED MedDRA QUERIES (SMQs)

One new SMQs has been added for MedDRA Version 25.0 - SMQ *Noninfectious myocarditis/pericarditis*. The focus of this SMQ is to identify cases of noninfectious myocarditis and/or pericarditis possibly related to exposure to drugs, vaccines, and biologics. It has relevance for cardiac adverse events following immunization (AEFIs) with mRNA COVID-19 vaccines. There are now 110 level 1 SMQs in production as of this version. In addition, there were 309 approved PT changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA Version 25.0 Version Report.

Please see the MedDRA Version 25.0 SMQ Introductory Guide for detailed information on new SMQ *Noninfectious myocarditis/pericarditis.*

## 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 25.0 change request processing period, there were no open or implemented proactivity requests. 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   SNOMED CT – MedDRA MAPPING UPDATE

On 30 April 2021, ICH and SNOMED International announced the first production release of important new maps between SNOMED CT and MedDRA. This collaborative agreement between SNOMED International and ICH has produced two independent maps (MedDRA to SNOMED CT and SNOMED CT to MedDRA) which are intended to facilitate the exchange of data between regulatory databases and healthcare databases/electronic health records.

Licensed users of either MedDRA or SNOMED CT can obtain the maps free of charge from either the MSSO or SNOMED International. Users can also contribute to the ongoing maintenance of the maps by submitting requests for new mappings or changes to existing mappings by using a mapping change request submission tool, MapCR, on the MedDRA website (https://mapcr.meddra.org).

**Figure 3-1 MapCR Change Request Tool**

Since the first production release in April 2021, approximately 250 requests for new term mappings have been received and will be implemented in the next production release in April 2022. A preview set of these supplemental mappings for the upcoming production release is available on the Downloads page of the MedDRA website.



**Figure 3-2 SNOMED CT – MedDRA Package and Supplemental Release**

The April 2022 production release will be based on MedDRA Version 24.1 (September 2021) and the January 2022 release of SNOMED CT International Edition. In addition, the updated release will include relevant COVID-19 terms and changes resulting from version updates of the two terminologies.

## 3.5   NEW MedDRA LANGUAGES UNDER DEVELOPMENT

In 2020, the MedDRA Management Committee (MC) approved additional MedDRA translations for the European Economic Area (EEA) official languages. This includes up to a total of 17 additional European languages 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, Greek, Latvian, Maltese, Polish, and Swedish translations are in development and are expected to be completed in the first half of 2022. The MSSO will begin development of four new European languages in 2022 – Estonian, Finnish, Icelandic, and Norwegian. The remaining languages in the EEA region will be translated and made available between the years of 2023 to 2024. The MSSO will provide estimated release dates for these languages as they become available.

Additionally, in July 2021 the MedDRA Management Committee approved an Arabic MedDRA translation. This translation began development in 2022 and will include all MedDRA user documentation. The MSSO expects to deploy Arabic MedDRA before the end of 2022.

## 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 25.0. For detailed information on the changes to Version 25.0, please see the MedDRA Version Report in MVAT.

| File Name | Number of Records in V24.1 | Number of Records in V25.0 | Change |
|---|---|---|---|
| hlgt.asc | 337 | 337 | 0 |
| hlgt_hlt.asc | 1,755 | 1,755 | 0 |
| hlt.asc | 1,737 | 1,737 | 0 |
| hlt_pt.asc | 36,633 | 37,186 | 553 |
| llt.asc | 84,139 | 85,091 | 952 |
| meddra_history_english.asc* | 132,027 | 133,409 | 1,382 |
| meddra_release.asc* | 1 | 1 | 0 |
| mdhier.asc | 38,767 | 39,352 | 585 |
| pt.asc | 25,077 | 25,412 | 335 |
| soc.asc | 27 | 27 | 0 |
| soc_hlgt.asc | 354 | 354 | 0 |
| intl_ord.asc | 27 | 27 | 0 |
| smq_list.asc | 229 | 230 | 1 |
| smq_content.asc | 90,597 | 92,226 | 1,629 |

**Table 4-1  MedDRA Term File Counts**

MedDRA Version 25.0 is a complex change version which means changes may be made at any level of the MedDRA hierarchy. In this case, there were two additions and two merges of HLGTs and HLTs. See section 2.2 Complex Changes above. As a result, the net number of changes to the HLT and HLGT record counts remain the same as last release.

* The meddra_history_english.asc and meddra_release.asc 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 | v24.1 | v25.0 |
|:---:|:---:|:---:|:---:|
| **LLT** | Current Terms | 74,838 | 75,787 |
| **LLT** | Non-current Terms | 9,301 | 9,304 |
| **LLT** | Total LLTs[1] | 84,139 | 85,091 |

**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 | v24.1 | v25.0 |
|:---:|:---:|:---:|:---:|
| **1** | 1 | 109 | 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 25.0. Please see the MedDRA Version Report in MVAT for details.

| File Name | Number of Records in Table |
|-----------|----------------------------|
| hlgt.seq | 4 |
| hlgt_hlt.seq | 20 |
| hlt.seq | 4 |
| hlt_pt.seq | 985 |
| llt.seq | 1,209 |
| mdhier.seq | 1,749 |
| pt.seq | 421 |
| soc.seq | 0 |
| soc_hlgt.seq | 4 |
| 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* | 1,241 | 318 | 4,543 | 1,113 | 87 | 17 |
| *Cardiac disorders* | 1,553 | 381 | 2,571 | 683 | 36 | 10 |
| *Congenital, familial and genetic disorders* | 4,304 | 1,716 | 4,304 | 1,716 | 100 | 19 |

# Summary of Changes

| SOC | LLTs (Primary)[1] | PTs (Primary)[1] | LLTs (Primary and Secondary)[2] | PTs (Primary and Secondary)[2] | HLTs[3] | HLGTs[3] |
|---|---|---|---|---|---|---|
| *Ear and labyrinth disorders* | 453 | 100 | 914 | 242 | 17 | 6 |
| *Endocrine disorders* | 719 | 202 | 1,971 | 603 | 38 | 9 |
| *Eye disorders* | 2,655 | 669 | 4,076 | 1,146 | 63 | 13 |
| *Gastrointestinal disorders* | 4,105 | 950 | 8,025 | 1,888 | 105 | 21 |
| *General disorders and administration site conditions* | 2,534 | 1,017 | 3,530 | 1,381 | 35 | 7 |
| *Hepatobiliary disorders* | 722 | 221 | 1,582 | 471 | 19 | 4 |
| *Immune system disorders* | 576 | 165 | 3,086 | 871 | 26 | 4 |
| *Infections and infestations* | 7,633 | 2,133 | 8,055 | 2,258 | 150 | 12 |
| *Injury, poisoning and procedural complications* | 7,156 | 1,345 | 10,183 | 2,664 | 78 | 9 |
| *Investigations* | 14,590 | 6,111 | 14,590 | 6,111 | 106 | 23 |
| *Metabolism and nutrition disorders* | 1,032 | 306 | 2,969 | 873 | 63 | 14 |
| *Musculoskeletal and connective tissue disorders* | 2,771 | 518 | 7,090 | 1,482 | 59 | 11 |

**Summary of Changes**

| SOC | LLTs (Primary)[1] | PTs (Primary)[1] | LLTs (Primary and Secondary)[2] | PTs (Primary and Secondary)[2] | HLTs[3] | HLGTs[3] |
|---|---|---|---|---|---|---|
| Neoplasms benign, malignant and unspecified (incl cysts and polyps) | 8,916 | 2,067 | 9,774 | 2,411 | 201 | 39 |
| Nervous system disorders | 3,969 | 1,065 | 7,964 | 2,212 | 108 | 20 |
| Pregnancy, puerperium and perinatal conditions | 1,706 | 248 | 3,068 | 671 | 48 | 8 |
| Product issues | 907 | 179 | 937 | 193 | 21 | 2 |
| Psychiatric disorders | 2,467 | 566 | 3,454 | 864 | 77 | 23 |
| Renal and urinary disorders | 1,292 | 384 | 2,773 | 806 | 32 | 8 |
| Reproductive system and breast disorders | 1,837 | 527 | 4,502 | 1,289 | 52 | 16 |
| Respiratory, thoracic and mediastinal disorders | 1,894 | 591 | 4,612 | 1,285 | 49 | 12 |
| Skin and subcutaneous tissue disorders | 2,293 | 560 | 5,821 | 1,552 | 56 | 10 |
| Social circumstances | 667 | 287 | 667 | 287 | 20 | 7 |
| Surgical and medical procedures | 5,670 | 2,446 | 5,670 | 2,446 | 141 | 19 |

| SOC | LLTs (Primary)[1] | PTs (Primary)[1] | LLTs (Primary and Secondary)[2] | PTs (Primary and Secondary)[2] | HLTs[3] | HLGTs[3] |
|---|---|---|---|---|---|---|
| *Vascular disorders* | 1,429 | 340 | 7,316 | 1,834 | 68 | 11 |
| **Total** | **85,091** | **25,412** | | | | |

**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 three terms at the LLT level in MedDRA Version 25.0 that had a change in currency status along with the rationale for the change.

| Lowest Level Term | Currency Status Changed to | Rationale |
|---|---|---|
| Hypoglossal nerve stimulator | Non-current | LLT *Hypoglossal nerve stimulator* (under PT *Hypoglossal nerve stimulation*) was changed to a status of non-current because the concept represents the name of a device which is out of scope of MedDRA. |
| Infusion related hypotension | Non-current | LLT *Infusion related hypotension* (under PT *Infusion related reaction*) was changed to a status of non-current because the concept represents a combination of infusion related reaction and a systemic event. |

| Lowest Level Term | Currency Status Changed to | Rationale |
|---|---|---|
| Red man | Non-current | Vancomycin infusion reaction, a new PT added in Version 25.0, is now the currently accepted nomenclature for this specific drug reaction and is intended to provide an alternative term for the concept of "Red Man Syndrome" which carries racist connotations and implies a white male reference. |

**Table 4-6  LLT Currency Changes**