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# **What's New MedDRA Version 26.0**

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**000913**

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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 25.1 and 26.0.

Section 2, Version 26.0 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 26.0, highlights changes in Version 26.0 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](mailto:mssohelp@meddra.org).

## **2. VERSION 26.0 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 26.0 is a complex change version which means changes may be made at any level of the MedDRA.

Change requests involve both MedDRA updates and SMQ changes. There was a total of 1,912 change requests processed for this version; 1,585 change requests were approved and implemented, and 317 change requests were not approved. There are, in addition, 10 change request suspended for further consideration and resolution beyond this version.

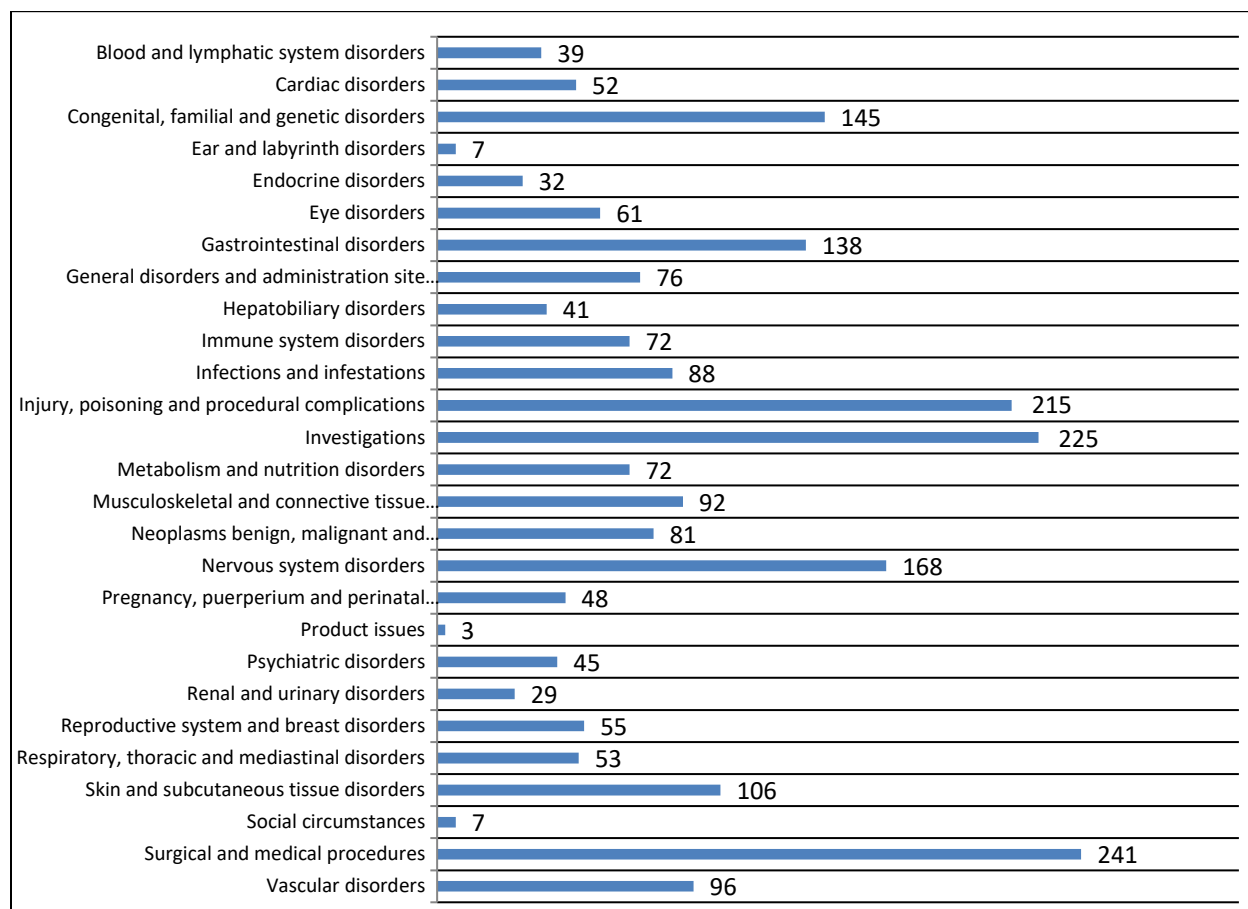
Information on specific changes (e.g., new terms added, LLT promotions, PT demotions, PT primary SOC changes, etc.) which occurred since the prior MedDRA release can be obtained via the Version Report included with each respective MedDRA download. In addition, users may wish to use the [MedDRA Version 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 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 26.0 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 26.0 (shown in Table 4-5) and the corresponding information for Version 25.1. Additionally, LLT currency status changes are included in Figure 2-1.

Please see Section 4 for a summary of the changes in MedDRA Version 26.0.



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

## 2.2 COMPLEX CHANGES

The proposals for complex changes considered during Version 26.0 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 1 August 2022 to 23 September 2022. Complex changes were followed by further internal review and consensus discussions which resulted in the final approved set of 4 complex changes.

The complex changes implemented in Version 26.0 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's.

**At the HLGT level:** No changes were made to existing HLGT's.

**At the HLT level:** There were two High Level Terms (HLTs) added and two HLTs merged as a result of complex changes in Version 26.0.

**The changes are as follows:**

**New HLTs**

New HLT	To SOC
Fertility analyses and other reproductive function procedures	Investigations
Urinary tract lithiasis NEC	Renal and urinary disorders

**Table 2-1 New HLTs**

**Merged HLTs**

HLT	To HLT	SOC
Fertility analyses	Fertility analyses and other reproductive function procedures	Investigations
Urinary tract lithiasis (excl renal)	Urinary tract lithiasis NEC	Renal and urinary disorders

**Table 2-2 Merged HLTs**

### 3. NEW DEVELOPMENTS IN VERSION 26.0

#### 3.1 ADDITIONAL COVID-19 RELATED TERMS

The MSSO continued to add COVID-19 related terms in MedDRA Version 26.0 based upon MedDRA user requests. A total of 8 new COVID-19 related terms 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
COVID-19 breath test	COVID-19 breath test	Virus identification and serology	Investigations
Symptomatic COVID-19	COVID-19	Coronavirus infections	Infections and infestations
Vaccine-vaccine interaction	Vaccine interaction	Interactions	General disorders and administration site conditions

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

#### 3.2 STANDARDISED MedDRA QUERIES (SMQs)

No new SMQs have been added for MedDRA Version 26.0. There were 342 approved PT changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA Version 26.0 Version Report.

#### 3.3 PROACTIVITY REQUESTS

The proactive maintenance process allows MedDRA users to propose general changes to MedDRA outside of the established change request process. These proactivity requests may address inconsistencies, make corrections, or suggest improvements. During the Version 26.0 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 NEW MedDRA LANGUAGES DEPLOYED AND UNDER DEVELOPMENT

The MSSO deployed the Arabic translation of MedDRA in January 2023 upon approval of the MedDRA Management Committee. The Arabic translation of MedDRA includes all MedDRA terms and all user documentation.

Additionally, the MSSO released the Greek and Polish translation of MedDRA in November 2022. Greek and Polish are part of the 17 European Economic Area (EEA) official languages, approved 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, Croatian, Estonian, Finnish, Icelandic, Lithuanian, Maltese, Norwegian, and Slovenian translations are in development. The remaining languages in the EEA region will be translated and made available in 2024. 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.

### 3.5 MedDRA APIs

In the first quarter of 2023, the MSSO deployed a set of Application Program Interfaces (APIs) for use by the MedDRA user community. The MedDRA APIs are an open software model, which accurately depicts MedDRA and provides access to all MedDRA versions and MedDRA translations. Because the MedDRA APIs may be integrated with user developed tools, some of which may be validated versus the MSSO's other software products which are used independently of a user's tool, the MSSO has developed four APIs to Good practice (GxP) standards.

Additionally, the MSSO also operates a separate environment called the "Sandbox" environment that contains additional APIs which are not maintained in a controlled GxP environment. MedDRA users may use the "Sandbox" environment to evaluate the APIs or use them in non-GxP applications.

For specific details on the APIs, including programmer's guides and documentation to support GxP validation, please click "Login for detailed API information" under "related documents" of the [API section](#) of the MedDRA website. A MedDRA user ID and subscription password are required to access API information.

If you have a specific MedDRA API question, please contact our [Help Desk](#) and include the subject of "APIs" in the subject line of the message.

## 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 26.0. For detailed information on the changes to Version 26.0, please see the MedDRA Version Report in MVAT.

File Name	Number of Records in V25.1	Number of Records in V26.0	Change
hlgt.asc	337	337	0
hlgt_hlt.asc	1,755	1,755	0
hlt.asc	1,737	1,737	0
hlt_pt.asc	37,468	37,984	516
llt.asc	85,668	86,714	1,046
meddra_history_english.asc*	134,220	135,727	1,507
meddra_release.asc*	1	1	0
mdhier.asc	39,647	40,187	540
pt.asc	25,592	25,916	324
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	92,825	93,785	960

**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	v25.1	v26.0
LLT	Current Terms	76,364	77,408
LLT	Non-current Terms	9,304	9,306
LLT	Total LLTs <sup>1</sup>	85,668	86,714

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

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

In MedDRA Version 26.0 the number of non-current LLTs is two more than the previous version of MedDRA. This was due to two changes. An existing term, LLT *Urine candida* was changed to a status of non-current. See section 4.4 of this document for an explanation of this change. The second change was following the addition of new term LLT *Retrograde nephroureteral stent*. Upon review, it was determined LLT *Retrograde nephroureteral stent* did not properly capture the procedural aspect of the concept. To clarify the nature of the concept, a new term LLT *Retrograde nephroureteral stent placement* was added under PT *Ureteral stent insertion*. As a result, LLT *Retrograde nephroureteral stent* was changed to a status of non-current. Since LLT *Retrograde nephroureteral stent* was added as a non-current LLT in MedDRA Version 26.0, it will not be listed in the Version Report or MVAT as a currency change.

### New SMQs

Level	Net Change	v25.1	v26.0
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 26.0. Please see the MedDRA Version Report in MVAT for details.

File Name	Number of Records in Table
hlgt.seq	0
hlgt_hlt.seq	4
hlt.seq	4
hlt_pt.seq	880
llt.seq	1,273
mdhier.seq	942
pt.seq	461
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.

## Summary of Changes

<b>SOC</b>	<b>LLTs (Primary)<sup>1</sup></b>	<b>PTs (Primary)<sup>1</sup></b>	<b>LLTs (Primary and Secondary)<sup>2</sup></b>	<b>PTs (Primary and Secondary)<sup>2</sup></b>	<b>HLTs<sup>3</sup></b>	<b>HLGTs<sup>3</sup></b>
<i>Blood and lymphatic system disorders</i>	1,256	328	4,593	1,132	87	17
<i>Cardiac disorders</i>	1,591	388	2,631	697	36	10
<i>Congenital, familial and genetic disorders</i>	4,440	1,775	4,440	1,775	100	19
<i>Ear and labyrinth disorders</i>	458	103	926	246	17	6
<i>Endocrine disorders</i>	729	204	2,013	614	38	9
<i>Eye disorders</i>	2,699	680	4,141	1,168	63	13
<i>Gastrointestinal disorders</i>	4,209	976	8,180	1,926	105	21
<i>General disorders and administration site conditions</i>	2,569	1,026	3,607	1,411	35	7
<i>Hepatobiliary disorders</i>	738	226	1,623	481	19	4
<i>Immune system disorders</i>	596	170	3,169	901	26	4
<i>Infections and infestations</i>	7,736	2,165	8,162	2,292	150	12
<i>Injury, poisoning and procedural complications</i>	7,265	1,388	10,401	2,741	78	9

## Summary of Changes

<b>SOC</b>	<b>LLTs (Primary)<sup>1</sup></b>	<b>PTs (Primary)<sup>1</sup></b>	<b>LLTs (Primary and Secondary)<sup>2</sup></b>	<b>PTs (Primary and Secondary)<sup>2</sup></b>	<b>HLTs<sup>3</sup></b>	<b>HLGTs<sup>3</sup></b>
<i>Investigations</i>	14,869	6,219	14,869	6,219	106	23
<i>Metabolism and nutrition disorders</i>	1,048	309	3,074	895	63	14
<i>Musculoskeletal and connective tissue disorders</i>	2,818	524	7,198	1,516	59	11
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	8,993	2,087	9,882	2,441	201	39
<i>Nervous system disorders</i>	4,057	1,106	8,143	2,281	108	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1,722	252	3,118	687	48	8
<i>Product issues</i>	915	180	945	194	21	2
<i>Psychiatric disorders</i>	2,484	568	3,509	876	77	23
<i>Renal and urinary disorders</i>	1,305	386	2,809	815	32	8
<i>Reproductive system and breast disorders</i>	1,874	540	4,576	1,315	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1,922	596	4,679	1,300	49	12

### 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>Skin and subcutaneous tissue disorders</i>	2,361	574	5,985	1,597	56	10
<i>Social circumstances</i>	677	289	677	289	20	7
<i>Surgical and medical procedures</i>	5,940	2,516	5,940	2,516	141	19
<i>Vascular disorders</i>	1,443	341	7,458	1,862	68	11
<b>Total</b>	<b>86,714</b>	<b>25,916</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 one term at the LLT level in MedDRA Version 26.0 that had a change in currency status along with the rationale for the change.

Lowest Level Term	Currency Status Changed to	Rationale
Urine candida	Non-current	The expression "Urine candida" is ambiguous as it can refer to an Investigation or Positive Test result. The existing LLT <i>Candiduria</i> may be considered for coding purposes.

Table 4-6 LLT Currency Changes

Note: Since the term LLT *Retrograde nephroureteral stent* was added as a non-current LLT in MedDRA 26.0, it will not be listed in the Version report or MVAT as a currency change. See section 4.1 of this document for the explanation of this change.