



What's New MedDRA Version 23.1

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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 23.0 and 23.1.

Section 2, Version 23.1 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 23.1, highlights changes in Version 23.1 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
- Modified Lowest Level Terms (LLT) and Preferred Term (PT) names
- 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 International AT&T Toll Free at 1-877-258-8280 or mssohelp@meddra.org.

2. VERSION 23.1 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 23.1 is a simple change version which means that changes are made at the PT and LLT level only.

Change requests involve both MedDRA updates and SMQ changes. There was a total of 1,541 change requests processed for this version; 1,182 change requests were approved and implemented, and 351 change requests were not approved. There are, in addition, 8 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 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 [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 23.1 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 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 23.1 (shown in Table 4-6) and the corresponding information for Version 23.0. Additionally, term name changes and LLT currency status changes are included in Figure 2-1.

Please see Section 4 for a summary of the changes in MedDRA Version 23.1.

Version 23.1 Change Requests

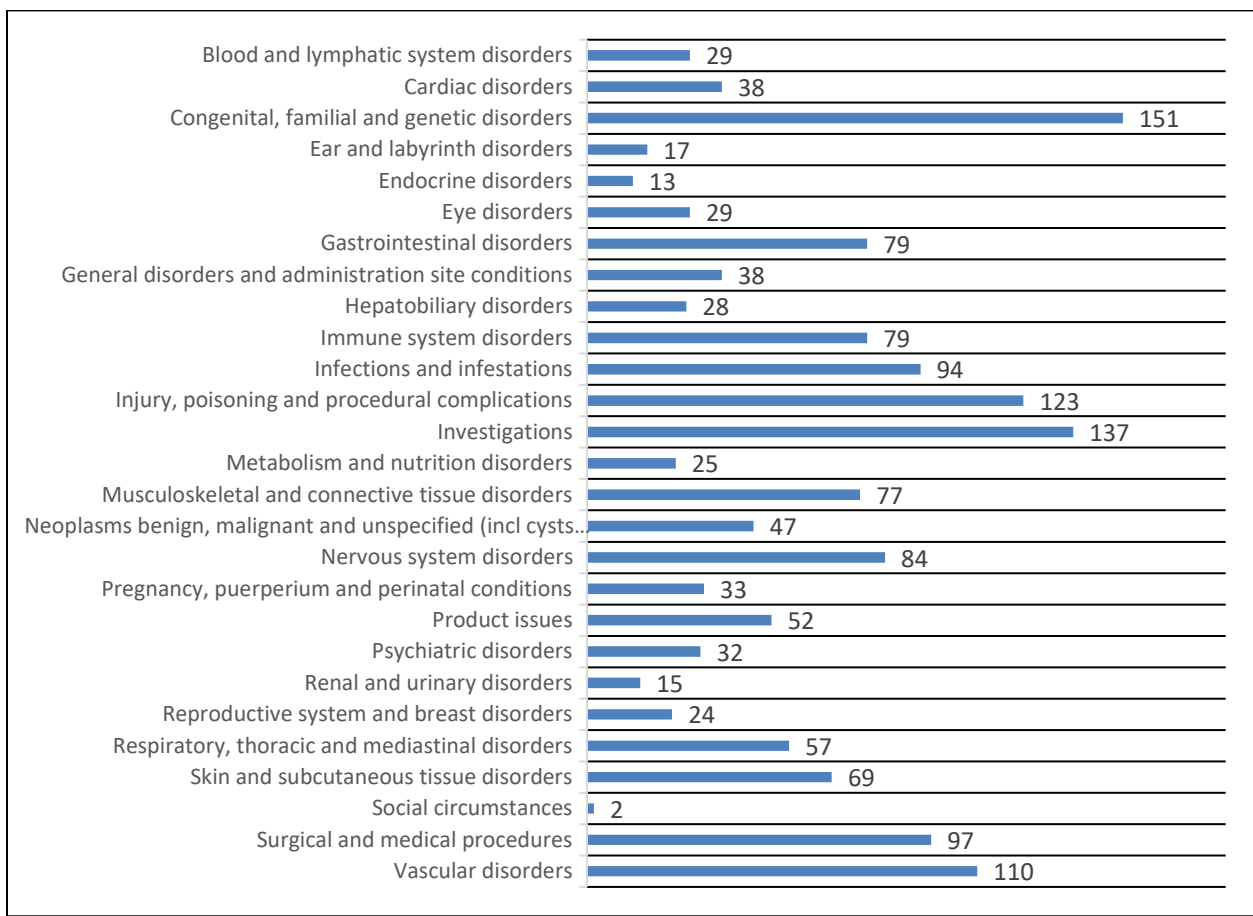


Figure 2-1 Net Changes of Terms per SOC

3. NEW DEVELOPMENTS IN VERSION 23.1

3.1 NEW COVID-19 TERMS AND CHANGES

In April 2020, the MSSO re-released MedDRA Version 23.0 to include COVID-19 related terms and revisions. The MSSO continued to add new COVID-19 related terms in MedDRA Version 23.1 based upon MedDRA user requests. Over 50 new COVID-19 related LLTs/PTs were added. See the table below for several examples:

LLT	PT	HLT	Primary SOC
COVID-19 aggravated	COVID-19	Coronavirus infections	Infections and infestations
Multisystem inflammatory syndrome in children	Multisystem inflammatory syndrome in children	Immune and associated conditions NEC	Immune system disorders
SARS-CoV-2 sepsis	SARS-CoV-2 sepsis	Coronavirus infections	Infections and infestations
SARS-CoV-2 molecular test positive	SARS-CoV-2 test positive	Virus identification and serology	Investigations
SARS-CoV-2 IgG antibody test	SARS-CoV-2 antibody test	Virus identification and serology	Investigations
Drug shortage due to pandemic	Product availability issue	Product supply and availability issues	Product issues

Table 3-1 New COVID-19 Related Term Examples

Additionally, LLT *SARS-CoV-2 antibody test*, LLT *SARS-CoV-2 antibody test negative* and *SARS-CoV-2 antibody test positive* were promoted to the PT level and appropriate “antibody test” terms were moved under these PTs. These changes allow the distinction to be made at the PT level between viral (diagnostic) tests for active infection (e.g., SARS CoV-2 test) and antibody (serology) tests for previous infection (e.g., SARS-CoV-2 antibody test).

3.2 STANDARDISED MedDRA QUERIES (SMQs)

Two new SMQs have been added for MedDRA Version 23.1 - SMQ *Immune-mediated/autoimmune disorders* and SMQ *COVID-19*. There are now 108 level 1 SMQs in production as of this version. In addition, there were 296 approved PT changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA Version 23.1 Version Report.

Please see the MedDRA Version 23.1 SMQ Introductory Guide for detailed information on new SMQ *Immune-mediated/autoimmune disorders* and SMQ *COVID-19*.

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 23.1 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 MedDRA APPLICATION PROGRAM INTERFACES

In October of 2020, the MSSO expects to deploy a set of MedDRA application program interfaces (APIs) that may be used by subscribing organizations. The MedDRA APIs were developed in response to user requests and provide similar features as the Web-Based Browser and MedDRA Version Analysis Tool. These features include browsing and searching for MedDRA terms and SMQs, term detail information, term history, hierarchy and SMQ analysis and data impact and version report information.

The MedDRA APIs are an open software model which allow users more flexibility in developing their own MedDRA tools or extending existing tools. The APIs accurately depict MedDRA and deliver access to all MedDRA versions and MedDRA translations.

Presently the MedDRA APIs are in a user evaluation period until October 2020. For further information, including detailed documentation on the APIs, please go to the [API section](#) of the MedDRA website.

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 23.1. These tables are intended only as a reference. For detailed information on the changes to Version 23.1, please see the MedDRA Version Report included within the MedDRA download or in MVAT. Note that the Version 23.0 numbers below are inclusive of the 83 COVID-19 new terms and changes deployed in April of 2020.

SOC, HLGT, HLT Changes

Level	Change Request Action	Net Change	v23.0	v23.1
SOC	Total SOCs	0	27	27
HLGT	New HLGTs	0	1	0
	Merged HLGTs	0	1	0
	Total HLGTs ¹	0	337	337
HLT	New HLTs	0	4	0
	Merged HLTs	0	3	0
	Total HLTs ¹	0	1,738	1,738

Table 4-1 Summary of Impact on SOCs, HLGTs, HLTs

MedDRA v23.1 is a simple change version which means changes are only made at the PT and LLT levels of the MedDRA hierarchy; hence there are no changes in the number of HLTs and HLGTs.

¹ Total net change of HLGTs or HLTs equals the number of new HLGTs or HLTs minus the number of respective merged HLGTs or HLTs.

Summary of Changes

PT Changes

Level	Change Request Action	v23.0	v23.1
PT	New PTs	370	274
	Promoted LLTs	47	15
	Demoted PTs	58	31
	Net Change ¹	359	258
	Total PTs	24,313	24,571

Table 4-2 Summary of Impact on PTs

¹Net change of PTs equals the number of new PTs plus the number of promoted LLTs minus the number of demoted PTs.

LLT Changes

Level	Currency Status	Net Change	v23.0	v23.1
LLT	Current Terms	697	72,587	73,284
LLT	Non-current Terms	1	9,298	9,299
LLT	Total LLTs ¹	698	81,885	82,583

Table 4-3 Summary of Impact on LLTs

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

New SMQs

Level	Net Change	v23.0	v23.1
1	2	106	108
2	0	82	82
3	0	20	20

Summary of Changes

Level	Net Change	v23.0	v23.1
4	0	16	16
5	0	2	2

Table 4-4 Summary of Impact on SMQs

4.2 SUMMARY OF IMPACT ON RECORDS IN MedDRA FILES

The table below summarizes the impact on MedDRA in Version 23.1. The table is intended only as a reference.

INTL_ORD.ASC	Added	0
	Removed	0
	Modified	0
SOC.ASC	Added	0
	Removed	0
	Modified	0
SOC_HLGT.ASC	Added	0
	Removed	0
	Modified	0
HLGT.ASC	Added	0
	Removed	0
	Modified	0
HLGT_HLT.ASC	Added	0
	Removed	0
	Modified	0
HLT.ASC	Added	0
	Removed	0
	Modified	0
HLT_PT.ASC	Added	474
	Removed	59
	Modified	0
MDHIER.ASC	Added	508
	Removed	71
	Modified	0

Summary of Changes

PT.ASC	Added	289
	Removed	31
	Modified	4
LLT.ASC	Added	698
	Removed	0
	Modified	191
SMQ_LIST.ASC¹	Added ¹	2
	Removed	0
	Modified	226
SMQ_CONTENT.ASC	Added	3,027
	Removed	0
	Modified	136

Table 4-5 Summary of Impact on Records in MedDRA Files

¹ The number of SMQs added includes both top level (Level 1) and sub-search SMQs.

4.3 MedDRA TERM COUNTS

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	HLT³	HLGT³
<i>Blood and lymphatic system disorders</i>	1,197	303	4,431	1,061	88	17
<i>Cardiac disorders</i>	1,508	368	2,486	656	36	10
<i>Congenital, familial and genetic disorders</i>	4,136	1,647	4,136	1,647	100	19
<i>Ear and labyrinth disorders</i>	445	95	885	230	17	6

Summary of Changes

SOC	LLTs (Primary) ¹	PTs (Primary) ¹	LLTs (Primary and Secondary) ²	PTs (Primary and Secondary) ²	HLTs ³	HLGTs ³
<i>Endocrine disorders</i>	692	195	1,898	578	38	9
<i>Eye disorders</i>	2,549	645	3,950	1,103	63	13
<i>Gastrointestinal disorders</i>	4,008	919	7,830	1,817	105	21
<i>General disorders and administration site conditions</i>	2,473	1,000	3,420	1,348	35	7
<i>Hepatobiliary disorders</i>	699	216	1,547	461	19	4
<i>Immune system disorders</i>	537	154	2,891	809	26	4
<i>Infections and infestations</i>	7,443	2,056	7,844	2,173	150	12
<i>Injury, poisoning and procedural complications</i>	6,978	1,294	9,823	2,548	78	9
<i>Investigations</i>	14,249	5,950	14,249	5,950	106	23
<i>Metabolism and nutrition disorders</i>	998	297	2,861	835	63	14
<i>Musculoskeletal and connective tissue disorders</i>	2,684	492	6,905	1,427	59	11
<i>Neoplasms benign, malignant and unspecified</i>	8,756	2,007	9,573	2,336	202	39

Summary of Changes

SOC	LLTs (Primary)¹	PTs (Primary)¹	LLTs (Primary and Secondary)²	PTs (Primary and Secondary)²	HLTs³	HLGTs³
<i>(incl cysts and polyps)</i>						
<i>Nervous system disorders</i>	3,824	1,021	7,662	2,124	108	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1,676	239	3,001	648	48	8
<i>Product issues</i>	864	173	883	182	21	2
<i>Psychiatric disorders</i>	2,406	551	3,368	844	77	23
<i>Renal and urinary disorders</i>	1,267	374	2,711	785	32	8
<i>Reproductive system and breast disorders</i>	1,811	512	4,414	1,243	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1,818	569	4,446	1,225	49	12
<i>Skin and subcutaneous tissue disorders</i>	2,211	536	5,638	1,494	56	10
<i>Social circumstances</i>	650	280	650	280	20	7
<i>Surgical and medical procedures</i>	5,299	2,347	5,299	2,347	141	19
<i>Vascular disorders</i>	1,405	331	7,112	1,768	68	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
Total	82,583	24,571				

Table 4-6 MedDRA Term Counts

¹Primary count only includes the number of terms that are primarily linked to the designated SOC at either the LLT level or the PT level. The sums of primary LLTs and PTs match those in Tables 4-2 and 4-3.

²Total count includes the number of terms that are both primarily and secondarily linked to the designated SOC at either the LLT level or the PT level. Therefore, the sums of total LLTs and PTs are greater than those in Tables 4-2 and 4-3.

³The HLT and HLGT counts are not necessarily unique values given MedDRA's multi-axiality (see Section 2.2 of the Introductory Guide for a discussion of multi-axiality). There are some HLTs that are counted in more than one SOC. For example, HLT *Connective tissue disorders congenital* and HLGT *Musculoskeletal and connective tissue disorders congenital* are counted in both SOC *Congenital, familial and genetic disorders* and SOC *Musculoskeletal and connective tissue disorders*. The sums of HLTs and HLGTs are greater than those found in Table 4-1.

4.4 MODIFIED PT AND LLT NAMES

As part of ongoing MedDRA maintenance activities, existing PTs and LLTs can be modified (renamed) to correct for misspelling, double spacing, capitalization, or other errors that meet the renaming criteria in MedDRA. This rename provision retains the original MedDRA code of the term and preserves its original meaning.

The table below summarizes terms modified in English MedDRA Version 23.1.

Code	Level	Term Name in v23.0	Term Name in v23.1
10081385	PT	Hepatobilliary disorder prophylaxis	Hepatobiliary disorder prophylaxis

Table 4-7 Modified PT/LLT Names

4.5 LLT CURRENCY STATUS CHANGES

The following table reflects one term at the LLT level in MedDRA Version 23.1 that had a change in currency status along with the rationale for the change.

Lowest Level Term	Currency Status Changed to	Rationale
Platelet aggregation	Non-current	PT <i>Platelet aggregation</i> was demoted under new PT <i>Platelet aggregation test</i> and its status was changed to non-current. The concept is ambiguous as it could convey a test or an abnormality.

Table 4-8 LLT Currency Changes