What's New
MedDRA Version 24.0

ACKNOWLEDGEMENTS

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TABLE OF CONTENTS

LIST OF FIGURES

LIST OF TABLES

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 23.1 and 24.0.

Section 2, Version 24.0 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 24.0, highlights changes in Version 24.0 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

- 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 24.0 CHANGE REQUESTS

2.1 TEMINOLOGY 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 24.0 is a complex change version which means that changes may be made above PT level.

Change requests involve both MedDRA updates and SMQ changes. There was a total of 1,446 change requests processed for this version; 1,165 change requests were approved and implemented, and 274 change requests were not approved. There are, in addition, 7 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 identical 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 24.0 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 24.0 (shown in Table 4-6) and the corresponding information for Version 23.1. 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 24.0.
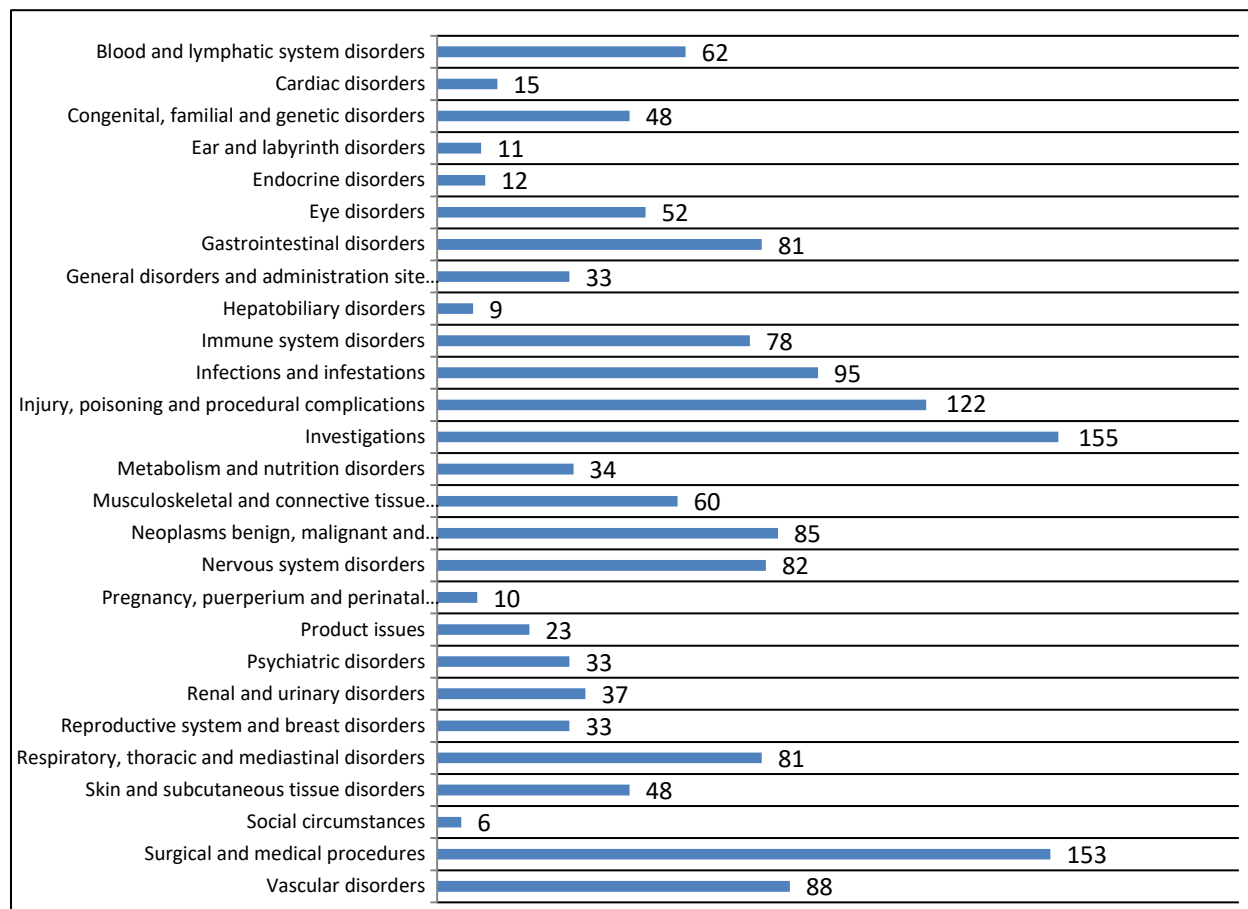
Figure 2-1 Net Changes of Terms per SOC

SOC	Net Changes
Blood and lymphatic system disorders	62
Cardiac disorders	15
Congenital, familial and genetic disorders	48
Ear and labyrinth disorders	11
Endocrine disorders	12
Eye disorders	52
Gastrointestinal disorders	81
General disorders and administration site…	33
Hepatobiliary disorders	9
Immune system disorders	78
Infections and infestations	95
Injury, poisoning and procedural complications	122
Investigations	155
Metabolism and nutrition disorders	34
Musculoskeletal and connective tissue…	60
Neoplasms benign, malignant and…	85
Nervous system disorders	82
Pregnancy, puerperium and perinatal…	10
Product issues	23
Psychiatric disorders	33
Renal and urinary disorders	37
Reproductive system and breast disorders	33
Respiratory, thoracic and mediastinal disorders	81
Skin and subcutaneous tissue disorders	48
Social circumstances	6
Surgical and medical procedures	153
Vascular disorders	88

2.2   COMPLEX CHANGES

The proposals for complex changes considered during Version 24.0 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 31 July 2020 to 25 September 2020. Complex changes were followed by further internal review and consensus discussions which resulted in the final approved set of 7 complex changes.

The complex changes implemented in Version 24.0 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 were three High Level Terms (HLTs) added and four merged as a result of complex changes in Version 24.0. The changes are as follows:

New HLTs

New HLT	To SOC
Auditory and vestibular diagnostic procedures	Investigations
Follicular lymphomas	Multi-axial to Blood and lymphatic system disorders and Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Hepatitis virus infections	Infections and infestations

Table 2-1 New HLTs

Merged HLTs

HLT	To HLT	SOC
Auditory function diagnostic procedures	Auditory and vestibular diagnostic procedures	Investigations
Follicle centre lymphomas diffuse predominantly small cell	Follicular lymphomas	Multi-axial to Blood and lymphatic system disorders and Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Follicle centre lymphomas, follicular grade I, II, III	Follicular lymphomas	Multi-axial to Blood and lymphatic system disorders and Neoplasms benign, malignant and unspecified (incl cysts and polyps)
Hepatitis viral infections	Hepatitis virus infections	Infections and infestations

Table 2-2 Merged HLTs

3.   NEW DEVELOPMENTS IN VERSION 24.0

3.1   NEW COVID-19 TERMS AND REVIEW OF VACCINE RELATED TERMS

The MSSO continued to add new COVID-19 terms to MedDRA Version 24.0 based on users' requests. A spreadsheet of COVID-19 terms added to MedDRA can be found on the COVID-19 section of the MedDRA website. See the table below for several examples:

LLT	PT	HLT	Primary SOC
Congenital SARS-CoV-2 infection	Congenital COVID-19	Viral infections congenital	Congenital, familial and genetic disorders
Laboratory confirmed SARS-CoV-2 infection without symptoms	Asymptomatic COVID-19	Coronavirus infections	Infections and infestations
Long COVID	Post-acute COVID-19 syndrome	Coronavirus infections	Infections and infestations
COVID-19 screening	COVID-19 screening	Virus identification and serology	Investigations

Table 3-1 New COVID-19 Term Examples

With the rollout of SARS-CoV-2 vaccines, there is a global focus on monitoring the effectiveness and safety of these vaccines. In anticipation of this, the MSSO proactively reviewed the vaccine-related terms in MedDRA and solicited feedback from an international group of regulatory and industry users on the MSSO's proposals for new terms for Version 24.0, as well as any other potential terms for additions. As a result of this review, 15 new terms and changes were implemented in Version 24.0. See the table below for several examples which include certain Adverse Events Following Immunisation (AEFI) relevant for SARS-CoV-2 vaccines:

PT	HLT	Primary SOC
Vaccine associated enhanced disease	Immune and associated conditions NEC	Immune system disorders
Vaccine derived SARS-CoV-2 infection	Coronavirus infections	Infections and infestations

PT	HLT	Primary SOC
SARS-CoV-2 RNA increased	Virus identification and serology	Investigations
Acute aseptic arthritis	Arthropathies NEC	Musculoskeletal and connective tissue disorders
Bell's palsy (promoted from PT *Facial paralysis*)	Facial cranial nerve disorders	Nervous system disorders

Table 3-2 Vaccine Related Term Examples

3.2 STANDARDISED MedDRA QUERIES (SMQs)

No new SMQs were added for MedDRA Version 24.0. There were 302 approved PT changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA Version 24.0 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 24.0 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 MedDRA APPLICATION PROGRAM INTERFACES IN BETA RELEASE

As of January 2021, the MedDRA Application Program Interfaces (APIs) are now available to MedDRA users in a Beta release phase. The MSSO will begin work on extending and formalizing API information to align with "Good practice" (GxP) quality guidelines and regulations. Once this work is complete and the necessary information is available to users, the APIs will be in production.

In the meantime, MedDRA users are welcome to continue to review and make plans for using the MedDRA APIs. The APIs are deployed onto a high availability cloud environment and no planned future modifications to API inputs or outputs will be made from this point forward to disrupt MedDRA user review and evaluation.

The MedDRA APIs provide similar features and functions to the Web-Based Browser and the MedDRA Version Analysis tool. For specific details on the APIs, please see "related documents" section of API page on the MedDRA website. Included on the API page are a programmer's guide, input examples and answers to frequently asked questions.

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 24.0. These tables are intended only as a reference. For detailed information on the changes to Version 24.0, please see the MedDRA Version Report included within the MedDRA download or in MVAT.

SOC, HLGT, HLT Changes

Level	Change Request Action	Net Change	v23.1	v24.0
SOC	Total SOCs	0	27	27
HLGT	New HLGTs	0	0	0
	Merged HLGTs	0	0	0
	Total HLGTs[1]	0	337	337
HLT	New HLTs	3	0	3
	Merged HLTs	4	0	4
	Total HLTs[1]	-1	1,738	1,737

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

[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.

PT Changes

Level	Change Request Action	v23.1	v24.0
PT	New PTs	274	262
	Promoted LLTs	15	23
	Demoted PTs	31	36
	Net Change[1]	258	249
	Total PTs	24,571	24,820

Table 4-2 Summary of Impact on PTs

[1]Net 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	v23.1	v24.0
LLT	Current Terms	707	73,284	73,991
LLT	Non-current Terms	1	9,299	9,300
LLT	Total LLTs[1]	708	82,583	83,291

Table 4-3 Summary of Impact on LLTs

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

New SMQs

Level	Net Change	v23.1	v24.0
1	0	108	108
2	0	82	82
3	0	20	20

Level	Net Change	v23.1	v24.0
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 24.0. 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	3
	Removed	4
	Modified	0
HLT.ASC	Added	3
	Removed	4
	Modified	0
HLT_PT.ASC	Added	538
	Removed	153
	Modified	0
MDHIER.ASC	Added	586
	Removed	183
	Modified	0

PT.ASC	Added	285
	Removed	36
	Modified	9
LLT.ASC	Added	708
	Removed	0
	Modified	175
SMQ_LIST.ASC[1]	Added[1]	0
	Removed	0
	Modified	228
SMQ_CONTENT.ASC	Added	874
	Removed	0
	Modified	222

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]	HLTs[3]	HLGTs[3]
Blood and lymphatic system disorders	1,211	309	4,468	1,087	87	17
Cardiac disorders	1,510	367	2,499	658	36	10
Congenital, familial and genetic disorders	4,173	1,658	4,173	1,658	100	19
Ear and labyrinth disorders	447	96	893	233	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]
Endocrine disorders	698	198	1,907	581	38	9
Eye disorders	2,595	655	3,985	1,120	63	13
Gastrointestinal disorders	4,045	931	7,889	1,839	105	21
General disorders and administration site conditions	2,495	1,008	3,447	1,354	35	7
Hepatobiliary disorders	704	217	1,556	461	19	4
Immune system disorders	544	157	2,950	828	26	4
Infections and infestations	7,512	2,079	7,915	2,197	150	12
Injury, poisoning and procedural complications	7,023	1,302	9,921	2,572	78	9
Investigations	14,352	6,002	14,352	6,002	106	23
Metabolism and nutrition disorders	1,006	295	2,892	838	63	14
Musculoskeletal and connective tissue disorders	2,703	497	6,951	1,441	59	11
Neoplasms benign, malignant and unspecified	8,796	2,032	9,627	2,368	201	39

SOC	LLTs (Primary)[1]	PTs (Primary)[1]	LLTs (Primary and Secondary)[2]	PTs (Primary and Secondary)[2]	HLTs[3]	HLGTs[3]
(incl cysts and polyps)						
Nervous system disorders	3,839	1,032	7,728	2,140	108	20
Pregnancy, puerperium and perinatal conditions	1,678	239	3,008	651	48	8
Product issues	870	173	901	187	21	2
Psychiatric disorders	2,434	560	3,394	851	77	23
Renal and urinary disorders	1,281	379	2,738	795	32	8
Reproductive system and breast disorders	1,819	515	4,436	1,254	52	16
Respiratory, thoracic and mediastinal disorders	1,846	577	4,506	1,246	49	12
Skin and subcutaneous tissue disorders	2,229	540	5,674	1,506	56	10
Social circumstances	656	280	656	280	20	7
Surgical and medical procedures	5,412	2,389	5,412	2,389	141	19
Vascular disorders	1,413	333	7,182	1,786	68	11

SOC	LLTs (Primary)[1]	PTs (Primary)[1]	LLTs (Primary and Secondary)[2]	PTs (Primary and Secondary)[2]	HLTs[3]	HLGTs[3]
Total	83,291	24,820				

Table 4-6 MedDRA Term Counts

[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 4-2 and 4-3.

[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 4-2 and 4-3.

[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   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. There were no term name changes made for English MedDRA Version 24.0.

4.5   LLT CURRENCY STATUS CHANGES

The following table reflects one term at the LLT level in MedDRA Version 24.0 that had a change in currency status along with the rationale for the change.

Lowest Level Term	Currency Status Changed to	Rationale
Platelet aggregation NOS	Non-current	PT *Platelet aggregation* was demoted to an LLT under new PT *Platelet aggregation test* and made non-current in Version 23.1 because the term is ambiguous and could refer either to a test or an abnormality. LLT *Platelet aggregation NOS* is also ambiguous and will be made non-current based the same rationale.

Table 4-7 LLT Currency Changes