



What's New MedDRA Version 21.0

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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 20.1 and 21.0.

Section 2, Version 21.0 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 21.0, highlights changes in Version 21.0 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:

- Term history
- 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
- All 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 21.0 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 21.0 is a complex change version which means that changes may be made at all levels of the MedDRA hierarchy.

Change requests involve both MedDRA updates and SMQ changes. There were a total of 1,575 change requests processed for this version; 1,360 change requests were approved and implemented, and 203 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 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. The supplemental files 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 21.0 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 21.0 (shown in Table 4-6) and the corresponding information for Version 20.1. 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 21.0.

Version 21.0 Change Requests

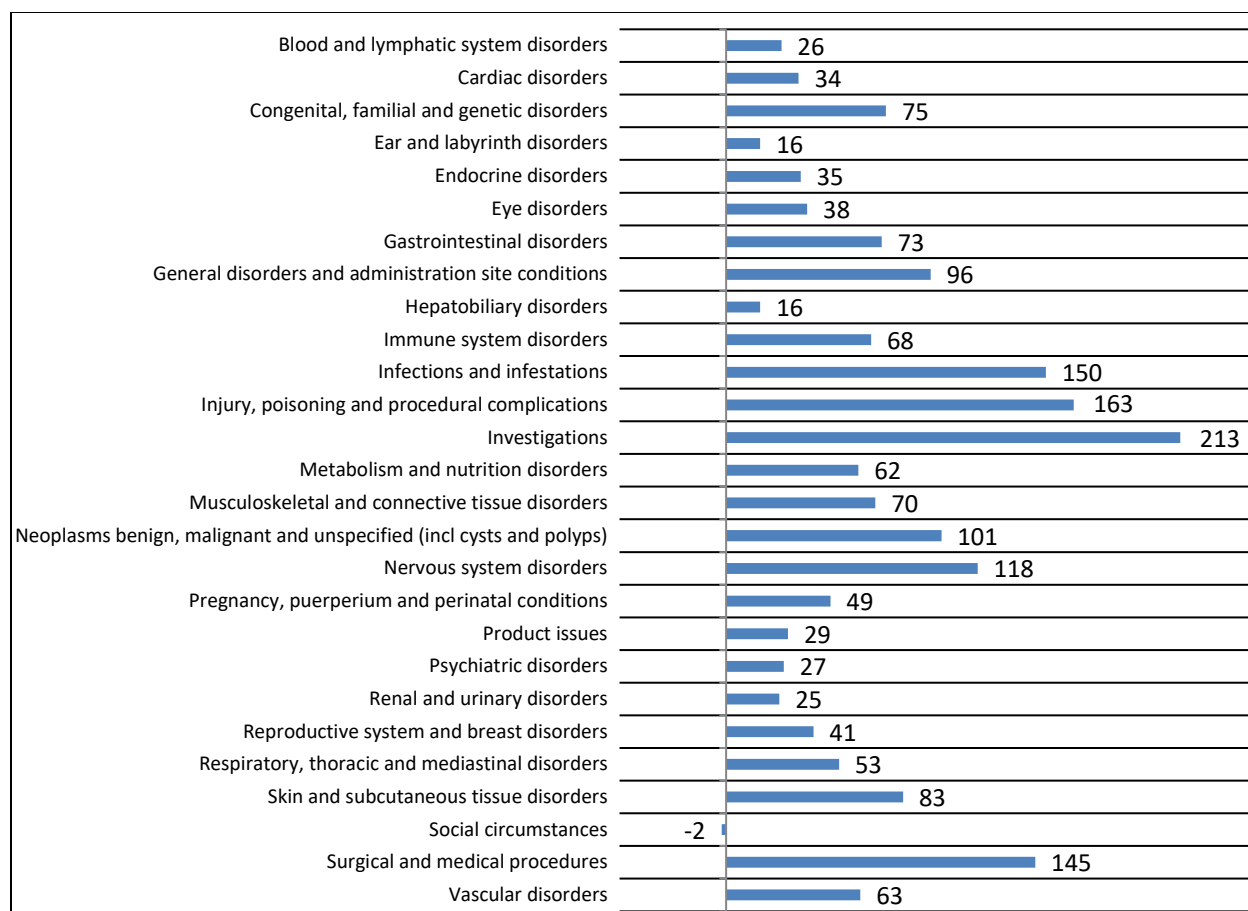


Figure 2-1 Net Changes of Terms per SOC

2.2 COMPLEX CHANGES

The proposals for complex changes considered during Version 21.0 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 28 July 2017 to 22 September 2017. Complex changes were followed by further internal review and consensus discussions which resulted in the final approved set of 10 complex changes.

The complex changes implemented in Version 21.0 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.

At the HLT level: No changes were made to existing HLTs.

At the HLT level: There were four new High Level Terms (HLTs) added, five HLTs merged, and one moved as a result of complex changes in Version 21.0. The changes are as follows:

New HLTs

New HLT	To SOC
Anaesthetic and allied procedural complications	Injury, poisoning and procedural complications
Chest and respiratory tract injuries NEC	Injury, poisoning and procedural complications
Musculoskeletal and connective tissue conditions NEC	Musculoskeletal and connective tissue disorders
Visual impairment and blindness (excl colour blindness)	Eye disorders

Table 2-1 New HLTs

Merged HLTs

HLT	To HLT	SOC
Anaesthetic complications	Anaesthetic and allied procedural complications	Injury, poisoning and procedural complications
Blindness (excl colour blindness)	Visual impairment and blindness (excl colour blindness)	Eye disorders
Chest and lung injuries NEC	Chest and respiratory tract injuries NEC	Injury, poisoning and procedural complications
Musculoskeletal and connective tissue signs and symptoms NEC	Musculoskeletal and connective tissue conditions NEC	Musculoskeletal and connective tissue disorders
Partial vision loss	Visual impairment and blindness (excl colour blindness)	Eye disorders

Table 2-2 Merged HLTs

HLT Moves

HLT	From HLGT	To HLGT	In SOC
Bartonella infections	Rickettsial infectious disorders	Bacterial infectious disorders	Infections and infestations

Table 2-3 Moved HLT**2.3 TRANSLATION CHANGES****2.3.1 Translation Review**

As part of our regular quality process, the MSSO is conducting a review of terms translated from English into the supported MedDRA languages, except Japanese. This will be an ongoing effort that is expected to last through MedDRA Version 21.1 (September 2018) and will result in updates to term names in the respective translations of MedDRA. The list of terms updated will be available in the associated version reports included in the MedDRA download for each language. Please see the [Change Request section](#) of the MedDRA website if you wish to request an improvement in the translation of a term or terms in any non-English or non-Japanese translation of MedDRA.

3. NEW DEVELOPMENTS IN VERSION 21.0

3.1 PATIENT PROBLEM CODES

In MedDRA Version 21.0 38 new terms were added as a result of a terminology interoperability initiative to map a set of patient problem codes to MedDRA. See the table below for examples.

PT	Primary HLT	Primary SOC
Discharge	General signs and symptoms NEC	General disorders and administration site conditions
Tissue injury	Non-site specific injuries NEC	Injury, poisoning and procedural complications
LLT	PT	Primary SOC
Thrombus	Thrombosis	Vascular disorders

Table 3-1 New Terms added for Patient Problem List

3.2 PILOT ICD10 TO MedDRA MAPPING OF INFECTION TERMS

As part of another terminology interoperability initiative, the MSSO conducted a pilot study of the feasibility of mapping of 919 ICD10 Chapter 1 terms (Certain infectious and parasitic diseases) and a corresponding set of 7079 terms in SOC *Infections and infestations*. As a result of this pilot study, the MSSO added 59 new terms and made three changes to existing terms. See below for new term examples:

PT	Primary HLT	Primary SOC
Brazilian purpuric fever	Haemophilus infections	Infections and infestations
Rocio virus infection	Flaviviral infections	Infections and infestations
LLT	PT	Primary SOC
Generalized tularemia	Tularaemia	Infections and infestations

Table 3-2 New Terms added for ICD10 Pilot Mapping

3.3 STANDARDISED MedDRA QUERIES (SMQs)

New SMQ *Dehydration* was added in MedDRA Version 21.0. There are now 103 level 1 SMQs in production as of this version. Additionally, there were 295 approved changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA Version 21.0 Version Report.

Please see the MedDRA Version 21.0 SMQ Introductory Guide for detailed information on the new SMQ *Dehydration*.

3.4 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 21.0 change request processing period, the MSSO implemented complex changes as a follow on task to a proactivity proposal implemented in MedDRA Version 20.1. See below for details. 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.

3.4.1 Complex Changes Related to the review of foreign body terms

In MedDRA Version 20.1 the MSSO moved site specific LLTs under PT *Foreign body* to a more appropriate placement in MedDRA as part of a proactivity request. For example, LLT *Foreign body in nose* was moved from PT *Foreign body* to new PT *Foreign body in respiratory tract*. As a follow up action to complete this request, the MSSO replaced one HLT to broaden the scope of terms represented underneath it.

HLT *Chest and lung injuries NEC* was replaced with new HLT *Chest and respiratory tract injuries NEC* to accommodate terms pertaining to parts of the respiratory tract such as the nose and pharynx and not just the lungs, such as PT *Foreign body in respiratory tract*. Please see the table below.

New Developments in Version 21.0

New HLT	Old HLT	SOC
Chest and respiratory tract injuries NEC	Chest and lung injuries NEC	Injury, poisoning and procedural complications

Table 3-3 Foreign Body Term Related Complex Change

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 21.0. These tables are intended only as a reference. For detailed information on the changes to Version 21.0, please see the MedDRA Version Report included within the MedDRA download.

SOC, HLGT, HLT Changes

Level	Change Request Action	Net Change	v20.1	v21.0
SOC	Total SOC's	0	27	27
HLGT	New HLGTs	0	0	0
	Merged HLGTs	0	0	0
	Total HLGTs ¹	0	337	337
HLT	New HLTs	4	0	4
	Merged HLTs	5	0	5
	Total HLTs ¹	-1	1,738	1,737

Table 4-1 Summary of Impact on SOC's, 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.

Summary of Changes

PT Changes

Level	Change Request Action	v20.1	v21.0
PT	New PTs	288	342
	Promoted LLTs	24	25
	Demoted PTs	37	53
	Net Change ¹	275	314
	Total PTs	22,774	23,088

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	v20.1	v21.0
LLT	Current Terms	774	68,757	69,531
LLT	Non-current Terms	8	9,269	9,277
LLT	Total LLTs ¹	782	78,026	78,808

Table 4-3 Summary of Impact on LLTs

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

Summary of Changes

New SMQs

Level	Net Change	v20.1	v21.0
1	1	102	103
2	0	82	82
3	0	20	20
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 21.0. 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	5
	Removed	6
	Modified	0
HLT.ASC	Added	4
	Removed	5
	Modified	0

Summary of Changes

HLT_PT.ASC	Added	694
	Removed	204
	Modified	0
MDHIER.ASC	Added	721
	Removed	218
	Modified	0
PT.ASC	Added	367
	Removed	53
	Modified	9
LLT.ASC	Added	782
	Removed	0
	Modified	252
SMQ_LIST.ASC¹	Added ¹	1
	Removed	0
	Modified	222
SMQ_CONTENT.ASC	Added	1,006
	Removed	0
	Modified	124

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.

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>	1,159	295	4,270	1,015	88	17
<i>Cardiac disorders</i>	1,460	347	2,393	620	36	10

Summary of Changes

SOC	LLTs* (Primary)¹	PTs (Primary)¹	LLTs* (Primary and Secondary)²	PTs (Primary and Secondary)²	HLTs³	HLGTs³
<i>Congenital, familial and genetic disorders</i>	3,566	1,360	3,566	1,360	98	19
<i>Ear and labyrinth disorders</i>	435	90	822	213	17	6
<i>Endocrine disorders</i>	678	190	1,804	543	38	9
<i>Eye disorders</i>	2,472	608	3,762	1,023	63	13
<i>Gastrointestinal disorders</i>	3,852	866	7,588	1,727	108	21
<i>General disorders and administration site conditions</i>	2,486	1,003	3,327	1,311	36	7
<i>Hepatobiliary disorders</i>	663	199	1,481	434	19	4
<i>Immune system disorders</i>	469	143	2,648	717	26	4
<i>Infections and infestations</i>	7,210	1,957	7,565	2,056	149	12
<i>Injury, poisoning and procedural complications</i>	6,665	1,185	9,295	2,349	78	9
<i>Investigations</i>	13,739	5,659	13,739	5,659	106	23
<i>Metabolism and nutrition disorders</i>	965	284	2,697	773	63	14

Summary of Changes

SOC	LLTs* (Primary)¹	PTs (Primary)¹	LLTs* (Primary and Secondary)²	PTs (Primary and Secondary)²	HLTs³	HLGTs³
<i>Musculoskeletal and connective tissue disorders</i>	2,575	458	6,551	1,280	59	11
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	8,575	1,964	9,308	2,271	202	39
<i>Nervous system disorders</i>	3,600	956	7,242	1,943	107	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1,641	225	2,910	597	48	8
<i>Product issues</i>	647	155	657	161	21	2
<i>Psychiatric disorders</i>	2,355	522	3,213	766	76	23
<i>Renal and urinary disorders</i>	1,225	353	2,619	740	32	8
<i>Reproductive system and breast disorders</i>	1,743	486	4,205	1,175	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1,727	534	4,236	1,149	49	12
<i>Skin and subcutaneous tissue disorders</i>	2,095	499	4,803	1,376	56	10
<i>Social circumstances</i>	640	273	640	273	20	7

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>Surgical and medical procedures</i>	4,820	2,166	4,820	2,166	141	19
<i>Vascular disorders</i>	1,346	311	6,745	1,636	68	11
Total	78,808	23,088				

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 21.0.

Code	Level	Term Name in v20.1	Term Name in v21.0
*	LLT	Example: Angioimmunoblastic (AILD, LgX (Kiel Classification))	Example: Angioimmunoblastic (AILD, LgX) (Kiel Classification)
10007041	LLT	Calve-Perthe's disease	Calve-Perthes disease

Summary of Changes

Code	Level	Term Name in v20.1	Term Name in v21.0
*	LLT	Example: Carcinoma colon Duke's	Example: Carcinoma colon Dukes
10053329	PT	Parovarian cystectomy	Paraovarian cystectomy
10034735	LLT	Perthes' disease	Perthes disease
10048016	LLT	Wood worker's lung	Woodworker's lung

Table 4-7 Modified PT/LLT Names

* There were 35 terms updated to correct the spelling of “Duke’s” classification concepts to “Dukes” and 7 updates to adjust the parentheses of terms with “(AILD, LgX (Kiel Classification))” to “(AILD, LgX) (Kiel Classification)”. For the complete list of terms, please see the MedDRA 21.0 Version Report or use MVAT.

4.5 LLT CURRENCY STATUS CHANGES

The following table reflects the 8 terms at the LLT level in MedDRA Version 21.0 that have a change in their currency status along with the rationale for the change.

Lowest Level Term	Currency Status Changed to	Rationale
Betoglobulin	Non-current	The concept Beta globulin is normally expressed in medical literature using two words. Accordingly, LLT <i>Betoglobulin</i> , under PT <i>Beta globulin</i> , was changed from current to non-current status. The current LLT <i>Beta globulin</i> correctly represents the concept.
Betoglobulin abnormal	Non-current	The concept Beta globulin is expressed in medical literature using two words. Accordingly, LLT <i>Betoglobulin abnormal</i> , under PT <i>Beta globulin abnormal</i> , was changed from current to non-current status. The current LLT <i>Beta globulin abnormal</i> correctly represents the concept.
Betoglobulin normal	Non-current	The concept Beta globulin is expressed in medical literature using two words. Accordingly, LLT <i>Betoglobulin normal</i> , under PT <i>Beta globulin normal</i> , was changed from current to non-current status. The current LLT <i>Beta globulin normal</i> correctly represents the concept.
Blood tryptase absent	Non-current	Tryptase is a normal protein in mast cells with a reference range of < 11.4 ng/mL. The concept of blood

Summary of Changes

Lowest Level Term	Currency Status Changed to	Rationale
		tryptase being absent has no meaning and therefore LLT <i>Blood tryptase absent</i> was changed to a non-current status.
Blood tryptase present	Non-current	Tryptase is a normal protein in mast cells with a reference range of < 11.4 ng/mL. The qualifier “present” does not convey any value and therefore LLT <i>Blood tryptase present</i> was changed to a non-current status.
Lumbar syndrome	Non-current	The more specific term for this disorder, LLT <i>Lumbar facet syndrome</i> , has been added under PT <i>Facet joint syndrome</i> for MedDRA Version 20.1. LLT <i>Lumbar syndrome</i> is a vague term and was made non-current.
Mucosal thickness	Non-current	LLT <i>Mucosal thickness</i> was changed to a status of non-current and replaced by the more appropriate LLT <i>Mucosal thickening</i> .
Urine oxalate present	Non-current	Oxalate in urine is a normal finding up to a certain level and the qualifier "present" does not convey any value.

Table 4-8 LLT Currency Changes