



What's New MedDRA Version 21.1

September 2018

000224



ACKNOWLEDGEMENTS

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Table of Contents

Table of Contents

1. DOCUMENT OVERVIEW	1
2. VERSION 21.1 CHANGE REQUESTS	2
2.1 TERMINOLOGY CHANGES	2
2.2 TRANSLATION CHANGES	3
2.2.1 Translation Review	3
3. NEW DEVELOPMENTS IN VERSION 21.1	4
3.1 STANDARDISED MedDRA QUERIES (SMQS)	4
3.2 PROACTIVITY REQUESTS	4
3.2.1 Differentiation Between Administration Errors / Issues and Medication Errors / Product Use Issues	4
3.2.2 Prophylaxis Terms	5
3.2.3 LLTs Under PT <i>Procedural complication</i>	6
4. SUMMARY OF CHANGES	7
4.1 SUMMARY OF IMPACT ON THE TERMINOLOGY	7
4.2 SUMMARY OF IMPACT ON RECORDS IN MedDRA FILES	9
4.3 MedDRA TERM COUNTS	10
4.4 MODIFIED PT AND LLT NAMES	13
4.5 LLT CURRENCY STATUS CHANGES	14

LIST OF FIGURES

Figure 2-1 Net Changes of Terms per SOC	3
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LIST OF TABLES

Table 3-1 Updates to “Administration” and “Use” Terms	5
Table 3-2 New Prophylaxis Terms and Existing Term Change Examples	6
Table 3-3 Examples of LLTs Moved from PT <i>Procedural complication</i>	6
Table 4-1 Summary of Impact on SOC, HLGTS, HLTs	7
Table 4-2 Summary of Impact on PTs	8
Table 4-3 Summary of Impact on LLTs	8
Table 4-4 Summary of Impact on SMQs	9
Table 4-5 Summary of Impact on Records in MedDRA Files	10
Table 4-6 MedDRA Term Counts	13
Table 4-7 Modified PT/LLT Names	14
Table 4-8 LLT Currency Changes	14

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 21.0 and 21.1.

Section 2, Version 21.1 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 21.1, highlights changes in Version 21.1 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 21.1 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 21.1 is a simple change version which means that changes are made only at the PT and LLT levels of the MedDRA hierarchy.

Change requests involve both MedDRA updates and SMQ changes. There was a total of 1,516 change requests processed for this version; 1,283 change requests were approved and implemented, and 229 change requests were not approved. There are, in addition, 4 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 21.1 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 21.1 (shown in Table 4-6) and the corresponding information for Version 21.0. 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 21.1.

Version 21.1 Change Requests

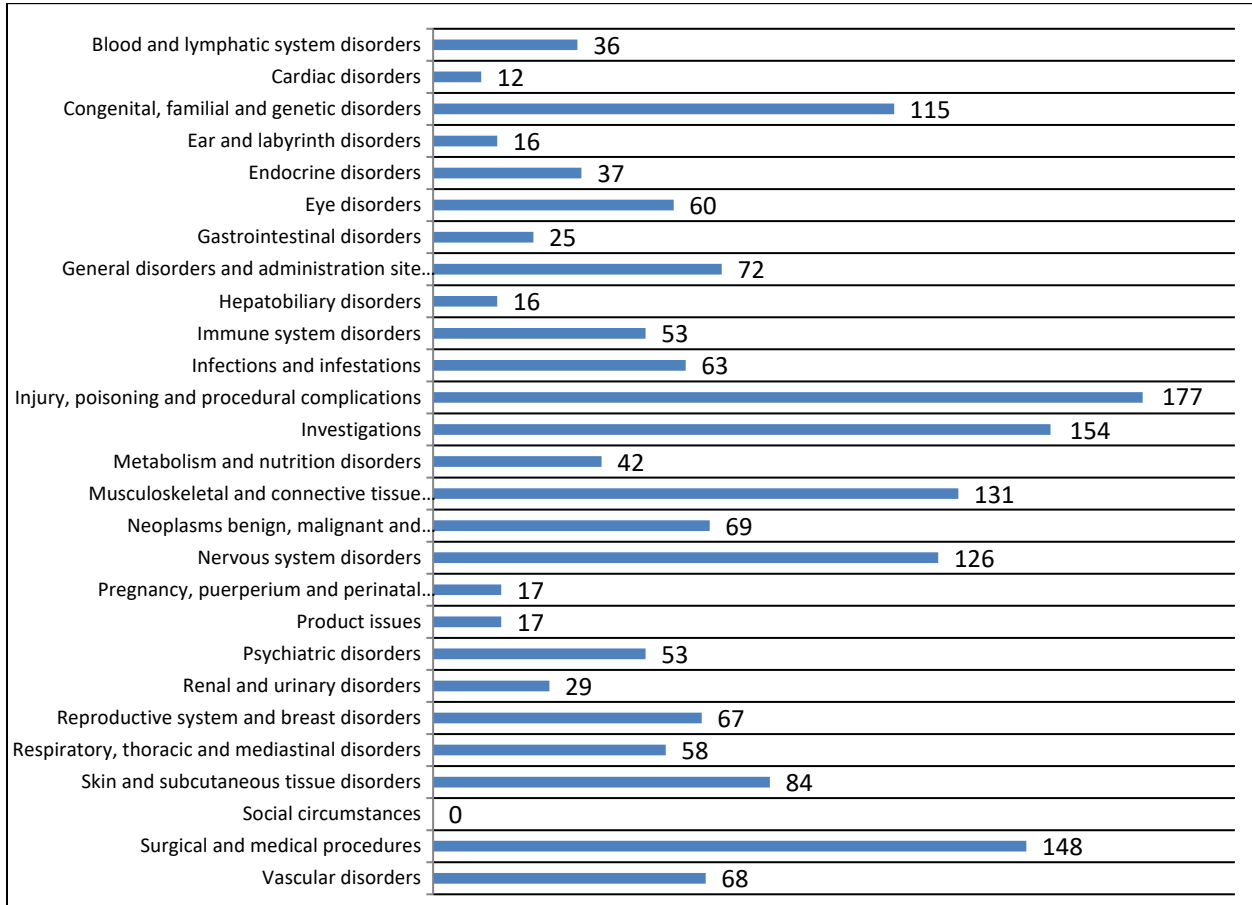


Figure 2-1 Net Changes of Terms per SOC

2.2 TRANSLATION CHANGES

2.2.1 Translation Review

As part of our regular quality process, the MSSO has completed, as of MedDRA Version 21.1, a review of terms translated from English into the supported MedDRA languages, except Japanese. 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 supported language, except the Japanese translation of MedDRA.

3. NEW DEVELOPMENTS IN VERSION 21.1

3.1 STANDARDISED MedDRA QUERIES (SMQs)

No new SMQs were introduced into MedDRA Version 21.1, but there were 307 approved changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA Version 21.1 Version Report.

3.2 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 21.1 change request processing period, the MSSO reviewed four requests and implemented three of them. 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.

3.2.1 Differentiation Between Administration Errors / Issues and Medication Errors / Product Use Issues

A MedDRA user proposed improving the differentiation between administration errors/issues and medication errors/product use issues on the LLT and PT level. The MSSO performed a careful review of “administration” and “use” terms in HLGT *Medication errors and other product use errors and issues* and made four changes for better alignment and consistency of placement. These include placing “unapproved use” concepts under PT *Product use issue* because the main concept is the unapproved use, rather than an administration error/issue. In addition, the concepts of discontinued, expired, recalled, counterfeit products being administered are all to be represented at the PT level to facilitate retrieval and analysis because they are potentially important safety issues. The changes, which were implemented in MedDRA version 21.1, included moving two LLTs, adding a new PT and promoting an LLT to the PT level. See the table below for details.

New Developments in Version 21.1

Moved LLT	From PT	To PT
Drug use in unapproved age group	Drug administered to patient of inappropriate age	Product use issue
Recalled drug administered	Product use issue	Recalled product administered*
PT	HLT	Primary SOC
Discontinued product administered ⁺	Product administration errors and issues	Injury, poisoning and procedural complications
Recalled product administered ⁺	Product administration errors and issues	Injury, poisoning and procedural complications

Table 3-1 Updates to “Administration” and “Use” Terms

*New PT for MedDRA Version 21.1

+Promoted LLT

3.2.2 Prophylaxis Terms

The MSSO assessed the placement of existing prophylaxis/prevention terms in HLT *Prophylactic procedures NEC* and moved them to more specific HLTs to optimize their placement in MedDRA as part of a proactive review requested by a MedDRA User. The MSSO generally refrains from adding a new prophylaxis term for every specific medical disorder represented in MedDRA because an overwhelmingly large number of such potential terms would likely result. However, on the basis of this review, new terms were added that represent prophylaxis and prevention concepts pertaining to general disorder/disease categories. A total of 70 changes were made including the addition of 17 new terms and moving 53 existing terms. See below for examples.

New PT	HLT	Primary SOC
Gastrointestinal disorder prophylaxis	Gastrointestinal therapeutic procedures NEC	Surgical and medical procedures
Eye disorder prophylaxis	Eye therapeutic procedures NEC	Surgical and medical procedures
Skin disorder prophylaxis	Skin and subcutaneous tissue therapeutic procedures NEC	Surgical and medical procedures

New Developments in Version 21.1

Moved PT	From HLT	To HLT*
Antibiotic prophylaxis	Prophylactic procedures NEC	Antiinfective therapies
Dental disorder prophylaxis	Prophylactic procedures NEC	Dental and gingival therapeutic procedures
Migraine prophylaxis	Prophylactic procedures NEC	Nervous system therapeutic procedures NEC

Table 3-2 New Prophylaxis Terms and Existing Term Change Examples

*Moved PTs are primary to SOC *Surgical and medical procedures*

3.2.3 LLTs Under PT *Procedural complication*

The MSSO performed a proactivity review of all LLTs under PT *Procedural complication* in SOC *Injury, poisoning and procedural complications* and made changes to align these terms to a more anatomically appropriate placement by moving them to an existing PT or under a new PT. These changes were based on a suspended request to promote LLT *Intraoperative neurological injury* from PT *Procedural complication*. A total of 37 changes were made which included moving existing LLTs and the addition of 13 PTs. See the table below for examples.

Moved LLT	From PT	To PT
Intraoperative breast injury	Procedural complication	Breast procedural complication*
Intraoperative cardiac injury	Procedural complication	Cardiac procedure complication
Intraoperative neurological injury	Procedural complication	Neurological procedural complication*
Intraoperative splenic injury	Procedural complication	Spleen procedural complication*

Table 3-3 Examples of LLTs Moved from PT *Procedural complication*

*New PT primary to SOC *Injury, poisoning and procedural complications*

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 21.1. These tables are intended only as a reference. For detailed information on the changes to Version 21.1, please see the MedDRA Version Report included within the MedDRA download.

SOC, HLGT, HLT Changes

Level	Change Request Action	Net Change	v21.0	v21.1
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	0	0	0
	Merged HLTs	0	0	0
	Total HLTs ¹	0	1,737	1,737

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

MedDRA v21.1 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	v21.0	v21.1
PT	New PTs	342	347
	Promoted LLTs	25	19
	Demoted PTs	53	65
	Net Change ¹	314	301
	Total PTs	23,088	23,389

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	v21.0	v21.1
LLT	Current Terms	698	69,531	70,229
LLT	Non-current Terms	1	9,277	9,278
LLT	Total LLTs ¹	699	78,808	79,507

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	v21.0	v21.1
1	0	103	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 21.1. 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

Summary of Changes

	Removed	0
	Modified	0
HLT_PT.ASC	Added	653
	Removed	158
	Modified	0
MDHIER.ASC	Added	711
	Removed	173
	Modified	0
PT.ASC	Added	366
	Removed	65
	Modified	7
LLT.ASC	Added	699
	Removed	0
	Modified	341
SMQ_LIST.ASC¹	Added ¹	0
	Removed	0
	Modified	223
SMQ_CONTENT.ASC	Added	604
	Removed	0
	Modified	96

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	HLT ³	HLGT ³
<i>Blood and lymphatic system disorders</i>	1,149	293	4,302	1,026	88	17

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>Cardiac disorders</i>	1,467	348	2,403	622	36	10
<i>Congenital, familial and genetic disorders</i>	3,635	1,406	3,635	1,406	98	19
<i>Ear and labyrinth disorders</i>	439	92	834	217	17	6
<i>Endocrine disorders</i>	678	190	1,828	556	38	9
<i>Eye disorders</i>	2,488	618	3,800	1,045	63	13
<i>Gastrointestinal disorders</i>	3,880	871	7,638	1,737	108	21
<i>General disorders and administration site conditions</i>	2,500	1,010	3,381	1,330	36	7
<i>Hepatobiliary disorders</i>	666	200	1,493	438	19	4
<i>Immune system disorders</i>	493	145	2,687	732	26	4
<i>Infections and infestations</i>	7,252	1,972	7,611	2,073	149	12
<i>Injury, poisoning and procedural complications</i>	6,746	1,221	9,430	2,391	78	9
<i>Investigations</i>	13,828	5,730	13,828	5,730	106	23

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>Metabolism and nutrition disorders</i>	968	285	2,724	788	63	14
<i>Musculoskeletal and connective tissue disorders</i>	2,611	464	6,648	1,315	59	11
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	8,621	1,978	9,396	2,293	202	39
<i>Nervous system disorders</i>	3,665	969	7,327	1,983	107	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1,636	225	2,922	602	48	8
<i>Product issues</i>	653	157	670	165	21	2
<i>Psychiatric disorders</i>	2,370	528	3,246	786	76	23
<i>Renal and urinary disorders</i>	1,232	356	2,640	748	32	8
<i>Reproductive system and breast disorders</i>	1,757	492	4,257	1,190	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1,736	534	4,283	1,161	49	12
<i>Skin and subcutaneous tissue disorders</i>	2,124	510	4,861	1,401	56	10

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>Social circumstances</i>	640	273	640	273	20	7
<i>Surgical and medical procedures</i>	4,924	2,211	4,924	2,211	141	19
<i>Vascular disorders</i>	1,349	311	6,797	1,652	68	11
Total	79,507	23,389				

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.

Summary of Changes

The table below summarizes terms modified in English MedDRA Version 21.1.

Code	Level	Term Name in v21.0	Term Name in v21.1
10023327	LLT	Keilland's forceps delivery	Kielland's forceps delivery
10031160	LLT	Osteo-arthritis of neck	Osteoarthritis of neck
10081096	LLT	Thoracic facet arthosis	Thoracic facet arthrosis

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 21.1 that had a change in currency status along with the rationale for the change.

Lowest Level Term	Currency Status Changed to	Rationale
Hutchison's melanotic freckle	Non-current	LLT <i>Hutchison's melanotic freckle</i> is misspelled and was changed to a status of non-current. The correctly spelled LLT <i>Hutchinson's melanotic freckle</i> is an existing term in MedDRA.

Table 4-8 LLT Currency Changes