



What's New MedDRA Version 20.1

September 2017

000088



ACKNOWLEDGEMENTS

MedDRA® trademark is owned by IFPMA on behalf of ICH.

Disclaimer and Copyright Notice

This document is protected by copyright and may be used, reproduced, incorporated into other works, adapted, modified, translated or distributed under a public license provided that ICH's copyright in the document is acknowledged at all times. In case of any adaption, modification or translation of the document, reasonable steps must be taken to clearly label, demarcate or otherwise identify that changes were made to or based on the original document. Any impression that the adaption, modification or translation of the original document is endorsed or sponsored by the ICH must be avoided.

The document is provided "as is" without warranty of any kind. In no event shall the ICH or the authors of the original document be liable for any claim, damages or other liability arising from the use of the document.

The above-mentioned permissions do not apply to content supplied by third parties. Therefore, for documents where the copyright vests in a third party, permission for reproduction must be obtained from this copyright holder.

Table of Contents

Table of Contents

1. DOCUMENT OVERVIEW	1
2. VERSION 20.1 CHANGE REQUESTS.....	2
2.1 TERMINOLOGY CHANGES.....	2
2.2 TRANSLATION CHANGES	3
2.2.1 Translation Review	3
3. NEW DEVELOPMENTS IN VERSION 20.1	4
3.1 REVISIONS TO “DRUG USE DISORDER” TERMS.....	4
3.2 STANDARDISED MedDRA QUERIES (SMQS)	5
3.3 PROACTIVITY REQUESTS	5
3.3.1 Review of foreign body terms	5
3.4 SELF-SERVICE APPLICATION	6
4. SUMMARY OF CHANGES.....	8
4.1 SUMMARY OF IMPACT ON THE TERMINOLOGY	8
4.2 SUMMARY OF IMPACT ON RECORDS IN MedDRA FILES.....	10
4.3 MedDRA TERM COUNTS	11
4.4 MODIFIED PT AND LLT NAMES	14
4.5 LLT CURRENCY STATUS CHANGES.....	15

LIST OF FIGURES

Figure 2-1 Net Changes of Terms per SOC	3
Figure 3-1 Revisions to “Drug use disorder” terms.....	4
Figure 3-2 PT <i>Foreign body</i>	6
Figure 3-3 Self-Service Application Home Page	7

LIST OF TABLES

Table 4-1 Summary of Impact on SOCs, HLGTS, HLTs.....	8
Table 4-2 Summary of Impact on PTs.....	9
Table 4-3 Summary of Impact on LLTs	9
Table 4-4 Summary of Impact on SMQs	10
Table 4-5 Summary of Impact on Records in MedDRA Files	11
Table 4-6 MedDRA Term Counts.....	14
Table 4-7 Modified PT/LLT Names.....	14
Table 4-8 LLT Currency Changes	17

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 20.0 and 20.1.

Section 2, Version 20.1 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 20.1, highlights changes in Version 20.1 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:

- 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 20.1 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 20.1 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 were a total of 1,764 change requests processed for this version; 1,476 change requests were approved and implemented, and 272 change requests were not approved. There are, in addition, 16 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 20.1 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 20.1 (shown in Table 4-6) and the corresponding information for Version 20.0. 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 20.1.

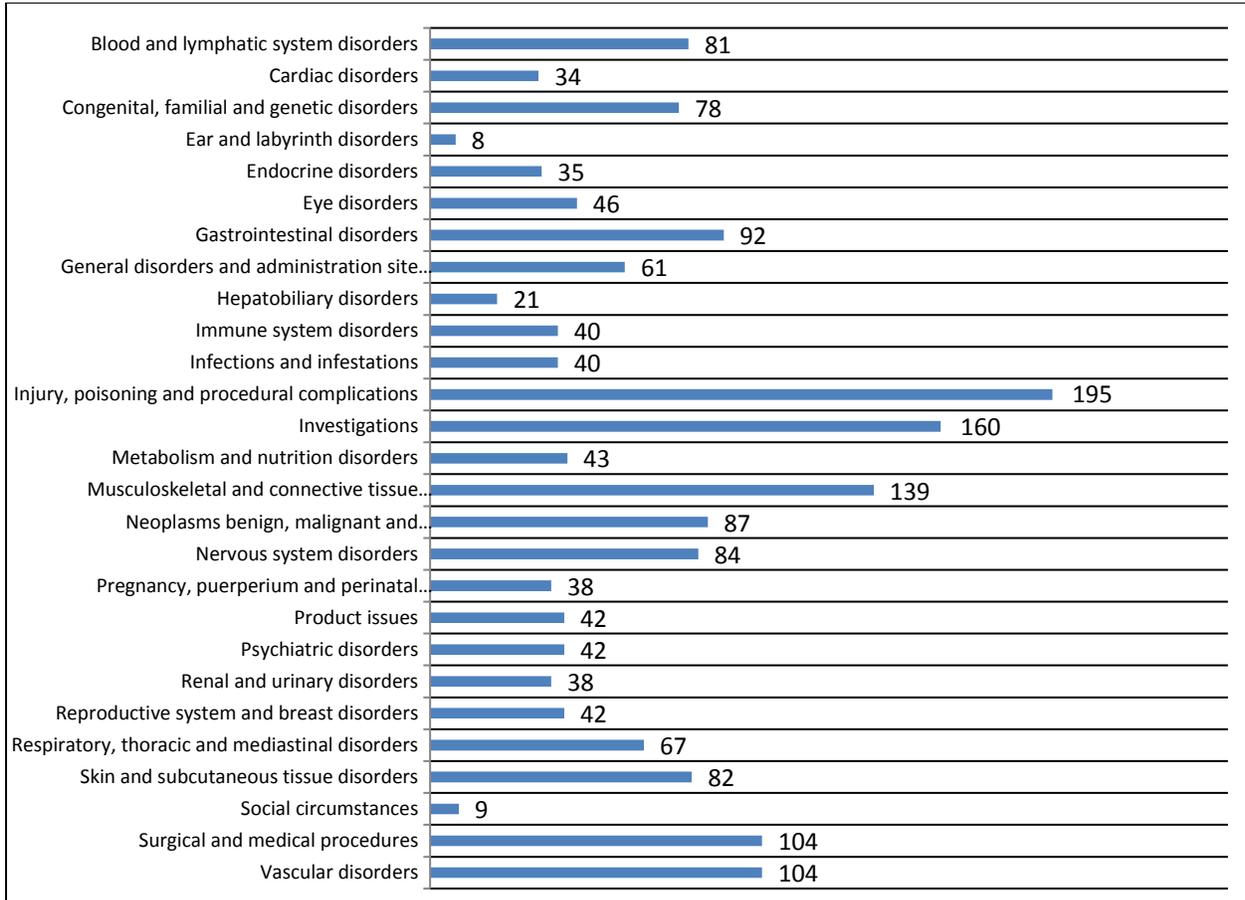


Figure 2-1 Net Changes of Terms per SOC

2.2 TRANSLATION CHANGES

2.2.1 Translation Review

As part of our regular quality process, the MSSO 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 until MedDRA Version 21.0 (March 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 20.1

3.1 REVISIONS TO “DRUG USE DISORDER” TERMS

In MedDRA Version 20.0, several drug/substance abuse and dependence PTs were demoted under new drug/substance use disorder PTs in accordance with the updated DSM-5 criteria which combine the categories of “abuse” and “dependence” in a single disorder. The MSSO has reconsidered these demotions based on feedback from users who note that from a pharmacovigilance perspective, abuse and dependence are distinct and important concepts that warrant separate representation at the PT level. Therefore LLT *Drug abuse* and LLT *Drug dependence* were promoted to PT level from under PT *Drug use disorder*. Similarly, LLT *Drug dependence, antepartum* and LLT *Drug dependence, postpartum* were promoted to PT level from under PT *Drug use disorder, antepartum* and PT *Drug use disorder, postpartum*, respectively. In addition, LLT *Substance abuse* and LLT *Substance dependence* were promoted to PT level from under PT *Substance use disorder*. The LLTs that were previously subordinate to these PTs in MedDRA Version 19.1 were moved under the newly promoted PTs. The figure below shows the concepts of abuse, dependence, and use disorder as separate PTs under HLT *Substance related and addictive disorders* in MedDRA Version 20.1.



Figure 3-1 Revisions to “Drug use disorder” terms

3.2 STANDARDISED MedDRA QUERIES (SMQs)

New SMQ *Infective pneumonia* was added in MedDRA Version 20.1. There are now 102 level 1 SMQs in production as of this version. Additionally, there were 297 approved changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA Version 20.1 Version Report.

Please see the MedDRA Version 20.1 SMQ Introductory Guide for detailed information on the new SMQ *Infective pneumonia*.

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 20.1 change request processing period, the MSSO evaluated three proactivity proposals submitted by MedDRA users. Of the three proposals, one was implemented and two were not approved. See below for details on the implemented request. 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.

3.3.1 Review of foreign body terms

A MedDRA user requested that the MSSO consider reviewing the placement of “foreign body” LLTs under PT *Foreign body* because there were a number of site-specific LLTs mapped to HLT *Non-site specific injuries NEC* such as LLT *Foreign body in nose* that were not optimally placed.

After performing a review, several modifications were made to accommodate this request. A total of 6 new PTs have been added for MedDRA Version 20.1 and one LLT has been promoted to the PT level with HLT links to the appropriate site of specificity. The PTs are as follows:

- PT *Foreign body in gastrointestinal tract*
- PT *Foreign body in reproductive tract*
- PT *Foreign body in respiratory tract*
- PT *Foreign body in urogenital tract*

- PT *Foreign body in ear**
- PT *Musculoskeletal foreign body*
- PT *Soft tissue foreign body*

***Promoted LLT**

LLTs have been moved from PT *Foreign body* to more specific PTs accordingly. See the figure below for how PT *Foreign body* and underlying LLTs will appear in MedDRA Version 20.1.

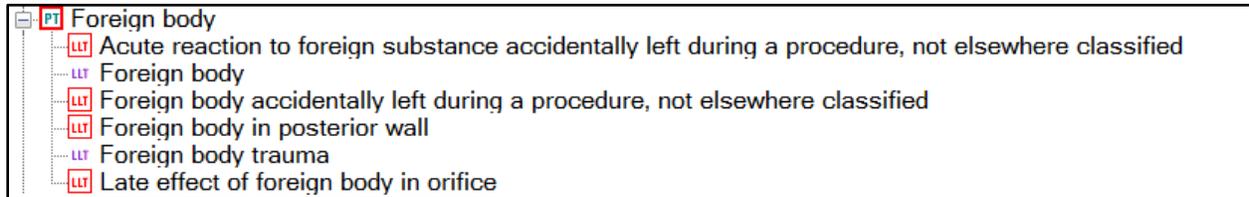


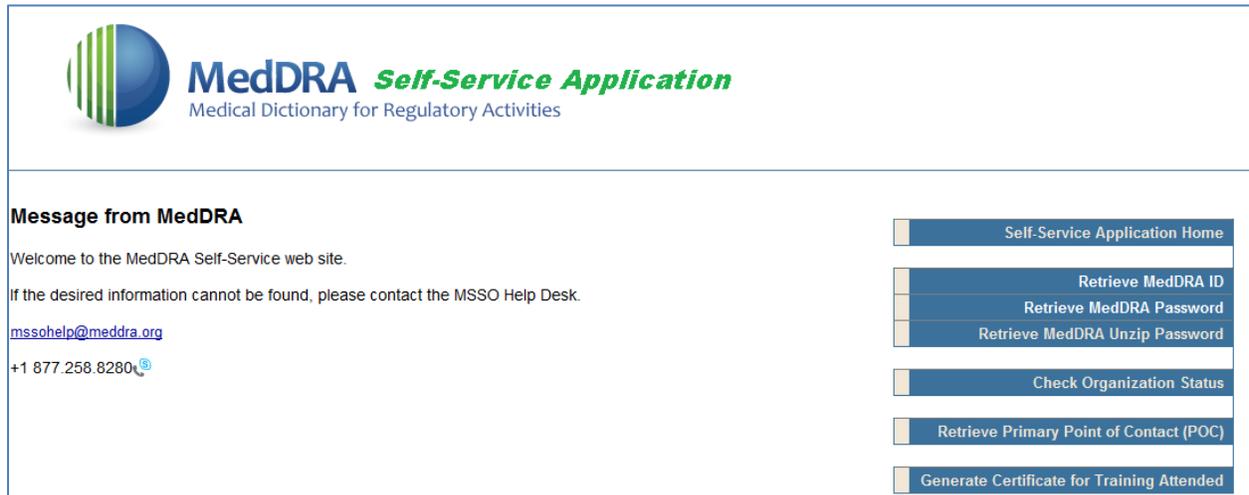
Figure 3-2 PT *Foreign body*

3.4 SELF-SERVICE APPLICATION

The MSSO has developed a new web-based tool called the “Self-Service Application” to provide support for frequently asked Help Desk questions. The Self-Service Application can be accessed at the following URL: <https://apps.meddra.org/selfservice/>. See the figure below which shows the Self-Service Application home page.

The functions for the new tool focus on providing support for frequently asked Help Desk questions and include the following functions:

- Primary Point of Contacts can retrieve their organization’s MedDRA password and unzip passwords for MedDRA release files
- Retrieve your organization’s MedDRA ID and the email address for your organization’s Primary Point of Contact
- Check the MedDRA subscription status of business partners
- Print or save to PDF training certificates for face-to-face classes attended



Message from MedDRA

Welcome to the MedDRA Self-Service web site.

If the desired information cannot be found, please contact the MSSO Help Desk.

mssohelp@meddra.org

+1 877.258.8280

- Self-Service Application Home
- Retrieve MedDRA ID
- Retrieve MedDRA Password
- Retrieve MedDRA Unzip Password
- Check Organization Status
- Retrieve Primary Point of Contact (POC)
- Generate Certificate for Training Attended

Figure 3-3 Self-Service Application Home Page

Instead of providing password and account information via email, the MSSO plans to refer users to the Self-Service Application to obtain this information. A short videocast has been developed to explain how to use this tool which can be found in the Training Materials section of the MedDRA website under “Tools” - <https://www.meddra.org/training-materials>.

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 20.1. These tables are intended only as a reference. For detailed information on the changes to Version 20.1, please see the MedDRA Version Report included within the MedDRA download.

SOC, HLGT, HLT Changes

Level	Change Request Action	Net Change	v20.0	V20.1
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	1,738	1,738

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

MedDRA v20.1 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	v20.0	V20.1
PT	New PTs	324	288
	Promoted LLTs	24	24
	Demoted PTs	59	37
	Net Change ¹	289	275
	Total PTs	22,499	22,774

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	Change Request Action	Net Change	v20.0	V20.1
LLT	Current Terms	762	67,995	68,757
LLT	Non-current Terms	16	9,253	9,269
LLT	Total LLTs ¹	778	77,248	78,026

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	v20.0	V20.1
1	1	101	102
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 20.1. 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

Summary of Changes

HLT_PT.ASC	Added	504
	Removed	63
	Modified	0
MDHIER.ASC	Added	552
	Removed	83
	Modified	0
PT.ASC	Added	312
	Removed	37
	Modified	9
LLT.ASC	Added	778
	Removed	0
	Modified	434
SMQ_LIST.ASC¹	Added ¹	1
	Removed	0
	Modified	221
SMQ_CONTENT.ASC	Added	1,823
	Removed	0
	Modified	158

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>	1,152	293	4,255	1,011	88	17
<i>Cardiac disorders</i>	1,445	339	2,369	610	36	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>Congenital, familial and genetic disorders</i>	3,512	1,338	3,512	1,338	98	19
<i>Ear and labyrinth disorders</i>	431	88	813	206	17	6
<i>Endocrine disorders</i>	677	191	1,779	533	38	9
<i>Eye disorders</i>	2,452	600	3,735	1,011	64	13
<i>Gastrointestinal disorders</i>	3,841	859	7,558	1,717	108	21
<i>General disorders and administration site conditions</i>	2,443	989	3,259	1,284	36	7
<i>Hepatobiliary disorders</i>	655	195	1,470	429	19	4
<i>Immune system disorders</i>	465	142	2,601	697	26	4
<i>Infections and infestations</i>	7,113	1,916	7,461	2,008	149	12
<i>Injury, poisoning and procedural complications</i>	6,598	1,158	9,170	2,305	78	9
<i>Investigations</i>	13,611	5,578	13,611	5,578	106	23
<i>Metabolism and nutrition disorders</i>	956	282	2,651	757	63	14

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>Musculoskeletal and connective tissue disorders</i>	2,539	450	6,498	1,264	59	11
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	8,545	1,955	9,262	2,257	202	39
<i>Nervous system disorders</i>	3,553	945	7,146	1,917	107	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1,635	223	2,873	584	48	8
<i>Product issues</i>	626	152	633	156	21	2
<i>Psychiatric disorders</i>	2,348	518	3,191	757	76	23
<i>Renal and urinary disorders</i>	1,220	352	2,600	734	32	8
<i>Reproductive system and breast disorders</i>	1,725	477	4,177	1,160	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1,717	528	4,200	1,133	49	12
<i>Skin and subcutaneous tissue disorders</i>	2,080	493	4,738	1,356	56	10
<i>Social circumstances</i>	641	274	641	274	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>	4,713	2,130	4,713	2,130	141	19
<i>Vascular disorders</i>	1,333	309	6,694	1,624	68	11
Total	78,026	22,774				

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 lists two terms modified in English MedDRA Version 20.1.

Code	Level	Term Name in v20.0	Term Name in v20.1
10059971	LLT	Bordet-Wasserman reaction	Bordet-Wassermann reaction
10052456	LLT	Parovarian cyst	Paraovarian cyst

Table 4-7 Modified PT/LLT Names

Summary of Changes

4.5 LLT CURRENCY STATUS CHANGES

The following table reflects the 16 terms at the LLT level in MedDRA Version 20.1 that have a change in their currency status along with the rationale for the change.

Lowest Level Term	Currency Status Changed to	Rationale
Communication issue	Non-current	LLT <i>Communication issue</i> was changed to a status of non-current to avoid potential confusion with PT <i>Product communication issue</i> and other general communication disorder concepts. Note LLT <i>Communication issue</i> was a PT that was demoted to an LLT under PT <i>Product communication issue</i> for MedDRA Version 20.1.
Delayed adverse reactions to gadolinium	Non-current	LLT <i>Delayed adverse reactions to gadolinium</i> was changed to a non-current status because the term is ambiguous. It could refer to a hypersensitivity type IV reaction or to the retention of gadolinium and its long term effects.
Dementia due to Creutzfeld-Jakob disease	Non-current	Dementia due to Creutzfeld-Jakob disease represents a "due to" concept which was inherited from other terminologies. The term does not conform with the general convention for the inclusion of combination terms in MedDRA and was changed to a status of non-current. A combination term is a single medical concept combined with additional medical wording that provides important information on pathophysiology or etiology, and is an internationally recognized, distinct and robust medical concept.
Dementia due to Creutzfeldt-Jacob disease	Non-current	Dementia due to Creutzfeldt-Jacob disease represents a "due to" concept which was inherited from other terminologies. The term does not conform with the general convention for the inclusion of combination terms in MedDRA and was changed to a status of non-current. A combination term is a single medical concept combined with additional medical wording that provides important information on pathophysiology or etiology, and is an internationally recognized, distinct and robust medical concept.
Dementia due to head trauma	Non-current	Dementia due to head trauma represents a "due to" concept which was inherited from other terminologies. The term does not conform with the general convention for the inclusion of combination terms in MedDRA and was changed to a status of non-current. A combination term is a single medical concept combined with additional medical wording that provides important information on pathophysiology or etiology, and is an internationally recognized, distinct and robust medical concept.

Summary of Changes

Lowest Level Term	Currency Status Changed to	Rationale
Dementia due to Huntington's disease	Non-current	Dementia due to Huntington's disease represents a "due to" concept which was inherited from other terminologies. The term does not conform with the general convention for the inclusion of combination terms in MedDRA and was changed to a status of non-current. A combination term is a single medical concept combined with additional medical wording that provides important information on pathophysiology or etiology, and is an internationally recognized, distinct and robust medical concept.
Enteritis due to calcivirus	Non-current	LLT <i>Enteritis due to calcivirus</i> was misspelled. The correctly spelled LLT <i>Enteritis due to calcivirus</i> is an existing term.
Fracture of upper end or unspecified of tibia and fibula, open	Non-current	LLT <i>Fracture of upper end or unspecified of tibia and fibula, open</i> represents a combination of two separate existing PTs – PT <i>Tibia fracture</i> and PT <i>Fibula fracture</i> .
Fracture of upper end or unspecified part of tibia and fibula, closed	Non-current	LLT <i>Fracture of upper end or unspecified part of tibia and fibula, closed</i> represents a combination of two separate existing PTs – PT <i>Tibia fracture</i> and PT <i>Fibula fracture</i> .
Gastroenteritis calciviral	Non-current	LLT <i>Gastroenteritis calciviral</i> is misspelled. The correctly spelled LLT <i>Gastroenteritis calciviral</i> is an existing term.
Hair colour graying	Non-current	LLT <i>Hair colour graying</i> was changed to a status of non-current because it is a mixture of British English and American English. Note that both LLT <i>Hair color graying</i> and LLT <i>Hair colour greying</i> are available as of MedDRA Version 20.1.
Lymphocyte abnormal	Non-current	Lymphocyte abnormal can refer to either count, percentage or morphology and therefore is ambiguous in meaning.
Misleading product information	Non-current	The word "information" is too broad in meaning as an LLT under PT <i>Product advertising issue</i> for which LLT <i>Misleading product information</i> was added. The term was changed to a status of non-current because "misleading product information" may also refer to instructions, labeling information or other specifications about the product, in addition to advertising information.
Non-NSF delayed adverse events to gadolinium	Non-current	LLT <i>Non-NSF delayed adverse events to gadolinium</i> was changed to a status of non-current because the preferred wording is "reaction" rather than "event" in the context of this sub-concept LLT. The correct wording of this concept "Non-NSF delayed adverse reaction to gadolinium" was added as sub-concept LLT to PT <i>Gadolinium deposition disease</i> .

Summary of Changes

Lowest Level Term	Currency Status Changed to	Rationale
Procidencia	Non-current	Procidencia is an ambiguous term that is often used to describe uterine prolapse, but also can refer to the more general concept of prolapse.
Umbilical cyst	Non-current	Umbilical cyst is an ambiguous term and could be used to refer to urachal cysts or to umbilical cord cysts. There are specific LLTs / PTs for these concepts, for example LLT <i>Urachal cyst</i> and LLT <i>Umbilical cord cyst</i> .

Table 4-8 LLT Currency Changes