



What's New MedDRA Version 20.0

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000001



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 19.1 and 20.0.

Section 2, Version 20.0 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 20.0, highlights changes in Version 20.0 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 20.0 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 20.0 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 3,405 change requests processed for this version; 3,066 change requests were approved and implemented, and 331 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. 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 20.0 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 20.0 (shown in Table 4-6) and the corresponding information for Version 19.1. 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 20.0.

Version 20.0 Change Requests

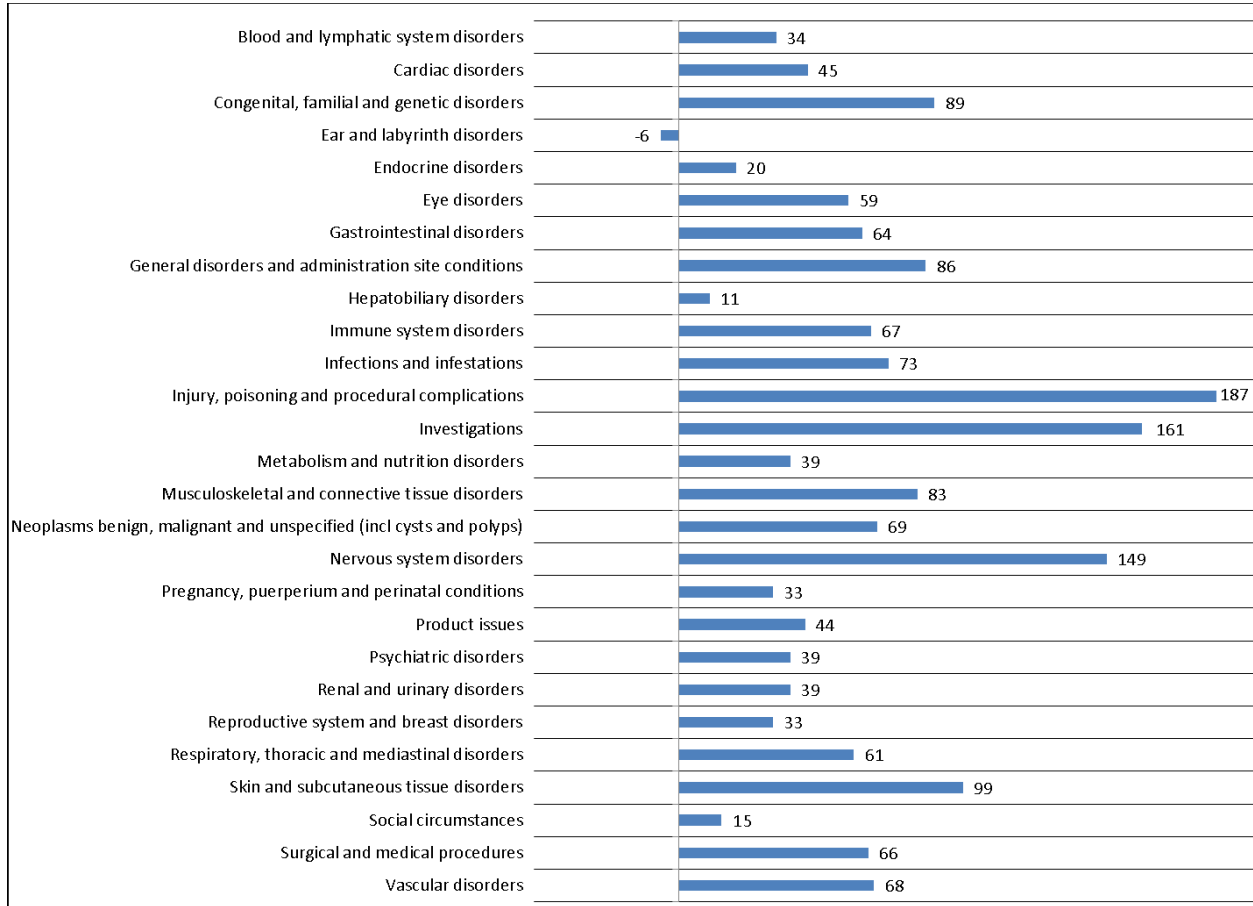


Figure 2-1 Net Changes of Terms per SOC

2.2 COMPLEX CHANGES

The proposals for complex changes considered during Version 20.0 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 27 July 2016 to 23 September 2016. Complex changes were followed by further internal review and consensus discussions which resulted in the final approved set of 31 complex changes.

The complex changes implemented in Version 20.0 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's.

Version 20.0 Change Requests

At the HLGT level: Four new High Level Group Terms (HLGTs) were added, two HLGTs were merged as a result of complex changes in Version 20.0. The changes are as follows:

New HLGTs

New HLGT	To SOC
Medication errors and other product use errors and issues	Injury, poisoning and procedural complications
Off label uses and intentional product misuses/use issues	Injury, poisoning and procedural complications
Overdoses and underdoses NEC	Injury, poisoning and procedural complications
Respiratory tract signs and symptoms	Respiratory, thoracic and mediastinal disorders

Table 2-1 New HLGTs

Merged HLGTs

Merged HLGT	To HLGT	To SOC
Medication errors	Medication errors and other product use errors and issues	Injury, poisoning and procedural complications
Product use issues	Medication errors and other product use errors and issues	Injury, poisoning and procedural complications

Table 2-2 Merged HLGTs

HLGT Moves: No HLGT moves were made.

At the HLT level: There were 14 new High Level Terms (HLTs) added, eight HLTs merged, and three moved as a result of complex changes in Version 20.0. The changes are as follows:

New HLTs

New HLT	To SOC
Fungal upper respiratory tract infections	Respiratory, thoracic and mediastinal disorders
Intentional product misuses	Injury, poisoning and procedural complications
Intentional product use issues	Injury, poisoning and procedural complications
Medication errors, product use errors and issues NEC	Injury, poisoning and procedural complications
Product administration errors and issues	Injury, poisoning and procedural complications
Product confusion errors and issues	Injury, poisoning and procedural complications
Product dispensing errors and issues	Injury, poisoning and procedural complications
Product monitoring errors and issues	Injury, poisoning and procedural complications
Product preparation errors and issues	Injury, poisoning and procedural complications
Product prescribing errors and issues	Injury, poisoning and procedural complications
Product selection errors and issues	Injury, poisoning and procedural complications
Product storage errors and issues in the product use system	Injury, poisoning and procedural complications
Product transcribing errors and communication issues	Injury, poisoning and procedural complications
Substance related and addictive disorders	Psychiatric disorders

Table 2-3 New HLTs

Merged HLTs

Merged HLT	To HLT	SOC
Intercepted medication errors	Product selection errors and issues	Injury, poisoning and procedural complications
Maladministrations	Product administration errors and issues	Injury, poisoning and procedural complications
Medication errors NEC	Medication errors, product use errors and issues NEC	Injury, poisoning and procedural complications
Medication monitoring errors	Product monitoring errors and issues	Injury, poisoning and procedural complications
Product use issues NEC	Medication errors, product use errors and issues NEC	Injury, poisoning and procedural complications
Sleep disorders due to general medical condition	Sleep disorders NEC	Psychiatric disorders

Version 20.0 Change Requests

Merged HLT	To HLT	SOC
Sleep disorders related to another mental condition	Sleep disorders NEC	Psychiatric disorders
Substance-related disorders	Substance related and addictive disorders	Psychiatric disorders

Table 2-4 Merged HLTs

HLT Moves

HLT	From HLGT	To HLGT	In SOC
Lower respiratory tract signs and symptoms	Respiratory disorders NEC	Respiratory tract signs and symptoms	Respiratory, thoracic and mediastinal disorders
Respiratory signs and symptoms NEC	Respiratory disorders NEC	Respiratory tract signs and symptoms	Respiratory, thoracic and mediastinal disorders
Upper respiratory tract signs and symptoms	Respiratory disorders NEC	Respiratory tract signs and symptoms	Respiratory, thoracic and mediastinal disorders

Table 2-5 Moved HLTs

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 several MedDRA releases 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 20.0

3.1 REVISIONS TO MEDICATION ERROR AND PRODUCT USE ISSUES HIERARCHIES

The addition of HLT *Product use issues* in MedDRA Version 18.0 has caused some confusion because it forced users to make a somewhat artificial distinction between product use issues in the newly added HLT and medication error concepts in existing HLT *Medication errors*. In practice, some of these concepts may overlap. For example, there were terms such as PT *Extra dose administered* under HLT *Medication errors* that do not specify error or accidental, and there were neutral terms in HLT *Product use issues NEC* such as PT *Drug administered to patient of inappropriate age* that could represent a medication error, misuse, or off label use, depending on the circumstances. To address this issue, the MSSO solicited input from the MedDRA Expert Panel and the ICH M1 Points to Consider Working Group on revisions to the medication error and product use issues hierarchies. The resulting complex change proposal was posted for feedback from the MedDRA user community. See the figure below for the new hierarchy implemented in MedDRA Version 20.0.

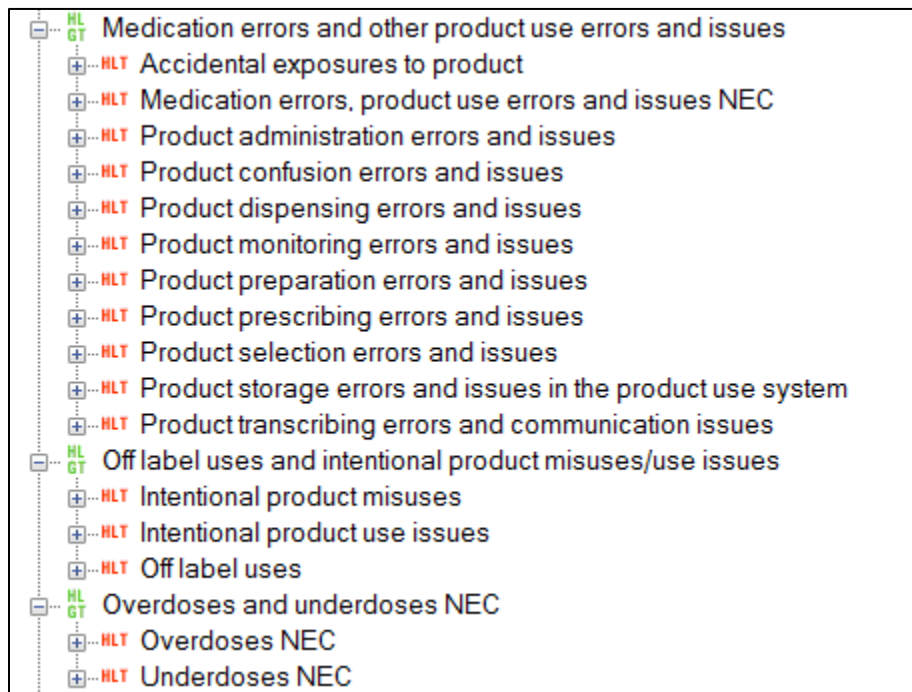


Figure 3-1 Medication error and Product use issues hierarchy

The new hierarchy groups the medication errors and unspecified product use issues terms together under new HLT *Medication errors and other product use errors and issues* avoiding the forced classification between these sometimes overlapping concepts. Additional advantages of the new hierarchy include:

- New HLTs have been added such as HLT *Product dispensing errors and issues* which correspond to the various stages in the medication/product use process (prescribing, storage, dispensing, preparation for administration, and administration)
- Intercepted medication errors have been moved under relevant stage HLTs; for example, PT *Intercepted drug prescribing error* is under HLT *Product prescribing errors and issues*
- By referring to “product,” the HLTs cover not only medication error/issues but other product concepts such as device use errors/issues
- Intentional concepts have been separated from errors/unspecified issues and now reside in HLGT *Off label uses and intentional product misuses/use issues*
- Intentional and unspecified overdose and underdose terms are grouped separately in HLGT *Overdoses and underdoses NEC*. Accidental overdose and underdose terms are in HLT *Product administration errors and issues*.

For detailed information on the placement of PTs in the revised hierarchy, please use the [Web-Based Browser](#).

3.2 STANDARDISED MedDRA QUERIES (SMQs)

No new level 1 SMQs were added in MedDRA Version 20.0. There were structural changes to existing SMQs. This included the addition of four level 4 sub-search SMQs (two each) to level 3 *Malignant tumours* (SMQ) and level 3 *Tumours of unspecified malignancy* (SMQ) which are under level 1 SMQ *Malignancies*. This was the result of work by the CIOMS SMQ Implementation Working Group to further enhance specificity options for case identification. The two sub-search SMQs added under *Malignant tumours* (SMQ) are:

- *Haematological malignant tumours* (SMQ)
- *Non-haematological malignant tumours* (SMQ)

The two sub-search SMQs added under *Tumours of unspecified malignancy* (SMQ) are:

- *Haematological tumours of unspecified malignancy* (SMQ)
- *Non-haematological tumours of unspecified malignancy* (SMQ)

See the graphic below which shows the full hierarchy of *Malignancies* (SMQ).

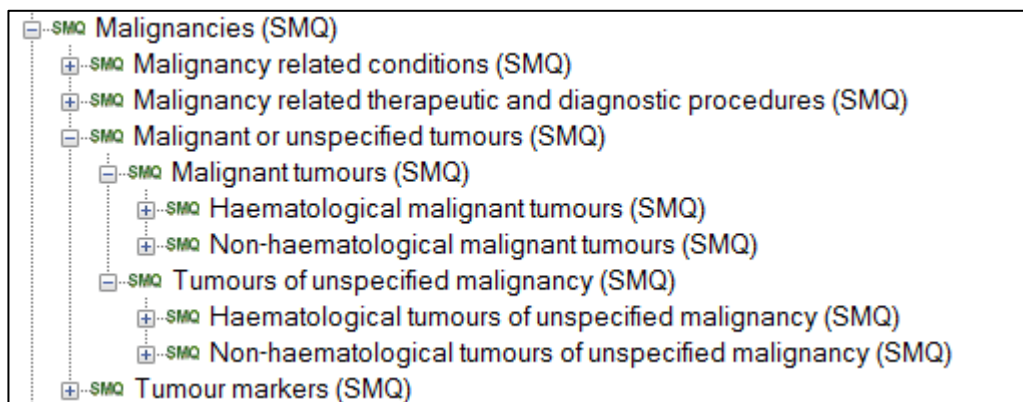


Figure 3-2 Malignancies (SMQ) Hierarchy

The PTs originally under *Malignant tumours (SMQ)* and *Tumours of unspecified malignancy (SMQ)* have been moved under the appropriate sub-search SMQs. For more information about the sub-search SMQs added to *Malignancies (SMQ)* please see the MedDRA Version 20.0 SMQ Introductory Guide.

3.3 UNQUALIFIED TEST NAME LIST

The MSSO has developed an Unqualified Test Name Term List and an explanatory document which are available for MedDRA users to download from the [support documentation](#) section of the MedDRA website. Unqualified test name terms, e.g., PT *Blood glucose*, are intended for use only in the test name data element in data transmission standards and are not meant for use in other data fields capturing information such as adverse events/adverse reactions or medical history.

The Unqualified Test Name Term List is an optional tool to help regulatory authority and industry users as a standardized list to check data quality by identifying the inappropriate use of unqualified test name terms in data fields other than the test name data element. The list is a comprehensive list of all unqualified test name terms at the Preferred Term (PT) and Lowest Level Term (LLT) levels in SOC *Investigations*. It is maintained and updated by the MSSO with every MedDRA release in spreadsheet form. Please contact the [MSSO Help Desk](#) if you have any questions.

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

3.4.1 Gradation of chemical burns

The MSSO reviewed a request to consider adding a set of terms for gradation of chemical burns to MedDRA. After careful review, the following PTs were added to MedDRA for Version 20.0:

- PT *First degree chemical burn of skin*
- PT *Second degree chemical burn of skin*
- PT *Third degree chemical burn of skin*
- PT *Fourth degree chemical burn of skin*

These terms were added to primary HLT *Chemical injuries* in SOC *Injury, poisoning and procedural complications* with a secondary link to HLT *Dermatitis ascribed to specific agent* in SOC *Skin and subcutaneous tissue disorders*. Additionally, the MSSO switched the positions of PT *Chemical injury* and LLT *Chemical burn* so that Chemical burn is a PT and Chemical injury is an LLT. Elevating Chemical burn to the PT level aligns this concept with the new PTs and could be used in situations where the stage of chemical burn is not known.

3.4.2 Provide options that convey a reduction in visual ability

A MedDRA user requested that the MSSO provide consistent coding options that convey a reduction in visual ability, including a differentiation between reduction in visual acuity (sharpness of vision) and other reductions in vision. After performing a review, the MSSO has taken the following actions:

- A total of 12 LLTs were moved from PT *Visual acuity reduced* to PT *Visual impairment* for better conceptual term alignment. Examples include LLT *Vision decreased* and LLT *Poor vision*. For similar reasons, LLT *Transient partial visual loss* was moved from PT *Visual acuity reduced transiently* to PT *Blindness transient*.

New Developments in Version 20.0

- While MedDRA includes an extensive variety of LLTs subordinate to PTs such as PT *Visual acuity reduced* and PT *Visual impairment* which convey a reduction of visual ability, there may not always be clear categorical distinctions among terms pertaining to blindness, partial vision loss, and other concepts relating to visual impairment. To address this situation, the MSSO will propose new HLT *Visual impairment and blindness (excl colour blindness)* for the next MedDRA Version 21.0 Complex Change review to group such terms.

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 20.0. These tables are intended only as a reference. For detailed information on the changes to Version 20.0, please see the MedDRA Version Report included within the MedDRA download.

SOC, HLGTT, HLT Changes

Level	Change Request Action	Net Change	v19.1	V20.0
SOC	Total SOCs	0	27	27
HLGTT	New HLGTTs	4	0	4
	Merged HLGTTs	2	0	2
	Total HLGTTs ¹	2	335	337
HLT	New HLTs	14	0	14
	Merged HLTs	8	0	8
	Total HLTs ¹	6	1,732	1,738

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

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

Summary of Changes

PT Changes

Level	Change Request Action	v19.1	V20.0
PT	New PTs	298	324
	Promoted LLTs	34	24
	Demoted PTs	42	59
	Net Change ¹	290	289
	Total PTs	22,210	22,499

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	v19.1	V20.0
LLT	Current Terms	773	67,222	67,995
LLT	Non-current Terms	7	9,246	9,253
LLT	Total LLTs ¹	780	76,468	77,248

Table 4-3 Summary of Impact on LLTs

¹Total LLTs include PTs as they are also represented as LLTs.

New SMQs

Level	Net Change	v19.1	V20.0
1	0	101	101
2	0	82	82

Summary of Changes

Level	Net Change	v19.1	V20.0
3	0	20	20
4	4	12	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 20.0. 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	4
	Removed	2
	Modified	0
HLGT.ASC	Added	4
	Removed	2
	Modified	0
HLGT_HLT.ASC	Added	21
	Removed	15
	Modified	0
HLT.ASC	Added	14
	Removed	8
	Modified	0
HLT_PT.ASC	Added	705
	Removed	220
	Modified	0

Summary of Changes

MDHIER.ASC	Added	843
	Removed	335
	Modified	0
PT.ASC	Added	348
	Removed	59
	Modified	13
LLT.ASC	Added	780
	Removed	0
	Modified	430
SMQ_LIST.ASC¹	Added ¹	4
	Removed	0
	Modified	217
SMQ_CONTENT.ASC	Added	8,203
	Removed	7,386
	Modified	1

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>	1,135	284	4,196	989	88	17
<i>Cardiac disorders</i>	1,430	335	2,344	601	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>	3,462	1,311	3,462	1,311	98	19
<i>Ear and labyrinth disorders</i>	428	87	807	204	17	6
<i>Endocrine disorders</i>	668	187	1,756	520	38	9
<i>Eye disorders</i>	2,432	592	3,701	998	64	13
<i>Gastrointestinal disorders</i>	3,807	847	7,486	1,697	108	21
<i>General disorders and administration site conditions</i>	2,412	977	3,213	1,265	36	7
<i>Hepatobiliary disorders</i>	650	191	1,455	423	19	4
<i>Immune system disorders</i>	457	142	2,567	687	26	4
<i>Infections and infestations</i>	7,079	1,907	7,430	2,000	149	12
<i>Injury, poisoning and procedural complications</i>	6,496	1,128	9,024	2,259	78	9
<i>Investigations</i>	13,512	5,518	13,512	5,518	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>	939	277	2,620	743	63	14
<i>Musculoskeletal and connective tissue disorders</i>	2,511	444	6,384	1,238	59	11
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	8,490	1,942	9,196	2,237	202	39
<i>Nervous system disorders</i>	3,531	938	7,085	1,898	107	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1,633	222	2,848	572	48	8
<i>Product issues</i>	589	145	596	149	21	2
<i>Psychiatric disorders</i>	2,341	508	3,170	740	76	23
<i>Renal and urinary disorders</i>	1,202	350	2,567	728	32	8
<i>Reproductive system and breast disorders</i>	1,715	475	4,147	1,150	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1,696	519	4,151	1,114	49	12
<i>Skin and subcutaneous tissue disorders</i>	2,054	489	4,670	1,341	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>	635	271	635	271	20	7
<i>Surgical and medical procedures</i>	4,632	2,107	4,632	2,107	141	19
<i>Vascular disorders</i>	1,312	306	6,613	1,601	68	11
Total	77,248	22,499				

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, and facilitates the reuse of the same MedDRA code for the renamed PT/LLTs.

Summary of Changes

The table below lists four terms modified in English MedDRA Version 20.0.

Code	Level	Term Name in v19.1	Term Name in v20.0
10012410	LLT	deQuervain's thyroiditis	De Quervain thyroiditis
10078658	PT	Medical device site hyperhidrosis	Medical device site hyperhidrosis
10044669	LLT	Trihammer pulse	Trip-hammer pulse
10050509	LLT	Urinary bladder perforation interoperative	Urinary bladder perforation intraoperative

Table 4-7 Modified PT/LLT Names

4.5 LLT CURRENCY STATUS CHANGES

The following table reflects the 11 terms at the LLT level in MedDRA Version 20.0 that have a change in their currency status along with the rationale for the change.

Lowest Level Term	Currency Status Changed to	Rationale
Angioedema of larynx	Current	Based on a MedDRA user request, LLT <i>Angioedema of larynx</i> was changed to a status of current as it is a valid concept.
Rash tongue	Current	LLT <i>Rash tongue</i> was made current to enhance coding options for reported verbatim terms.
Edema limbs-trunk of	Non-current	<i>LLT Edema limbs-trunk of</i> was changed to a non-current status because it represents a vague concept.
Extended oligoarthritis	Non-current	The status of LLT <i>Extended oligoarthritis</i> under PT <i>Juvenile idiopathic arthritis</i> was changed to non-current to avoid confusion with rare reports of extended oligoarthritis in adults. A more specific LLT <i>Extended juvenile oligoarthritis</i> was added under PT <i>Juvenile idiopathic arthritis</i> .
LE-like rash	Non-current	Because of the ambiguity of the abbreviation, "LE," the status of LLT <i>LE-like rash</i> was changed to non-current.

Summary of Changes

Lowest Level Term	Currency Status Changed to	Rationale
Oedema limbs-trunk of	Non-current	<i>LLT Oedema limbs-trunk of</i> was changed to a non-current status because it represents a vague concept.
Product difficult to remove	Non-current	Based on MedDRA user feedback, <i>LLT Product difficult to remove</i> has been used in practice to represent different concepts. It has largely been used to code patient/consumer complaints that a topical product is difficult to remove from its application site, leaving a residue, which is a quality issue. It has also been used to code reports that the product is difficult to remove from packaging. Given that the term has different interpretations and it is ambiguous, it has been made non-current. Note that terms have been added to provide specificity in coding the two concepts described above - <i>LLT Topical product difficult to remove from application site</i> under PT <i>Product quality issue</i> and <i>LLT Product packaging difficult to open</i> under PT <i>Product use complaint</i> .
Product reconstitution issue	Non-current	PT <i>Product reconstitution issue</i> was demoted to an LLT under new PT <i>Product reconstitution quality issue</i> and changed to a status of non-current. "Product reconstitution issue" is an ambiguous term as it can be interpreted as a product quality issue resulting from an issue with reconstitution or it can be interpreted as a medication error in the preparation of a product such as an inappropriate technique used in reconstitution.
Sore inflamed tongue	Non-current	<i>LLT Sore inflamed tongue</i> was changed to a status of non-current because it represents a combination of two concepts and the term "sore" could have multiple interpretations. Sore tongue is represented by existing <i>LLT Sore tongue</i> ; Inflamed tongue is represented by existing <i>LLT Inflammation tongue</i> .
Systemic erythematous rash	Non-current	The status of <i>LLT Systemic erythematous rash</i> (PT <i>Systemic lupus erythematous rash</i>) was changed to non-current because it is an ambiguous term and it is not clear that it specifically refers to a systemic lupus erythematous rash
Twilight vision	Non-current	Because "Twilight vision" is the normal ability to see in reduced illumination, the term as worded does not represent a vision disorder per se. Therefore, <i>LLT Twilight vision</i> was changed from current to non-current status.

Table 4-8 LLT Currency Changes