What's New
MedDRA Version 23.0

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 22.1 and 23.0.

Section 2, Version 23.0 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 23.0, highlights changes in Version 23.0 related to change request submissions, new initiatives, information on Standardised MedDRA Queries (SMQs), and any recent updates to software tools provided by the MSSO.

Section 4, Summary of Changes, contains details on:

- The impact of this version on the terminology (in tables)

- Impact on the records in MedDRA files

- MedDRA term and SMQ counts

- Modified Lowest Level Terms (LLT) and Preferred Term (PT) names

- LLTs in MedDRA that had a currency status change.

All updated documentation associated with this version is located in the distribution file in Adobe® Portable Document Format (PDF) or, for some documents, Microsoft Excel. Please refer to the Readme.txt file for a complete listing.

The Maintenance and Support Services Organization (MSSO) Help Desk can be reached at International AT&T Toll Free at 1-877-258-8280 or mssohelp@meddra.org.

2.   VERSION 23.0 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 23.0 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 was a total of 2,083 change requests processed for this version; 1,850 change requests were approved and implemented, and 225 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. Additionally, supplemental changes may be viewed in MedDRA Web-Based Browser via the "supplemental view" feature. Supplemental information may be helpful for users to identify changes that will be implemented in the next release.

An explanation of all changes considered (approved and not approved) for MedDRA Version 23.0 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 23.0 (shown in Table 4-6) and the corresponding information for Version 22.1. 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 23.0.

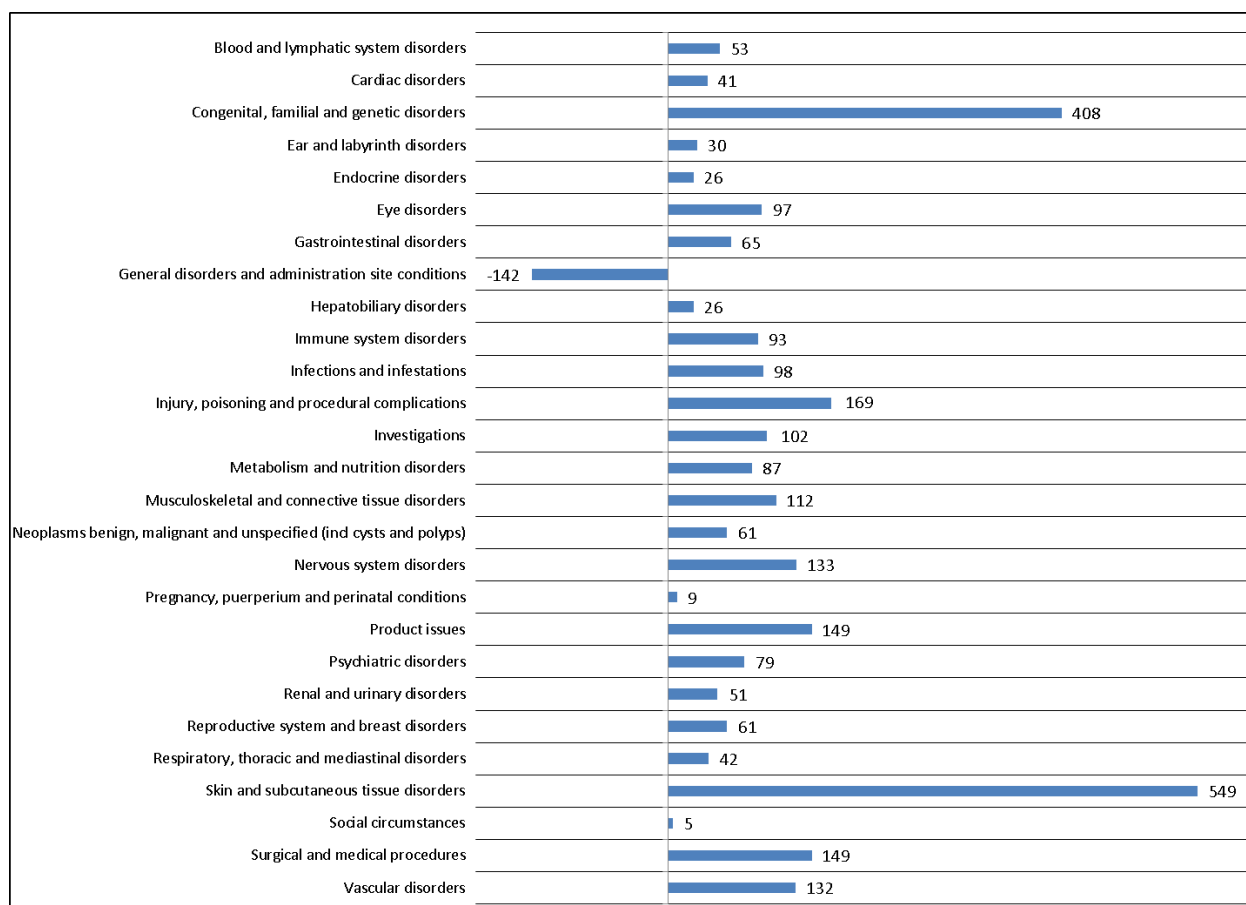| SOC	Net Change
Blood and lymphatic system disorders	53
Cardiac disorders	41
Congenital, familial and genetic disorders	408
Ear and labyrinth disorders	30
Endocrine disorders	26
Eye disorders	97
Gastrointestinal disorders	65
General disorders and administration site conditions	-142
Hepatobiliary disorders	26
Immune system disorders	93
Infections and infestations	98
Injury, poisoning and procedural complications	169
Investigations	102
Metabolism and nutrition disorders	87
Musculoskeletal and connective tissue disorders	112
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	61
Nervous system disorders	133
Pregnancy, puerperium and perinatal conditions	9
Product issues	149
Psychiatric disorders	79
Renal and urinary disorders	51
Reproductive system and breast disorders	61
Respiratory, thoracic and mediastinal disorders	42
Skin and subcutaneous tissue disorders	549
Social circumstances	5
Surgical and medical procedures	149
Vascular disorders	132

Figure 2-1 Net Changes of Terms per SOC

The changes in SOC *General disorders and administrative site conditions* and SOC *Congenital, familiar and genetic disorders* was due to the complex changes to update the placement of gene concepts in MedDRA. See sections 2.3 and 3.5 of this document for more details.   The number of changes in SOC *Skin and subcutaneous tissue disorders* was mostly due to the addition of secondary links to "burn" PTs such as PT *Thermal burn*, which have many underlying LLTs.

2.2   COMPLEX CHANGES

The proposals for complex changes considered during Version 23.0 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 29 July 2019 to 20 September 2019. Complex changes were followed by further internal review and consensus discussions which resulted in the final approved set of 12 complex changes.

The complex changes implemented in Version 23.0 are summarized below. Please see the "Related Documents" on the Change Request section of the MedDRA website for specific details.

At the SOC level: No changes were made to existing SOCs.

At the HLGT level: There was one High Level Group Term (HLGT) added and one merged as a result of complex changes in Version 23.0. The changes are as follows:

New HLGTs

New HLGT	To SOC
Chromosomal abnormalities, gene alterations and gene variants	Congenital, familial and genetic disorders

Table 2-1 New HLGTs

Merged HLGTs

HLGT	To HLGT	SOC
Chromosomal abnormalities and abnormal gene carriers	Chromosomal abnormalities, gene alterations and gene variants	Congenital, familial and genetic disorders

Table 2-2 Merged HLGTs

At the HLT level: There were three High Level Terms (HLTs) added, three merged and four moved as a result of complex changes in Version 23.0. The changes are as follows:

New HLTs

New HLT	To SOC
Abdominal and gastrointestinal injuries NEC	Injury, poisoning and procedural complications
Gene mutations and other alterations NEC	Congenital, familial and genetic disorders
Genetic polymorphisms	Congenital, familial and genetic disorders

Table 2-3 New HLTs

Merged HLTs

HLT	To HLT	SOC
Abdominal injuries NEC	Abdominal and gastrointestinal injuries NEC	Injury, poisoning and procedural complications
Acquired gene mutations and other alterations	Gene mutations and other alterations NEC	Congenital, familial and genetic disorders
Oral soft tissue pain and paraesthesia	Oral soft tissue signs and symptoms	Gastrointestinal disorders

Table 2-4 Merged HLTs

Moved HLTs

HLT	From HLGT	To HLGT	SOC
Abnormal gene carriers	Chromosomal abnormalities and abnormal gene carriers	Chromosomal abnormalities, gene alterations and gene variants	Congenital, familial and genetic disorders
Autosomal chromosomal abnormalities	Chromosomal abnormalities and abnormal gene carriers	Chromosomal abnormalities, gene alterations and gene variants	Congenital, familial and genetic disorders
Chromosomal abnormalities NEC	Chromosomal abnormalities and abnormal gene carriers	Chromosomal abnormalities, gene alterations and gene variants	Congenital, familial and genetic disorders
Sex chromosomal abnormalities	Chromosomal abnormalities and abnormal gene carriers	Chromosomal abnormalities, gene alterations and gene variants	Congenital, familial and genetic disorders

Table 2-5 Moved HLTs

3. NEW DEVELOPMENTS IN VERSION 23.0

3.1 BRAZILIAN PORTUGUESE MedDRA

The MSSO is pleased to announce that as of Version 23.0, Brazilian Portuguese MedDRA will be available to support the use of MedDRA in Brazil. Brazilian Portuguese MedDRA is provided to all users at no additional cost and includes the MedDRA term files, availability in the MedDRA Web-Based Browser and all the related documentation that is provided in other supported languages. Users may access Brazilian Portuguese MedDRA from the MedDRA website in the same manner as other languages. The MSSO will continue to maintain the European Portuguese translation of MedDRA.

Note that a Brazilian Portuguese Version Report and accessibility of Brazilian Portuguese term information in MVAT will be available in September 2020 when Version 23.1 debuts as there are not yet two Brazilian Portuguese versions to generate a comparison. For any specific questions about Brazilian Portuguese MedDRA and how to access it, please contact the MSSO Help Desk.

3.2 STANDARDISED MedDRA QUERIES (SMQs)

The SMQ *Opportunistic infections* was added in MedDRA Version 23.0. There are now 106 level 1 SMQs in production as of this version. In addition, there were 499 approved PT changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA Version 23.0 Version Report.

Please see the MedDRA Version 23.0 SMQ Introductory Guide for detailed information on new SMQ *Opportunistic infections.*

3.3 DEVICE PROBLEM TERMS

The MSSO added 114 terms and made 10 changes to existing terms as part of an initiative to include additional device problems in MedDRA. See the table below for examples.

LLT	PT	HLT	Primary SOC
Device fluid leak	Device leakage	Device issues NEC	Product issues
Device overinfusion	Device infusion issue	Device malfunction events NEC	Product issues
Device difficult to program	Device difficult to use	Medication errors, product use errors and issues NEC	Injury, poisoning and procedural complications

LLT	PT	HLT	Primary SOC
Incorrect measurement by device	Device information output issue	Device information output issues	Product issues

Table 3-1 Device Problem Terms

3.4   RARE AND ORPHAN DISEASES

The MSSO has added a set of 86 terms as part of an initiative to aid in coding indications for rare and orphan diseases. See the table below for examples.

LLT	PT	HLT	Primary SOC
Amyloid light-chain amyloidosis	Primary amyloidosis	Amyloidoses	Immune system disorders
Idiopathic CD4 lymphocytopenia	Idiopathic CD4 lymphocytopenia	Leukopenias NEC	Blood and lymphatic system disorders
FOXN1 deficient severe combined immunodeficiency	Combined immunodeficiency	Immune system abnormalities congenital	Congenital, familial and genetic disorders

Table 3-2 Examples of Rare and Orphan Disease Terms

3.5   UPDATES TO THE PLACEMENT OF GENE CONCEPTS

In Version 23.0, several terminology grouping changes were incorporated in SOC *Congenital, familial and genetic disorders* to improve the hierarchical placement of the gene concepts. HLGT *Chromosomal abnormalities and abnormal gene carriers* was replaced with new HLGT *Chromosomal abnormalities, gene alterations and gene variants* to represent that SOC *Congenital, familial and genetic disorders* is intended to cover gene concepts, whether they are acquired or congenital.

HLT *Gene mutations and other alterations NEC* was added to new HLGT *Chromosomal abnormalities, gene alterations and gene variants*, and former HLT *Acquired gene mutations and other alterations* was merged into the new HLT *Gene mutations and other alterations NEC*. This new HLT groups all gene conditions and alterations such as overexpressions, rearrangements, and mutations together, regardless of whether they are congenital or acquired, and separates gene concepts from chromosomal concepts which are represented in other HLTs of SOC *Congenital, familial and genetic disorders*.

Also, new HLT *Genetic polymorphisms* was added to HLGT *Chromosomal abnormalities, gene alteration and gene variants*. The creation of an HLT for genetic polymorphisms, which are considered gene variants rather than gene alterations, aids in the coding and retrieval of these concepts.

Section 6.3 of the Introductory Guide MedDRA Version 23.0 has been updated to reflect these changes. Additionally, 186 modifications were made to update the placement of the underlying PTs. See the examples in the table below.

PT Moved	From HLT	In SOC	To HLT	In SOC
Acquired gene mutation	Acquired gene mutations and other alterations	General disorders and administration site conditions	Gene mutations and other alterations NEC	Congenital, familial and genetic disorders
Acquired mitochondrial DNA deletion	Acquired gene mutations and other alterations	General disorders and administration site conditions	Genetic mitochondrial abnormalities NEC	Congenital, familial and genetic disorders
NAT1 polymorphism	Acquired gene mutations and other alterations	General disorders and administration site conditions	Genetic polymorphisms	Congenital, familial and genetic disorders
Vascular endothelial growth factor overexpression	Acquired gene mutations and other alterations	General disorders and administration site conditions	Gene mutations and other alterations NEC	Congenital, familial and genetic disorders

Table 3-3 Gene concept placement updates

For more information on the complex changes, please see section 2.2.

3.6   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 23.0 change request processing period, the MSSO reviewed three requests and implemented two 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.

3.6.1 Review of "disseminated" or "systemic" concepts

The MSSO assessed the placement of existing terms containing "disseminated" or "systemic" to improve the consistency of their placement in MedDRA as part of a proactive review requested by a MedDRA User. As a result of this review, 27 changes were made to better align these concepts and represent disseminated infection concepts at the PT level. See the examples in the table below.

New PT	HLT		Primary SOC
Disseminated toxoplasmosis	Toxoplasma infections		Infections and infestations
Promoted LLT	**From PT**	**To HLT**	**Primary SOC**
Disseminated blastomycosis	Blastomycosis	Blastomyces infections	Infections and infestations

Table 3-4 Examples of updates to "disseminated" and "systemic" concepts

3.6.2 Placement of "abrasion" terms

A MedDRA user requested a review of existing abrasion terms for consistency of placement in MedDRA. After reviewing the mapping of existing abrasion LLTs to injury PTs for appropriate representation of the underlying medical concept, the MSSO moved six existing abrasion LLTs from their erosion PTs to corresponding injury PTs. In addition, three new abrasion LLTs were added to corresponding injury PTs to improve coding options. See the tables below for examples.

LLT Moved	From PT	To PT
Abrasion of teeth	Tooth erosion	Tooth injury
Injection site abrasion	Injection site erosion	Injection site injury

New LLT	To PT
Lip abrasion	Lip injury
Mouth abrasion	Mouth injury

Table 3-5 Changes to "abrasion" terms

3.7 MedDRA MOBILE BROWSER MULTI-LINGUAL INTERFACE

The MSSO deployed a web-based mobile version of MedDRA Browser (MMB) in April 2019 designed to work on smartphones and tablet computers. In January 2020, the MMB was updated with a multi-lingual user interface (UI) for use on iOS and Android mobile devices. Users may choose any of the MedDRA languages as the UI language, including Chinese, Czech, Dutch, English, French, German, Hungarian, Italian, Japanese, Korean, Portuguese, Russian, and Spanish. In March 2020, with the release of Brazilian Portuguese MedDRA, the UI will also be available in Brazilian Portuguese.

Figure 3-1 Mobile MedDRA Browser Multi-lingual User Interface

To access the MMB, simply login using your MedDRA ID and Password. This password is the same password used to access the MedDRA website and other applications such as the Web-Based Browser and MVAT. If you don't know your User ID and Password, please use the MedDRA Self-Service Application.

4. SUMMARY OF CHANGES

4.1 SUMMARY OF IMPACT ON THE TERMINOLOGY

The tables below (Table*s* 4-1 through 4-5) summarize the impact on MedDRA in Version 23.0. These tables are intended only as a reference. For detailed information on the changes to Version 23.0, please see the MedDRA Version Report included within the MedDRA download or in MVAT.

SOC, HLGT, HLT Changes

Level	Change Request Action	Net Change	v22.1	v23.0
SOC	Total SOCs	0	27	27
HLGT	New HLGTs	1	0	1
	Merged HLGTs	1	0	1
	Total HLGTs[1]	0	337	337
HLT	New HLTs	3	0	3
	Merged HLTs	3	0	3
	Total HLTs[1]	0	1,737	1,737

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

[1] Total net change of HLGTs or HLTs equals the number of new HLGTs or HLTs minus the number of respective merged HLGTs or HLTs.

PT Changes

Level	Change Request Action	v22.1	v23.0
PT	New PTs	294	346
	Promoted LLTs	25	46

Level	Change Request Action	v22.1	v23.0
	Demoted PTs	73	57
	Net Change[1]	246	335
	Total PTs	23,954	24,289

Table 4-2 Summary of Impact on PTs

[1]Net change of PTs equals the number of new PTs plus the number of promoted LLTs minus the number of demoted PTs.

LLT Changes

Level	Currency Status	Net Change	v22.1	v23.0
LLT	Current Terms	913	71,603	72,516
LLT	Non-current Terms	5	9,291	9,296
LLT	Total LLTs[1]	918	80,894	81,812

Table 4-3 Summary of Impact on LLTs

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

New SMQs

Level	Net Change	v22.1	v23.0
1	1	105	106
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 23.0. 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	1
	Removed	1
	Modified	0
HLGT.ASC	Added	1
	Removed	1
	Modified	0
HLGT_HLT.ASC	Added	7
	Removed	7
	Modified	0
HLT.ASC	Added	3
	Removed	3
	Modified	0
HLT_PT.ASC	Added	848
	Removed	271
	Modified	0
MDHIER.ASC	Added	984
	Removed	353
	Modified	0
PT.ASC	Added	392
	Removed	57
	Modified	65
LLT.ASC	Added	918
	Removed	0
	Modified	305

SMQ_LIST.ASC[1]	Added[1]	1
	Removed	0
	Modified	225
SMQ_CONTENT.ASC	Added	4,484
	Removed	0
	Modified	187

Table 4-5 Summary of Impact on Records in MedDRA Files

[1] The number of SMQs added includes both top level (Level 1) and sub-search SMQs.

4.3 MedDRA TERM COUNTS

The table below shows term counts by SOC for HLGTs, HLTs, primary and secondary PTs and LLTs, and primary PTs and LLTs. Note that the number of LLTs also includes PTs.

SOC	LLTs (Primary)[1]	PTs (Primary)[1]	LLTs (Primary and Secondary)[2]	PTs (Primary and Secondary)[2]	HLTs[3]	HLGTs[3]
Blood and lymphatic system disorders	1,190	302	4,409	1,054	88	17
Cardiac disorders	1,509	366	2,455	648	36	10
Congenital, familial and genetic disorders	4,036	1,594	4,036	1,594	100	19
Ear and labyrinth disorders	445	95	872	226	17	6
Endocrine disorders	689	196	1,887	576	38	9
Eye disorders	2,541	642	3,930	1,094	63	13

Summary of Changes

SOC	LLTs (Primary)[1]	PTs (Primary)[1]	LLTs (Primary and Secondary)[2]	PTs (Primary and Secondary)[2]	HLTs[3]	HLGTs[3]
Gastrointestinal disorders	3,971	905	7,771	1,795	105	21
General disorders and administration site conditions	2,464	992	3,395	1,335	35	7
Hepatobiliary disorders	689	210	1,529	451	19	4
Immune system disorders	519	151	2,830	791	26	4
Infections and infestations	7,373	2,035	7,756	2,147	149	12
Injury, poisoning and procedural complications	6,925	1,277	9,730	2,511	78	9
Investigations	14,110	5,887	14,110	5,887	106	23
Metabolism and nutrition disorders	993	295	2,840	831	63	14
Musculoskeletal and connective tissue disorders	2,667	487	6,849	1,406	59	11
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	8,722	2,003	9,528	2,330	202	39
Nervous system disorders	3,792	1,007	7,608	2,094	108	20

Summary of Changes

SOC	LLTs (Primary)[1]	PTs (Primary)[1]	LLTs (Primary and Secondary)[2]	PTs (Primary and Secondary)[2]	HLTs[3]	HLGTs[3]
Pregnancy, puerperium and perinatal conditions	1,666	238	2,978	638	48	8
Product issues	812	173	831	182	21	2
Psychiatric disorders	2,401	545	3,348	832	77	23
Renal and urinary disorders	1,265	372	2,703	778	32	8
Reproductive system and breast disorders	1,801	509	4,395	1,236	52	16
Respiratory, thoracic and mediastinal disorders	1,793	557	4,395	1,205	49	12
Skin and subcutaneous tissue disorders	2,190	531	5,581	1,481	56	10
Social circumstances	649	279	649	279	20	7
Surgical and medical procedures	5,218	2,315	5,218	2,315	141	19
Vascular disorders	1,382	326	7,031	1,739	68	11
Total	**81,812**	**24,289**				

Table 4-6 MedDRA Term Counts

[1]Primary count only includes the number of terms that are primarily linked to the designated SOC at either the LLT level or the PT level. The sums of primary LLTs and PTs match those in Tables 4-2 and 4-3.

[2]Total count includes the number of terms that are both primarily and secondarily linked to the designated SOC at either the LLT level or the PT level. Therefore, the sums of total LLTs and PTs are greater than those in Tables 4-2 and 4-3.

[3]The HLT and HLGT counts are not necessarily unique values given MedDRA's multi-axiality (see Section 2.2 of the Introductory Guide for a discussion of multi-axiality). There are some HLTs that are counted in more than one SOC. For example, HLT *Connective tissue disorders congenital* and HLGT *Musculoskeletal and connective tissue disorders congenital* are counted in both SOC *Congenital, familial and genetic disorders* and SOC *Musculoskeletal and connective tissue disorders*. The sums of HLTs and HLGTs are greater than those found in Table 4-1.

4.4   MODIFIED PT AND LLT NAMES

As part of ongoing MedDRA maintenance activities, existing PTs and LLTs can be modified (renamed) to correct for misspelling, double spacing, capitalization, or other errors that meet the renaming criteria in MedDRA. This rename provision retains the original MedDRA code of the term and preserves its original meaning.

The table below summarizes terms modified in English MedDRA Version 23.0.

Code	Level	Term Name in v22.1	Term Name in v23.0
10082763	PT	Anaesthesic ophthalmic procedure	Anaesthetic ophthalmic procedure
10082784	LLT	Anesthesic ophthalmic procedure	Anesthetic ophthalmic procedure
10082946	LLT	Biospy site redness	Biopsy site redness
10065430	PT	HER-2 positive breast cancer	HER2 positive breast cancer
10066896	PT	HER-2 positive gastric cancer	HER2 positive gastric cancer
10075638	PT	HER-2 protein overexpression	HER2 protein overexpression
10083042	PT	Macrophage inflammatory protein - 1 alpha	Macrophage inflammatory protein-1 alpha
10083045	PT	Macrophage inflammatory protein 1-alpha decreased	Macrophage inflammatory protein-1 alpha decreased

Code	Level	Term Name in v22.1	Term Name in v23.0
10083049	PT	Macrophage inflammatory protein 1-alpha increased	Macrophage inflammatory protein-1 alpha increased

Table 4-7 Modified PT/LLT Names

4.5 LLT CURRENCY STATUS CHANGES

The following table reflects 3 terms at the LLT level in MedDRA Version 23.0 that had a change in currency status along with the rationale for the change.

Lowest Level Term	Currency Status Changed to	Rationale
Ear, nose and throat infection	Non-current	LLT *Ear, nose and throat infection* represents a combination concept of three distinct infection site concepts and therefore does not conform to MedDRA rules.
Pasteurella septica	Non-current	LLT *Pasteurella septica* was changed to a status of non-current status because this subspecies of Pasteurella multocida is very rarely used in contemporary medical literature and clinical descriptions. Furthermore, the term is ambiguous as it may refer to sepsis caused by the organism, or only the name of the organism itself, Pasteurella septica.
SVT	Non-current	Although SVT is commonly used as an abbreviation of Supraventricular tachycardia, the abbreviation is also used to represent other conditions, such as superficial vein thrombosis, subclavian vein thrombosis, sustained ventricular tachycardia, and supraventricular tachyarrhythmia. Because SVT may represent a variety of concepts, the status of LLT *SVT* was changed to non-current.

Table 4-8 LLT Currency Changes