What's New
MedDRA Version 14.0

MSSO-DI-6001-14.0.0

March 2011

ACKNOWLEDGEMENTS

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1. DOCUMENT OVERVIEW

This What's New document contains information on the source and types of changes made to the Medical Dictionary for Regulatory Activities (MedDRA) terminology between Version 13.1 and v14.0.

Section 2, Version 14.0 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, Proactive MedDRA Maintenance, describes a newly launched approach to MedDRA maintenance that does not rely on specific submitted change requests and that uses both MSSO and user input.

Section 4, New Developments in Version 14.0, highlights changes in v14.0 related to change request submissions, new initiatives, and information on Standardised MedDRA Queries (SMQs).

Section 5, 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 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). 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@ngc.com.

2. VERSION 14.0 CHANGE REQUESTS

2.1 TERMINOLOGY CHANGES

Changes to the MedDRA terminology originate from user change requests and MSSO internal change requests. Internal change requests result from MSSO maintenance activities as well as special working group activities in which the MSSO participates.

MedDRA v14.0 is a complex change version which means changes can be made at all levels of the MedDRA hierarchy.

There was a total of 4543 change requests processed for this version with SMQ changes comprising 80% of these changes (3645). Please see Section 4.2 for more information on SMQ changes. Out of 4543 changes, 4272 change requests were approved and implemented, and 248 change requests were rejected. There are 23 change requests suspended for further consideration and resolution beyond this version.

An electronic copy of all changes is accessible both as a cumulative Detail Report (one that includes all change requests and actions taken for v14.0) as well as a weekly supplemental update file (for v14.0). Additionally, MedDRA users may look up individual changes 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 v14.0 shown in Table 5-6 and the corresponding information for v13.1. Additionally, term name changes and LLT status changes are included in Figure 2-1.

Please see Section 5 for a summary of the changes in MedDRA v14.0.

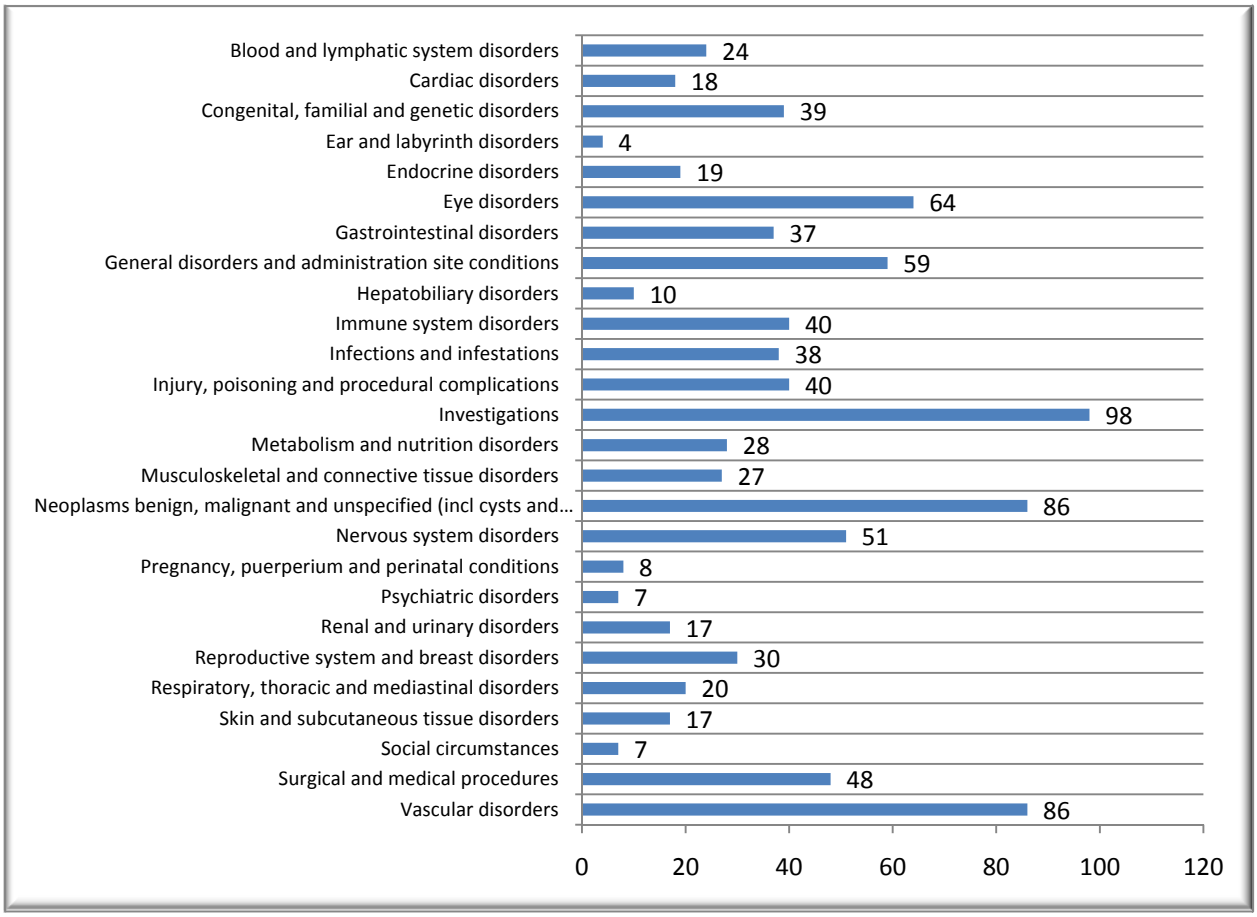

Figure 2-1. Changes per SOC

2.2 COMPLEX CHANGES

The proposals for complex changes considered during v14.0 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 MSSO Web site for feedback from the user community from 1 July 2010 to 30 July 2010. Complex changes were followed by further internal review and consensus discussions which resulted in the final approved set of 15 complex changes.

The complex changes implemented in v14.0 are summarized below. Please see the Complex Change section of the MSSO Web site for specific details.

At the SOC and HLGT level: No changes were made to existing SOC and HLGT terms and no new SOCs or HLGTs were added in v14.0.

At the HLT level: There were six new High Level Terms (HLTs) added and five HLTs merged as a result of the complex changes in v14.0. Additionally, three multi-axial HLTs were made uni-axial by removing one of their links, and one HLT was renamed. The changes are as follows:

New HLTs

New HLT	To HLGT
Acquired mutations NEC	General system disorders NEC
Disorders of purine metabolism	Purine and pyrimidine metabolism disorders
Disorders of pyrimidine metabolism	Purine and pyrimidine metabolism disorders
Enteroviral infections NEC	Viral infectious disorders
Peritoneal fluid and membrane function analyses	Gastrointestinal investigations
Social issues NEC	Lifestyle issues

Table 2-1. New HLTs

Merged HLTs

Merged HLT	To HLT
Enteroviral infections	Enteroviral infections NEC
Picornaviral infections	Viral infections NEC
Purine metabolism disorders NEC	Disorders of purine metabolism
Pyrimidine metabolism disorders NEC	Disorders of pyrimidine metabolism
Social issues	Social issues NEC

Table 2-2. Merged HLTs

HLT Link Changes

HLT unlinked	from HLGT
Purine metabolism disorders congenital	Purine and pyrimidine metabolism disorders
Pyrimidine metabolism disorders congenital	Purine and pyrimidine metabolism disorders
Renal disorders congenital	Renal disorders (excl nephropathies)

Table 2-3. Unlinked HLTs

Renamed HLTs

Code	Term Name in v13.1	Term Name in v14.0
10007208	Capnocytophagia infections	Capnocytophaga infections

Table 2-4. Renamed HLTs

HLT *Capnocytophagia infections* was renamed to HLT *Capnocytophaga infections* because Capnocytophaga is a more commonly used expression in medical literature than Capnocytophagia.

2.3 TRANSLATION CHANGES

In addition to terminology changes, there were 506 translation correction requests considered and 495 changes implemented to replace misspelled or mistranslated terms in the non-English versions of MedDRA. Below is a summary of the number of changes implemented and the language affected.

- 33 Chinese
- 1 Dutch
- 1 French
- 1 German
- 347 Italian
- 2 Portuguese
- 110 Spanish

The large number of changes to Italian MedDRA is due to continuing efforts by the MSSO and the Italian regulatory authority, Agenzia Italiana del Farmaco (AIFA), to identify and correct a set of issues with the Italian translation. The MSSO is in the

process of coordinating reviews of other European language translations for similar issues. Please see the Change Request section of the MSSO Web site if you wish to request corrections to a non-English version of MedDRA.

3. PROACTIVE MedDRA MAINTENANCE

Beginning in 2011, the MSSO is taking a more proactive approach to MedDRA maintenance.

Proactive Maintenance Definition

What is proactive MedDRA maintenance? In part, proactive maintenance means the MSSO may make corrections or improvements to MedDRA that it identifies without receiving specific change requests from users. Another part of proactivity relates to making more general changes to MedDRA – perhaps correcting a series of outdated terms or addressing an area of inconsistency – based on user input outside the change request process.

Submitting Ideas For Proactive Maintenance

The MSSO is interested to hear any ideas you may have about "proactive" improvements to MedDRA. Please e-mail your ideas for "proactive" MedDRA improvements to the MSSO Help Desk. Be as specific as possible in describing your idea.

Examples:

"Please identify all HLTs with only one PT and determine if the PT can be consolidated into other existing HLTs. Consolidating these 'single' PTs into existing HLTs could work to improve safety signal strength."

"There seem to be at the PT level inconsistency in the use of 'post-operative' and "post-procedural terms." It would be helpful for coders and would reduce their degree of effort and search time if these terms could be made consistent on one level of MedDRA."

A justification for submitted ideas would be appreciated.

Evaluating Proactive Maintenance Proposals

The MSSO will evaluate all input received for potential implementation in a future version of MedDRA. Please keep the following in mind:

- Unlike the change request process – the MSSO will not be obligated to respond to users on the disposition of their submitted "proactivity" ideas.
- The "proactivity" approach does not take the place of the usual change request process for individual changes in MedDRA. The MSSO will not process individual change requests submitted as "proactivity" ideas.

The latest information on proactive maintenance proposals can be found on the Proactivity section of the MSSO Web site.

4. NEW DEVELOPMENTS IN VERSION 14.0

4.1 ACRONYMS AND ABBREVIATIONS

In response to an independent medical review of the MedDRA terminology, the MSSO has published on the MSSO Web site a list of existing term acronyms and abbreviations. This list will be updated for each MedDRA version and includes the term name and spelled out name of each acronym and abbreviation. The intent is to provide more clarity and reduce the possibility of misinterpreting a specific acronym or abbreviation.

Please see the Abbreviation/Acronym section of the MSSO Web site for the current list of acronyms and abbreviations. If you find existing acronyms or abbreviations terms that are not in the list, please e-mail the MSSO Help Desk.

4.2 STANDARDISED MedDRA QUERIES (SMQS)

Based on input from users and from the CIOMS SMQ Working Group, several Standardised MedDRA Queries (SMQs) have undergone substantial changes for MedDRA v14.0. These are listed below for your information. Please see the Introductory Guide for Standardised MedDRA Queries (SMQs) v14.0 for more details on these changes.

"Malignant or unspecified" SMQs

Two new sub-search SMQs have been added to existing "malignant and/or unspecified" SMQs to allow users to retrieve malignant-only events/cases; events/cases of neoplasms of unspecified malignancy; or a combination of malignant and unspecified neoplasm events/cases. The new sub-search SMQs have been added to the following existing SMQs:

- Biliary neoplasms malignant and unspecified
- Breast neoplasms, malignant and unspecified
- Liver neoplasms, malignant and unspecified
- Malignant or unspecified tumours
- Ovarian neoplasms, malignant and unspecified
- Prostate neoplasms, malignant and unspecified
- Skin neoplasms, malignant and unspecified
- Uterine and fallopian tube neoplasms, malignant and unspecified

The PTs under the existing "malignant and/or unspecified" SMQs have been moved to the respective malignant only or unspecified malignancy sub-search SMQs. See the Table 4-1 below for examples.

PT Name	MedDRA 13.1 SMQ	Moved to sub-search SMQ for MedDRA v14.0
Bile duct cancer recurrent	Biliary neoplasms malignant and unspecified	Biliary malignant tumours
Biliary neoplasm	Biliary neoplasms malignant and unspecified	Biliary tumours of unspecified malignancy
Acral lentiginous melanoma stage I	Skin neoplasms, malignant and unspecified	Skin malignant tumours
Biopsy skin abnormal	Skin neoplasms, malignant and unspecified	Skin tumours of unspecified malignancy

Table 4-1. New malignant only and unspecified malignancy SMQs

SMQ *Premalignant disorders*

Approximately 130 PTs in the five sub-search SMQs of SMQ *Premalignant disorders* have been made inactive per recommendation of the CIOMS SMQ Working Group for the following reasons:

- "Biopsy abnormal" concepts (e.g., PT *Biopsy lip abnormal*) and other nonspecific procedure terms (e.g., PT *Nasal polypectomy*) are unlikely to retrieve events/cases of interest
- Upon review, some terms were nonspecific, or were either already malignant (e.g., PT *Chronic myelomonocytic leukaemia*) or not truly premalignant (e.g., PT *Seborrhoeic keratosis*)
- Terms for risk factors (e.g., PT *Coeliac disease*) were made inactive because most SMQs generally exclude terms for risk factors; instead, wording on approaches to retrieving data related to malignancy risk factors will be added to the SMQ Introductory Guide.

Additionally, all terms in the five sub-search SMQs of SMQ *Premalignant disorders* have been made narrow in scope.

"Pregnancy" SMQ

SMQ *Adverse pregnancy outcome/reproductive toxicity (incl neonatal disorders)* has been made inactive and replaced with a new "pregnancy" SMQ *Pregnancy and neonatal topics*. The sub-search SMQs in SMQ *Pregnancy and neonatal topics* have

been designed to reflect the regulatory goals for monitoring of product safety related to pregnancy outcomes.

Please see the list below of sub-search SMQs in SMQ *Pregnancy and neonatal topics.*

- Congenital, familial and genetic disorders
- Foetal disorders
- Lactation related topics (incl neonatal exposure through breast milk)
    - Functional lactation disorders+
    - Neonatal exposures via breast milk+
- Neonatal disorders
- Normal pregnancy conditions and outcomes
- Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth)
- Termination of pregnancy and risk of abortion

+ Sub-search SMQ of SMQ *Lactation related topics (incl neonatal exposure through breast milk)*

SMQ *Congenital, familial and genetic disorders* has been moved from SMQ *Adverse pregnancy outcome/reproductive toxicity (incl neonatal disorders)* to the new SMQ *Pregnancy and neonatal topics*. All the PTs under SMQ *Congenital, familial and genetic disorders* have been changed from broad to narrow scope.

The inactive SMQ *Adverse pregnancy outcome/reproductive toxicity (incl neonatal disorders)* will remain in the MedDRA ASCII files for MedDRA v14.0. The MSSO plans to remove this SMQ from the distribution files prior to the release of MedDRA v14.1 and make the SMQ available as a separate download, similar to the retired Special Search Categories (SSC), on the MSSO Web site. Please note that the archived version of *Adverse pregnancy outcome/reproductive toxicity (incl neonatal disorders) (SMQ)* will be as it was in MedDRA v13.1.

Other SMQ Changes

- SMQ *Hypertension* – All laboratory terms that are not specific hypertension diagnostic concepts were changed from narrow to broad scope.
- SMQ *Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous* – All PTs changed from broad to narrow scope to be consistent with the other two sister sub-search SMQs (SMQ *Embolic and thrombotic events, arterial* and SMQ *Embolic and thrombotic events, venous*).

- SMQ *Haematopoietic cytopenias* – The word "haematopoietic" was added to the names of three sub-search SMQs of SMQ *Haematopoietic cytopenias* to reflect the focus of these SMQs on disorders of production**,** and not destruction, of blood cells (See Table 4-2). The name of sub-search SMQ *Cytopenia and haematopoietic disorders affecting more than one type of blood cell* was also slightly modified.

MedDRA 13.1 SMQ Name	New SMQ Name in MedDRA v14.0
Cytopenia and haematopoietic disorders affecting more than one type of blood cell	Haematopoietic cytopenias affecting more than one type of blood cell
Erythropenia	Haematopoietic erythropenia
Leukopenia	Haematopoietic leukopenia
Thrombocytopenia	Haematopoietic thrombocytopenia

Table 4-2. Renamed SMQs

- After consulting the CIOMS SMQ Working Group, approximately 50 salivary gland terms have been added to the sub-search SMQs of SMQ *Oropharyngeal disorders*. Upon review, it was determined that salivary gland disorders fall into the definition and scope of this SMQ.

4.3 HUNGARIAN TRANSLATION OF MedDRA

The MSSO is pleased to announce the release of a Hungarian translation of MedDRA. The translation will be available on 15 March 2011. The Hungarian translation of MedDRA is free with a MedDRA subscription and may be downloaded, along with the other supported European languages, from the Download section of the MSSO Web site. If you wish to use the Hungarian translation with the MedDRA Desktop Browser (MDB), you will need to upgrade to the latest browser version (beta 3.0.2) released January 2011. The only change in v3.0.2 is to properly load and display the Hungarian translation of MedDRA. Please see the Download section of the MSSO Web site to obtain MDB beta 3.0.2.

5. SUMMARY OF CHANGES

5.1 SUMMARY OF IMPACT ON THE TERMINOLOGY

The tables below (See Tables 5-1 through 5.5) summarize the impact on the MedDRA terminology in v14.0. These tables are intended only as a reference. For detailed information on the changes to v14.0, please see the MedDRA Version Report included within the English language download.

SOC, HLGT, HLT Changes

Level	Change Request Action	Net Change	v13.1	v14.0
SOC	Total SOCs	0	26	26
HLGT	New HLGTs	0	0	0
	Merged HLGTs	0	0	0
	Total HLGTs[1]	0	335	335
HLT	New HLTs	6	0	6
	Merged HLTs	5	0	5
	Total HLTs[1]	1	1709	1710

Table 5-1. Summary of Impact on SOCs, HLGTs, HLTs

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

PT Changes

Level	Change Request Action	v13.1	v14.0
PT	New PTs	165	189
	Promoted LLTs	16	23
	Demoted PTs	48	45
	Net Change[1]	133	167
	Total PTs	18919	19086

Table 5-2. 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	Change Request Action	Net Change	v13.1	v14.0
LLT	Total LLTs[1]	358	68661	69019

Table 5-3. Summary of Impact on LLTs

[1]Total LLTs include PTs.

SMQ Changes

Level	Change Request Action	Net Change	v13.1	v14.0
SMQs	New SMQs[1]	1	84	85

Table 5-4. Summary of Impact on SMQs

[1] The number of SMQs shown only includes top level SMQs.

5.2 SUMMARY OF IMPACT ON RECORDS IN MedDRA FILES

The table below summarizes the impact on the MedDRA terminology in v14.0. The table is intended only as 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	6
	Removed	8
	Modified	0
HLT.ASC	Added	6
	Removed	5
	Modified	1
HLT_PT.ASC	Added	443
	Removed	143
	Modified	0
MDHIER.ASC	Added	475
	Removed	194
	Modified	0
PT.ASC	Added	212
	Removed	45
	Modified	15
LLT.ASC	Added	358
	Removed	0

	Modified	490
SMQ_LIST.ASC[1]	Added[1]	25
	Removed	0
	Modified	180
SMQ_CONTENT.ASC	Added	12130
	Removed[2]	8558
	Modified	7635

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

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

[2] The number of removed PTs represents terms moved from one SMQ to another. Please see the SMQ changes described in Section 4.2.

5.3 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]	HLTs[3]	HLGTs[3]
Blood and lymphatic system disorders	978	228	3855	858	87	17
Cardiac disorders	1288	288	2111	517	36	10
Congenital, familial and genetic disorders	3043	1110	3043	1110	99	19
Ear and labyrinth disorders	418	81	737	181	17	6
Endocrine disorders	563	155	1519	429	38	9
Eye disorders	2297	513	3312	843	64	13
Gastrointestinal disorders	3428	736	6758	1455	109	21
General disorders and administration site conditions	2137	662	2664	813	49	9
Hepatobiliary disorders	579	165	1282	359	19	4

SOC	LLTs* (Primary)[1]	PTs (Primary)[1]	LLTs* (Primary and Secondary)[2]	PTs (Primary and Secondary)[2]	HLTs[3]	HLGTs[3]
Immune system disorders	425	111	1909	482	24	4
Infections and infestations	6480	1702	6758	1773	147	12
Injury, poisoning and procedural complications	5618	766	7194	1374	59	7
Investigations	12205	4814	12205	4814	105	23
Metabolism and nutrition disorders	878	251	2321	630	63	14
Musculoskeletal and connective tissue disorders	2213	382	5680	982	60	11
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7908	1720	8441	1938	203	40
Nervous system disorders	3111	775	6093	1535	107	20
Pregnancy, puerperium and perinatal conditions	1550	199	2520	481	47	8
Psychiatric disorders	2135	468	2888	656	78	23

SOC	LLTs* (Primary)[1]	PTs (Primary)[1]	LLTs* (Primary and Secondary)[2]	PTs (Primary and Secondary)[2]	HLTs[3]	HLGTs[3]
Renal and urinary disorders	1092	301	2343	631	32	8
Reproductive system and breast disorders	1604	424	3714	973	52	16
Respiratory, thoracic and mediastinal disorders	1531	458	3712	971	48	11
Skin and subcutaneous tissue disorders	1838	410	3849	987	56	10
Social circumstances	618	253	618	253	20	7
Surgical and medical procedures	3972	1861	3972	1861	140	19
Vascular disorders	1110	253	5394	1231	68	11
Total	**69019**	**19086**				

Table 5-6. 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 5-2 and 5-3.

[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 5-2 and 5-3.

[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 5-1.

5.4 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. This facilitates the reuse of the same MedDRA code for the renamed PT/LLTs.

The table below lists the PTs and LLTs renamed in MedDRA v14.0.

Code	Level	Term Name in v13.1	Term Name in v14.0
10061738	PT	Capnocytophagia infection	Capnocytophaga infection
10007207	LLT	Capnocytophagia infection NOS	Capnocytophaga infection NOS
10070026	PT	Capnocytophagia test positive	Capnocytophaga test positive
10067961	PT	Eastern cooperative oncology group performance status	Eastern Cooperative Oncology Group performance status
10069725	PT	Eastern cooperative oncology group performance status improved	Eastern Cooperative Oncology Group performance status improved
10067962	PT	Eastern cooperative oncology group performance status worsened	Eastern Cooperative Oncology Group performance status worsened

Table 5-7. Modified PT/LLT Names

5.5 LLT CURRENCY STATUS CHANGES

The following table reflects terms at the LLT level in MedDRA v14.0 that have a change in their currency status along with the rationale for that change.

Lowest Level Term	Currency Status Changed to	Rationale
Allergy to plants	Current	Upon reconsideration, the status of LLT *Allergy to plants* was made current. In a related change, LLT *Allergy to plants* was promoted to a PT under HLT *Allergic conditions NEC*.
FOB positive	Current	A MedDRA user requested a large set of LLT abbreviations and acronyms be made non-current because they can have different interpretations and therefore, in their opinion, are ambiguous. The user originally requested LLT *FOB negative* to be made non-current, but despite possible multiple interpretations, it was kept current due to its common usage worldwide for faecal occult blood. This is in accordance with Section 4.2 of the MedDRA Introductory Guide Version 13.1. Following this thought, the MSSO changed existing non-current LLT *FOB positive* to a status of current.
LVF	Current	A MedDRA user requested a large set of LLT abbreviations and acronyms be made non-current because they can have different interpretations and therefore, in their opinion, are ambiguous. The user originally requested LLT *RVF* to be made non-current, but despite possible multiple interpretations, it was kept current due to its common usage worldwide for right ventricular failure. This is in accordance with Section 4.2 of the MedDRA Introductory Guide Version 13.1. Following this thought, the MSSO changed the existing non-current LLT *LVF* to a status of current.
ANF positive	Non-Current	A MedDRA user requested a large set of LLT abbreviations and acronyms be made non-current because they can have different interpretations and therefore, in their opinion, are ambiguous. After an internal review and analysis, the MSSO changed the status of LLT *ANF positive* to non-current because the concept could have multiple interpretations such as antinuclear antibody or atrial natriuretic factor.
APA	Non-Current	A MedDRA user requested a large set of LLT abbreviations and acronyms be made non-current because they can have different interpretations and therefore, in their opinion, are ambiguous. After an internal review and analysis, the MSSO changed the status of LLT *APA* to non-current because the concept could have multiple interpretations such as, aldosterone-producing adenoma, anticipatory postural

Lowest Level Term	Currency Status Changed to	Rationale
		adjustment, acute perforating appendicitis, or acute phlegmonous appendicitis.
APA negative	Non-Current	A MedDRA user requested a large set of LLT abbreviations and acronyms be made non-current because they can have different interpretations and therefore, in their opinion, are ambiguous. After an internal review and analysis, the MSSO changed the status of LLT *APA negative* to non-current because the concept could have multiple interpretations such as, aldosterone-producing adenoma, anticipatory postural adjustment, acute perforating appendicitis, or acute phlegmonous appendicitis.
APA positive	Non-Current	A MedDRA user requested a large set of LLT abbreviations and acronyms be made non-current because they can have different interpretations and therefore, in their opinion, are ambiguous. After an internal review and analysis, the MSSO changed the status of LLT *APA positive* to non-current because the concept could have multiple interpretations such as, aldosterone-producing adenoma, anticipatory postural adjustment, acute perforating appendicitis, or acute phlegmonous appendicitis.
CF positive	Non-Current	A MedDRA user requested a large set of LLT abbreviations and acronyms be made non-current because they can have different interpretations and therefore, in their opinion, are ambiguous. After an internal review and analysis, the MSSO changed the status of LLT *CF positive* to non-current because the concept could have multiple interpretations such a positive test or positive diagnosis of cystic fibrosis or complement fixation test.
Device firing issue	Non-Current	Per a user request, the MSSO added LLT *Mechanical device firing issue* under PT *Device malfunction* and LLT *Electrical device firing issue* under PT *Device electrical finding*. Based upon these new LLTs, the existing LLT *Device firing issue* was made non-current to avoid confusion between an electrical or mechanical firing issue.
DU	Non-Current	A MedDRA user requested a large set of LLT abbreviations and acronyms be made non-current because they can have different interpretations and therefore, in their opinion, are ambiguous. After an internal review and analysis, the MSSO changed the status of LLT *DU* to non-current because without a modifier such as bleeding, the term DU is ambiguous and can be used to represent decubitus ulcer or duodenal ulcer.

Lowest Level Term	Currency Status Changed to	Rationale
GU	Non-Current	A MedDRA user requested a large set of LLT abbreviations and acronyms be made non-current because they can have different interpretations and therefore, in their opinion, are ambiguous. After an internal review and analysis, the MSSO changed the status of LLT *GU* to non-current because without a modifier such as bleeding, the term GU is ambiguous and can be used to concepts such as genitourinary or gastric ulcer.
Positive ANF	Non-Current	A MedDRA user requested a large set of LLT abbreviations and acronyms be made non-current because they can have different interpretations and therefore, in their opinion, are ambiguous. After an internal review and analysis, the MSSO changed the status of LLT *Positive ANF* to non-current because the concept could have multiple interpretations such as antinuclear antibody or atrial natriuretic factor.
Unable to focus	Non-Current	The wording of this term is ambiguous and can refer to visual as well as cognitive disorders. For visual symptoms, LLT *Difficulty focusing eyes* may be considered. For concepts relating to lack of concentration, LLTs under PT *Disturbance in attention* may be considered in addition to a multitude of existing cognitive disorder terms.

Table 5-8. LLT Currency Changes