What's New
MedDRA Version 14.1

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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) between Version 14.0 and Version 14.1.

Section 2, Version 14.1 Change Requests, provides information on the number of change requests processed for the version.

Section 3, New Developments in Version 14.1, highlights changes in v14.1 related to change request submissions, new initiatives, and information on Standardised MedDRA Queries (SMQs).

Section 4, WebCR Upgrade Available, discusses the new WebCR application.

Section 5, Summary of Changes, contains details on:

- Tables to show the impact of this version on the terminology
- Impact on the records in MedDRA files
- MedDRA term counts
- Modified Preferred Term (PT) and Lowest Level Term (LLT) 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 14.1 CHANGE REQUESTS

2.1 TERMINOLOGY CHANGES

Changes to MedDRA result both from subscriber change requests and from internal change requests. Internal change requests result from MSSO-generated maintenance activities as well as special working group activities in which the MSSO participates.

MedDRA v14.1 is a simple change version which means changes were made only at the PT and LLT levels.

Change requests involve both MedDRA updates and SMQ changes. There were a total of 1337 change requests processed for this version; 1041 change requests were approved and implemented, and 233 change requests were rejected. There are, in addition, 63 change requests suspended for further consideration and resolution beyond this version.

The electronic version of these changes is accessible both as a cumulative Detail Report (all change requests and actions taken for v14.1) which is included in the MedDRA English version download as well as a weekly supplemental update file (for v14.1). In addition, subscribers may review all change requests from MedDRA v5.1 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 v14.1 shown in Table 5-6 and the corresponding information for v14.0. 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 v14.1.

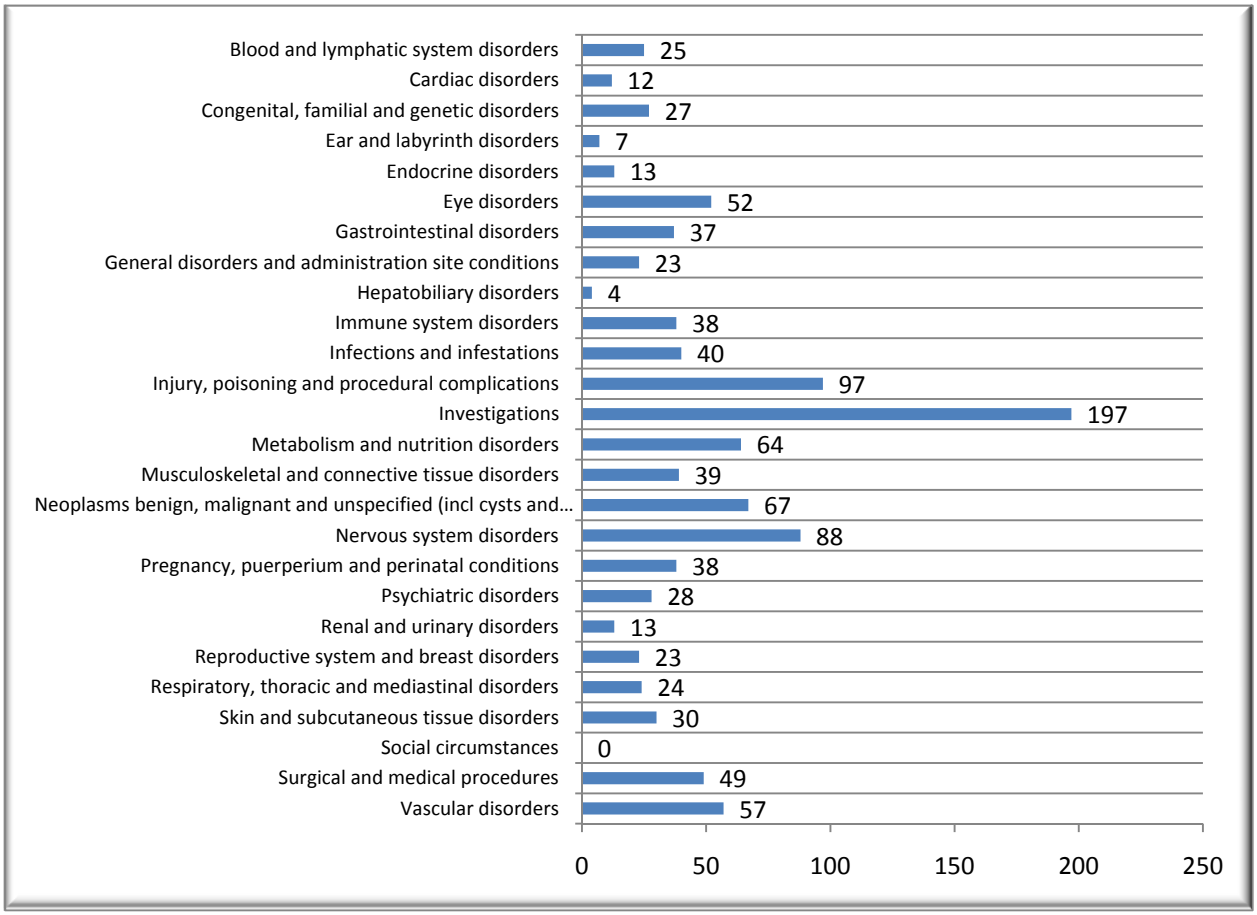

Figure 2-1 Changes Per SOC

2.2 TRANSLATION CHANGES

In addition to terminology changes, there were 106 translation correction requests considered and 103 changes implemented to replace misspelled or mistranslated terms in the non-English versions of MedDRA. Below is a summary of the number of changes made and the languages affected.

- 7 Chinese
- 90 French
- 4 German
- 2 Spanish

The large number of changes to French MedDRA is due to efforts by the MSSO and the Canadian regulatory authority, Health Canada, to identify and correct issues with the French translation. The MSSO is in the process of coordinating reviews of other European language translations for similar issues. MedDRA users that wish to send in translation corrections can enter them in WebCR or use the Translation Correction change request form located on change request section of the MSSO Web site.

3. NEW DEVELOPMENTS IN VERSION 14.1

3.1 PREGNANCY EXPOSURE TERMS

Based on suggestions from the ICH Points To Consider Working Group, new sets of pregnancy exposure terms have been added and existing terms reorganized to make them more self explanatory and easier to use for pharmacovigilance purposes.

Both the new and existing terms were organized to refer to circumstances involving transmission of various agents through intimate contact (e.g., mother to fetus or newborn, between partners, etc). The two main circumstances considered are exposures related to pregnancy and lactation, and terms representing relevant forms of potential transmission of various agents through intimate contact (e.g., PT *Exposure via partner*).

Existing terms where an actual harm is proved were not part of this set, even if they convey the concept of a pregnancy or intimate related previous exposure (e.g., PT *Maternal drugs affecting foetus* and PT *Anaesthetic complication foetal*). Additionally, existing exposure terms related to an agent or form of contamination which does not involve intimate contact and is only applicable to one individual (e.g., PT *Exposure to toxic agent*) were not included in this reorganization. Terms related to exposures to communicable diseases or environmental occupational and non-occupational exposures were not included either. Below is a summary of changes for MedDRA v14.1.

- 6 demoted PTs
- 19 moved terms (10 PTs, 9 LLTs)
- 29 new terms (14 PTs, 15 LLTs)

The MSSO plans to make additional changes to pregnancy exposure terms at the HLT and HLGT level for MedDRA v15.0. Please see the subscriber section of the MSSO Web site for a detailed list of changes made for v14.1 and changes for v15.0.

3.2 PHARMACOGENETIC TERMS

As a proactive Terminology Maintenance initiative, which originated from several MedDRA user submitted change requests, the MSSO added to MedDRA an initial group of pharmacogenetic and pharmacogenomic (PG) concepts of relevance to MedDRA users. The criteria used to add new terms focus on those genetic concepts and factors that have a potential impact on drug therapy. Below is a summary of changes for MedDRA v14.1.

- 2 demoted PTs
- 6 moved PTs

- 49 new terms (18 PTs, 31 LLTs)

The MSSO plans to make additional changes to PG concepts at the HLT level for MedDRA v15.0 Please see the subscriber section of the MSSO Web site for a detailed list of changes made for v14.1 and changes for v15.0.

3.3 STANDARDISED MedDRA QUERIES (SMQS)

Two new level 1 SMQs were released into production in MedDRA v14.1 – SMQ *Hypotonic-hyporesponsive episode* and SMQ *Fertility disorders*. There are now 86 level 1 SMQs in production as of this version.

SMQ *Events specifically reported as alcohol-related,* a subsearch SMQ under SMQ *Hepatic disorders,* was renamed to SMQ *Hepatic disorders specifically reported as alcohol-related.* The name of SMQ *Events specifically reported as alcohol-related*, when seen in isolation, could lead one to believe that the SMQ includes all alcohol related events, instead of events only related to alcohol-associated liver disease. The new name provides a more intuitive description for this SMQ.

Please see the Introductory Guide for Standardised MedDRA Queries (SMQs) v14.1 for details on these changes.

In addition to new and renamed SMQs, there has been one major change made to SMQs for this version - the removal of the inactive SMQ *Adverse pregnancy outcome/reproductive toxicity (incl neonatal disorders).* In MedDRA v14.0, the SMQ *Adverse pregnancy outcome/reproductive toxicity (incl neonatal disorders)* was made inactive and replaced with SMQ *Pregnancy and neonatal topics* which is designed to reflect the regulatory goals for monitoring of product safety related to pregnancy outcomes.

The MSSO removed SMQ *Adverse pregnancy outcome/reproductive toxicity (incl neonatal disorders)* from the MedDRA distribution files prior to the release of v14.1 and made it available as a separate download on the MSSO Web site in the SMQ archive section. Please note that the archived version of SMQ *Adverse pregnancy outcome/reproductive toxicity (incl neonatal disorders)* will be as it was in MedDRA v13.1, the most updated version of this SMQ.

4. WebCR UPGRADE AVAILABLE

The MSSO deployed an upgraded version of WebCR, the on-line application for MedDRA users to submit change requests, in July 2011. The enhanced version now supports Standardised MedDRA Queries (SMQs) and Translation Correction change requests. In addition, the user interface has been improved and issues with the previous WebCR version have been corrected.

For information about how to use WebCR, please view the WebCR Quick Reference guide located on the change request section of the MSSO Web site. More detailed information can be found in the Change Request Information document also located on the change request section of the MSSO Web site.

If you have any questions, please contact us at mssohelp@ngc.com.

5. SUMMARY OF CHANGES

5.1 SUMMARY OF IMPACT ON THE TERMINOLOGY

The tables below summarize the impact on MedDRA in v14.1. These tables are intended only as a reference. For detailed information on the changes to v14.1, please see the MedDRA Version Report located within the English language download.

SOC, HLGT, HLT Changes

Level	Change Request Action	Net Change	Version 14.0	Version 14.1
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	0	6	0
	Merged HLTs	0	5	0
	Total HLTs[1]	0	1710	1710

Table 5-1. 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 merged HLGTs or HLTs.

PT Changes

Level	Change Request Action	Version 14.0	Version 14.1
PT	New PTs	189	253
	Promoted LLTs	23	25
	Demoted PTs	45	70

Level	Change Request Action	Version 14.0	Version 14.1
	Net Change[1]	167	208
	Total PTs	19086	19294

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	Version 14.0	Version 14.1
LLT	Total LLTs[1]	505	69019	69524

Table 5-3. Summary of Impact on LLTs

[1]Total LLTs include PTs because every PT in MedDRA is also an LLT.

SMQ Changes

Level	Change Request Action	Net Change	Version 14.0	Version 14.1
SMQs	New SMQs[1]	1	85	86

Table 5-4. Summary of Impact on SMQs

[1] The number of SMQs shown only includes level 1 SMQs. Two level 1 SMQs were added, but an SMQ was removed for a net change of 1 SMQ. See Section 3-3 on the removal of inactive SMQ *Adverse pregnancy outcome/reproductive toxicity (incl neonatal disorders).*

5.2 SUMMARY OF IMPACT ON RECORDS IN MedDRA FILES

The table below summarizes the impact on MedDRA in v14.1. The table is intended only as reference.

ASCII File	Added, Removed, Modified	No. Records
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
HLT_PT.ASC	Added	461
	Removed	153
	Modified	0
MDHIER.ASC	Added	495
	Removed	176
	Modified	0
PT.ASC	Added	278
	Removed	70
	Modified	9

ASCII File	Added, Removed, Modified	No. Records
LLT.ASC	Added	505
	Removed	0
	Modified	364
SMQ_LIST.ASC[1]	Added[1]	2
	Removed[2]	4
	Modified	201
SMQ_CONTENT.ASC	Added	1130
	Removed[2]	3016
	Modified	123

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

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

[2] See Section 3-3 on the removal of inactive SMQ *Adverse pregnancy outcome/reproductive toxicity (incl neonatal disorders)*

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	981	236	3868	870	87	17
Cardiac disorders	1292	292	2119	522	36	10
Congenital, familial and genetic disorders	3060	1120	3060	1120	99	19
Ear and labyrinth disorders	418	81	742	183	17	6
Endocrine disorders	566	155	1527	434	38	9
Eye disorders	2323	524	3349	858	64	13
Gastrointestinal disorders	3426	741	6785	1467	109	21
General disorders and administration site conditions	2145	661	2682	817	49	9
Hepatobiliary disorders	584	166	1285	360	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	426	114	1932	498	24	4
Infections and infestations	6496	1705	6794	1780	147	12
Injury, poisoning and procedural complications	5675	784	7264	1400	59	7
Investigations	12351	4876	12351	4876	105	23
Metabolism and nutrition disorders	915	257	2373	642	63	14
Musculoskeletal and connective tissue disorders	2231	387	5708	992	60	11
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	7947	1735	8490	1955	203	40
Nervous system disorders	3147	789	6154	1562	107	20
Pregnancy, puerperium and perinatal conditions	1552	202	2551	488	47	8
Psychiatric disorders	2152	474	2908	663	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	1099	305	2351	636	32	8
Reproductive system and breast disorders	1610	428	3728	982	52	16
Respiratory, thoracic and mediastinal disorders	1540	463	3730	977	48	11
Skin and subcutaneous tissue disorders	1844	414	3870	996	56	10
Social circumstances	617	254	617	254	20	7
Surgical and medical procedures	4008	1874	4008	1874	140	19
Vascular disorders	1119	257	5432	1250	68	11
Total	**69524**	**19294**				

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]Primary and secondary PT counts include 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 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 RENAMED TERMS

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 v14.1.

Level	Code	Name in v14.0	Name in v14.1
PT/LLT	10015762	Extra-osseous Ewing's sarcoma nonmetastatic	Extra-osseous Ewing's sarcoma non-metastatic

Table 5-7. Modified PT/LLT Names

5.5 LLT CURRENCY STATUS CHANGES

The following table reflects terms at the LLT level in MedDRA v14.1 that have a change in their currency status along with the rationale for that change.

Lowest Level Term	Currency Status Changed to	Rationale
Pupillary block	Current	Although, pupillary block may develop into an etiological factor of glaucoma, it is nonetheless a concept unto itself. Therefore, pupillary block will be made current and promoted to the PT level under HLT *Anterior chamber structural change, deposit and degeneration*.
Exit block	Non-current	Even though the term 'exit block' is mainly used in context of device malfunctions, it also may be used for sinoatrial block and therefore it is appropriate to change the status to non-current. A new LLT *Device exit block* was added to PT *Device capturing issue.*

Lowest Level Term	Currency Status Changed to	Rationale
Post-traumatic syndrome	Non-current	The decision to make this term non-current originated with a request to promote *LLT Post-traumatic syndrome* to a PT. This request was rejected because promoting the term may lead to confusion with PT Post-traumatic stress disorder. For that reason, the MSSO changed the status of LLT *Post-traumatic syndrome* to non-current.
Stent-graft perforation	Non-current	Although the term may commonly be interpreted as a device material defect, it is an ambiguous term in that it may also pertain to complication of a device insertion procedure.

Table 5-8. LLT Currency Changes