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# What's New MedDRA Version 22.1

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September 2019

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**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 22.0 and 22.1.

Section 2, Version 22.1 Change Requests, provides a summary of information on the number of change requests processed for the version.

Section 3, New Developments in Version 22.1, highlights changes in Version 22.1 related to change request submissions, new initiatives, information on Standardised MedDRA Queries (SMQs), and any recent updates to software tools provided by the MSSO.

Section 4, Summary of Changes, contains details on:

- 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](mailto:mssohelp@meddra.org).

## 2. VERSION 22.1 CHANGE REQUESTS

### 2.1 TERMINOLOGY CHANGES

Changes to MedDRA result from user change requests, from proactivity requests submitted by MedDRA users, and from internal change requests. Internal change requests result from MSSO maintenance activities and from special working group activities in which the MSSO participates.

MedDRA Version 22.1 is a simple change version which means that changes are made only at the PT and LLT levels of the MedDRA hierarchy.

Change requests involve both MedDRA updates and SMQ changes. There was a total of 1,533 change requests processed for this version; 1,358 change requests were approved and implemented, and 174 change requests were not approved. There is, in addition, one change request 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.

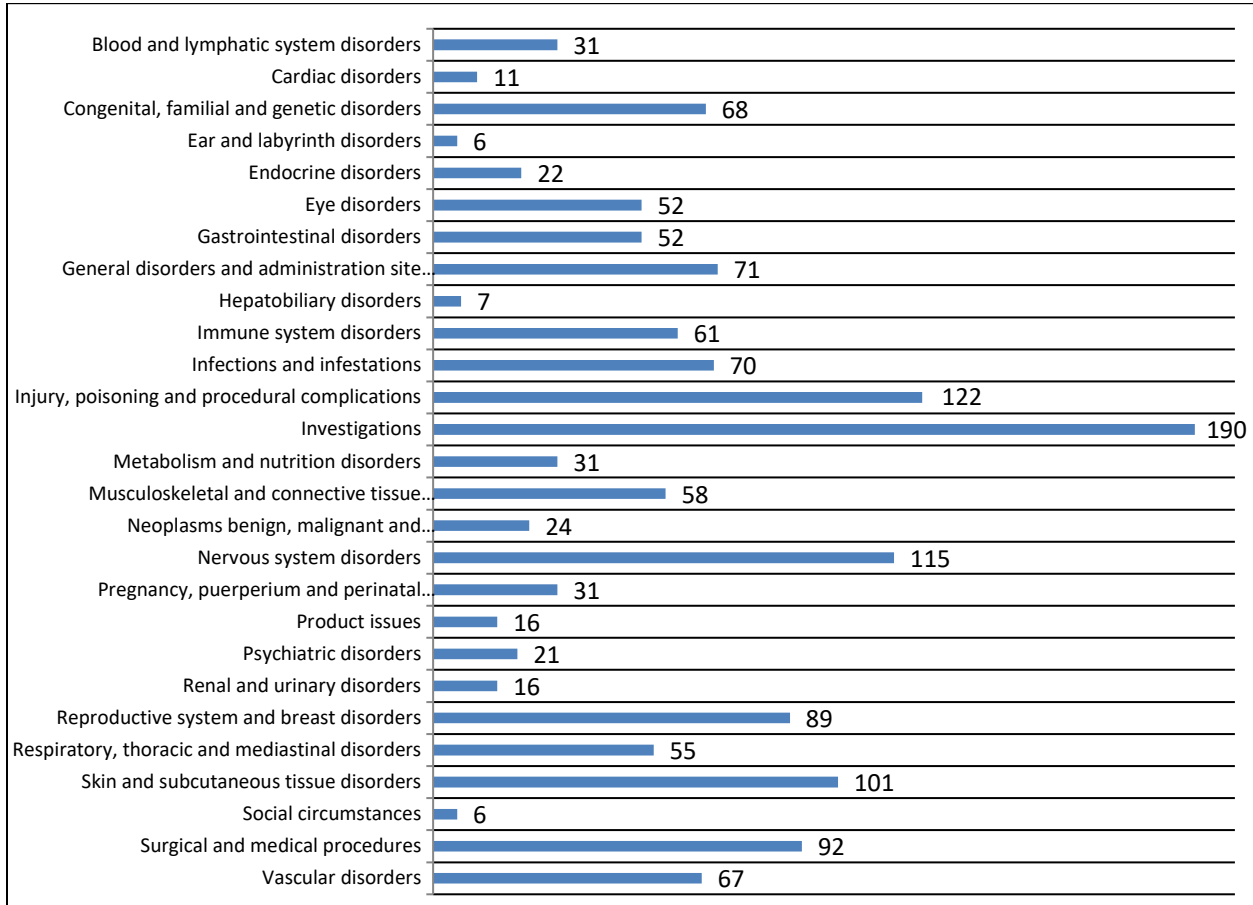
Between MedDRA releases, the MSSO makes available [weekly supplemental update](#) files, which are approved changes that will be implemented for the next MedDRA version. Additionally, supplemental changes may be viewed in MedDRA Web-Based Browser via the “supplemental view” feature. Supplemental information 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 22.1 is accessible as a cumulative Detail Report included in the MedDRA English version download. Users may review all change requests considered by the MSSO from MedDRA Version 5.1 to the present in [WebCR](#).

Figure 2-1 (shown below) summarizes all changes made per System Organ Class (SOC) and may be useful to gauge the impact of changes to a specific area of MedDRA. The data are derived from the difference in counts of primary and secondary PT/LLTs, HLTs, and HLGTS for Version 22.1 (shown in Table 4-6) and the corresponding information for Version 22.0. Additionally, term name changes and LLT currency status changes are included in Figure 2-1.

Please see Section 4 for a summary of the changes in MedDRA Version 22.1.

## New Developments in Version 22.1



**Figure 2-1 Net Changes of Terms per SOC**

### 3. NEW DEVELOPMENTS IN VERSION 22.1

#### 3.1 KOREAN MedDRA

The MSSO is pleased to announce that as of Version 22.1, Korean MedDRA will be available to MedDRA users. Korean 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 Korean MedDRA from the MedDRA website in the same manner as other languages. Note that a Korean Version Report and accessibility of Korean term information in MVAT will be available in March 2020 when Version 23.0 debuts as there are not yet two Korean versions to generate a comparison. For any specific questions about Korean MedDRA and how to access it, please contact the MSSO [Help Desk](#).

#### 3.2 STANDARDISED MedDRA QUERIES (SMQs)

New SMQ *Sepsis* was added in MedDRA Version 22.1. There are now 105 level 1 SMQs in production as of this version. Based on a review by regulatory and industry experts and endorsed by the CIOMS SMQ Implementation Working Group, *Sepsis* (SMQ) was created as an additional stand-alone SMQ and the relevant sepsis terms (55) in *Agranulocytosis* (SMQ) were made inactive. An additional 8 terms reflective of the hematologic changes associated with agranulocytosis were added to existing SMQ *Agranulocytosis*. In total, there were 331 approved PT changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA Version 22.1 Version Report.

Please see the MedDRA Version 22.1 SMQ Introductory Guide for detailed information on new SMQ *Sepsis* and changes to existing SMQ *Agranulocytosis*.

#### 3.3 PROACTIVITY REQUESTS

The proactive maintenance process allows MedDRA users to propose general changes to MedDRA outside of the established change request process. These proactivity requests may address inconsistencies, make corrections, or suggest improvements. During the Version 22.1 change request processing period, there were no open proactivity proposals that completed review. Two proposals are currently under review and are expected to be completed for the MedDRA Version 23.0 processing period. The MSSO publishes and updates a list of all proposals received and their status on the [Change Request](#) section of the MedDRA website.

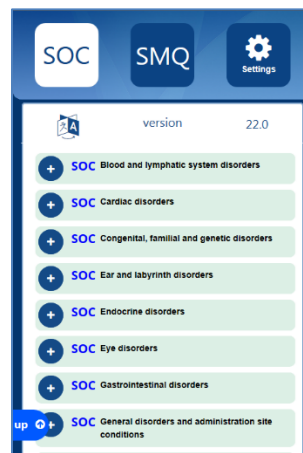
The MSSO is interested in learning about any ideas that users may have about “proactive” improvements to MedDRA. Please email your ideas for “proactive” MedDRA improvements to the MSSO Help Desk. Be as specific as possible in describing your

suggestion(s), and include a justification which explains why you think your proposal should be implemented.

### 3.4 MedDRA MOBILE BROWSER 3.0

The MSSO deployed a mobile version of MedDRA Browser (MMB) in April 2019 designed to work on smart phones and tablet computers. The mobile browser is a web based application that has many of the features of the Web-Based Browser including:

- Search MedDRA Term and Codes
- Browse the MedDRA hierarchy and SMQs
- Review term history
- Review term details



**Figure 3-1 Mobile MedDRA Browser**

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](#).

### 3.5 MedDRA VERSION ANALYSIS TOOL (MVAT) 3.0

The newest update to the [MedDRA Version Analysis Tool \(MVAT\)](#) is available for use as of June 2019. The following updates have been added to MVAT:

- An option to include Secondary SOC output in the Version or Data Impact reports
- Display changes between upcoming changes in the next release (Supplemental data) and the latest released version of MedDRA



## New Developments in Version 22.1

MedDRA Version Analysis Tool (MVAT)

Version Report Description

Select Different Versions to Compare

Language: English

Starting Version: MedDRA 21.1 English

Ending Version: MedDRA 22.0 English

Include Secondary SOC Information

Select SOCs to filter (default is all SOCs):

- Blood and lymphatic system disorders
- Cardiac disorders
- Congenital, familial and genetic disorders
- Ear and labyrinth disorders
- Endocrine disorders
- Eye disorders
- Gastrointestinal disorders
- General disorders and administration site conditions
- Hepatobiliary disorders
- Immune system disorders
- Infections and infestations
- Injury, poisoning and procedural complications

Clear Selection

Note: The starting MedDRA version must be older than the ending MedDRA version

Run Version Report

Preferred Language: English

Release/Supplemental View: Release

MVAT Home

Search Term Change

Data Impact Report

Logout

Figure 3-2 MVAT 3.0

To learn the new features of MVAT 3.0, please view or download the MVAT 3.0 videocast from the [Training Materials](#) section of the MedDRA.org website located under “Tools.”

To access the MVAT, 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. If you don't know your MedDRA ID and Password, please use the [MedDRA Self-Service Application](#) to retrieve them.

### 3.5.1 “Orphan” LLTs in SMQs

The latest update of the MedDRA Version Analysis Tool (MVAT 3.0) contains a new report showing LLT changes in SMQs. These changes result from SMQ maintenance performed by the MSSO including the addition of new PTs to SMQs and changes to existing LLTs such as promotions, demotions, and moves. During the course of MedDRA maintenance, an LLT may move from a PT that is in an SMQ to a PT that is not in an SMQ, in which case it is called an “orphan” LLT. These “orphan” LLTs are changed to an inactive status in the SMQ content file so that they no longer appear in the active term list of their original SMQ.

Due to an error in the SMQ implementation process, some of the inactive “orphan” LLTs had additional SMQ attributes modified such as scope and category. These SMQ attribute changes affected 11 “orphan” LLTs in MedDRA Versions 21.0 to 22.0 and will appear in the new MVAT LLT changes in SMQ report. The inadvertent changes to the “orphan” LLTs have no impact on the use of any SMQs. The process error has been fixed and will not affect MedDRA Version 22.1 and future versions. Please contact the Help Desk at [mssohelp@meddra.org](mailto:mssohelp@meddra.org) if more details are needed.

## 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 22.1. These tables are intended only as a reference. For detailed information on the changes to Version 22.1, please see the MedDRA Version Report included within the MedDRA download.

#### SOC, HLG T, HLT Changes

Level	Change Request Action	Net Change	v22.0	v22.1
<b>SOC</b>	Total SOCs	0	27	27
<b>HLGT</b>	New HLG Ts	0	0	0
	Merged HLG Ts	0	0	0
	Total HLG Ts <sup>1</sup>	0	337	337
<b>HLT</b>	New HLTs	0	0	0
	Merged HLTs	0	0	0
	Total HLTs <sup>1</sup>	0	1,737	1,737

**Table 4-1 Summary of Impact on SOCs, HLG Ts, HLTs**

MedDRA v22.1 is a simple change version which means changes are only made at the PT and LLT levels of the MedDRA hierarchy; hence there are no changes in the number of HLTs and HLG Ts.

<sup>1</sup> Total net change of HLG Ts or HLTs equals the number of new HLG Ts or HLTs minus the number of respective merged HLG Ts or HLTs.

## Summary of Changes

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### PT Changes

Level	Change Request Action	v22.0	v22.1
<b>PT</b>	New PTs	327	294
	Promoted LLTs	42	25
	Demoted PTs	50	73
	Net Change <sup>1</sup>	319	246
	Total PTs	23,708	23,954

**Table 4-2 Summary of Impact on PTs**

<sup>1</sup>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	v22.0	v22.1
<b>LLT</b>	Current Terms	626	70,977	71,603
<b>LLT</b>	Non-current Terms	6	9,285	9,291
<b>LLT</b>	Total LLTs <sup>1</sup>	632	80,262	80,894

**Table 4-3 Summary of Impact on LLTs**

<sup>1</sup>Total LLTs include PTs as they are also in the LLT distribution file.

**Summary of Changes**

**New SMQs**

<b>Level</b>	<b>Net Change</b>	<b>v22.0</b>	<b>v22.1</b>
<b>1</b>	1	104	105
<b>2</b>	0	82	82
<b>3</b>	0	20	20
<b>4</b>	0	16	16
<b>5</b>	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 22.1. The table is intended only as a reference.

<b>INTL_ORD.ASC</b>	Added	0
	Removed	0
	Modified	0
<b>SOC.ASC</b>	Added	0
	Removed	0
	Modified	0
<b>SOC_HLGT.ASC</b>	Added	0
	Removed	0
	Modified	0
<b>HLGT.ASC</b>	Added	0
	Removed	0
	Modified	0
<b>HLGT_HLT.ASC</b>	Added	0
	Removed	0
	Modified	0
<b>HLT.ASC</b>	Added	0
	Removed	0
	Modified	0

## Summary of Changes

<b>HLT_PT.ASC</b>	Added	530
	Removed	125
	Modified	0
<b>MDHIER.ASC</b>	Added	566
	Removed	149
	Modified	0
<b>PT.ASC</b>	Added	319
	Removed	73
	Modified	13
<b>LLT.ASC</b>	Added	632
	Removed	0
	Modified	252
<b>SMQ_LIST.ASC<sup>1</sup></b>	Added <sup>1</sup>	1
	Removed	0
	Modified	224
<b>SMQ_CONTENT.ASC</b>	Added	1020
	Removed	0
	Modified	281

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

<sup>1</sup> 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.

<b>SOC</b>	<b>LLTs (Primary)<sup>1</sup></b>	<b>PTs (Primary)<sup>1</sup></b>	<b>LLTs (Primary and Secondary)<sup>2</sup></b>	<b>PTs (Primary and Secondary)<sup>2</sup></b>	<b>HLT<sup>3</sup></b>	<b>HLGT<sup>3</sup></b>
<i>Blood and lymphatic system disorders</i>	1,169	297	4,367	1,043	88	17
<i>Cardiac disorders</i>	1,487	359	2,426	637	36	10

### Summary of Changes

SOC	LLTs (Primary) <sup>1</sup>	PTs (Primary) <sup>1</sup>	LLTs (Primary and Secondary) <sup>2</sup>	PTs (Primary and Secondary) <sup>2</sup>	HLTs <sup>3</sup>	HLGTs <sup>3</sup>
<i>Congenital, familial and genetic disorders</i>	3,760	1,465	3,760	1,465	98	19
<i>Ear and labyrinth disorders</i>	445	95	848	220	17	6
<i>Endocrine disorders</i>	683	195	1,866	571	38	9
<i>Eye disorders</i>	2,521	633	3,857	1,070	63	13
<i>Gastrointestinal disorders</i>	3,939	889	7,734	1,767	106	21
<i>General disorders and administration site conditions</i>	2,568	1,037	3,492	1,379	36	7
<i>Hepatobiliary disorders</i>	676	203	1,509	444	19	4
<i>Immune system disorders</i>	503	145	2,764	764	26	4
<i>Infections and infestations</i>	7,333	2,000	7,701	2,104	149	12
<i>Injury, poisoning and procedural complications</i>	6,861	1,259	9,610	2,462	78	9
<i>Investigations</i>	14,044	5,856	14,044	5,856	106	23
<i>Metabolism and nutrition disorders</i>	982	289	2,781	803	63	14

### Summary of Changes

SOC	LLTs (Primary) <sup>1</sup>	PTs (Primary) <sup>1</sup>	LLTs (Primary and Secondary) <sup>2</sup>	PTs (Primary and Secondary) <sup>2</sup>	HLTs <sup>3</sup>	HLGTs <sup>3</sup>
<i>Musculoskeletal and connective tissue disorders</i>	2,652	484	6,771	1,369	59	11
<i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i>	8,686	1,997	9,482	2,319	202	39
<i>Nervous system disorders</i>	3,758	994	7,512	2,053	108	20
<i>Pregnancy, puerperium and perinatal conditions</i>	1,660	234	2,977	630	48	8
<i>Product issues</i>	679	160	696	168	21	2
<i>Psychiatric disorders</i>	2,386	539	3,288	810	77	23
<i>Renal and urinary disorders</i>	1,246	365	2,667	763	32	8
<i>Reproductive system and breast disorders</i>	1,790	506	4,351	1,221	52	16
<i>Respiratory, thoracic and mediastinal disorders</i>	1,782	553	4,367	1,192	49	12
<i>Skin and subcutaneous tissue disorders</i>	2,163	523	5,059	1,453	56	10
<i>Social circumstances</i>	646	277	646	277	20	7

## Summary of Changes

SOC	LLTs (Primary) <sup>1</sup>	PTs (Primary) <sup>1</sup>	LLTs (Primary and Secondary) <sup>2</sup>	PTs (Primary and Secondary) <sup>2</sup>	HLTs <sup>3</sup>	HLGTs <sup>3</sup>
<i>Surgical and medical procedures</i>	5,109	2,277	5,109	2,277	141	19
<i>Vascular disorders</i>	1,366	323	6,931	1,707	68	11
<b>Total</b>	<b>80,894</b>	<b>23,954</b>				

**Table 4-6 MedDRA Term Counts**

<sup>1</sup>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.

<sup>2</sup>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.

<sup>3</sup>The HLT and HLGTT 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 HLGTT *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 HLGTTs 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 22.1.



### Summary of Changes

Code	Level	Term Name in v22.0	Term Name in v22.1
10066910	PT	LUMBAR syndrome	Lumbar syndrome
10082481	LLT	Obstructive sialadenitis	Obstructive sialadenitis
10082301	LLT	Serous incision site discharge	Incision site serous discharge
10082394	LLT	Severe achondroplasia with developmental delay and acanthosis nigrican	Severe achondroplasia with developmental delay and acanthosis nigricans
10082536	LLT	Transnasal humidified rapid-insufflation ventilator exchange	Transnasal humidified rapid-insufflation ventilatory exchange

**Table 4-7 Modified PT/LLT Names**

#### 4.5 LLT CURRENCY STATUS CHANGES

The following table reflects 6 terms at the LLT level in MedDRA Version 22.1 that had a change in currency status along with the rationale for the change.

Lowest Level Term	Currency Status Changed to	Rationale
Hepatomegaly tenderness	Non-current	Although LLT <i>Hepatomegaly tenderness</i> has been an LLT since MedDRA Version 2.1, this combination concept term may compromise signal detection if the term is selected to represent both hepatomegaly and hepatic tenderness. LLT <i>Hepatomegaly tenderness</i> is best represented with individual terms such as LLT <i>Liver tenderness</i> and LLT <i>Hepatomegaly</i> .
Hypersomnia related to another mental condition	Non-current	LLT <i>Hypersomnia related to another mental condition</i> was changed to a non-current status because the concept “another mental condition” is vague.
Insomnia related to another mental condition	Non-current	LLT <i>Insomnia related to another mental condition</i> was changed to a non-current status because the concept “another mental condition” is vague.
Lepromatous leprosy (type I)	Non-current	LLT <i>Lepromatous leprosy (type I)</i> was changed to a status of non-current because it is ambiguous and not consistent with current classifications which do not include a “type I”.

**Summary of Changes**

Lowest Level Term	Currency Status Changed to	Rationale
Lumbar syndrome	Non-current	“Lumbar syndrome” and “LUMBAR syndrome” are two different concepts distinguished only by the capitalization. Because many data systems do not recognize nor differentiate upper case from lower case characters, terms PT <i>Congenital LUMBAR syndrome</i> and LLT <i>Lumbar pain syndrome</i> were added in MedDRA Version 22.1 to avoid this issue. As a result, LLT <i>Lumbar syndrome</i> was changed to a status of non-current.
Other and unspecified nonspecific immunological findings	Non-current	LLT <i>Other and unspecified nonspecific immunological findings</i> was changed to a status of non-current because “findings” is a rather ambiguous term that does not represent a clear meaning.

**Table 4-8 LLT Currency Changes**