

Defining the Extent of MedDRA Versioning Updates: MSSO Recommendation

Purpose of This Document

This document addresses the question “what does it mean to update to the next version of MedDRA”? In that regard, it augments two “best practices” papers drafted by the MSSO

(<http://www.meddramsso.com/MSSOWeb/Docs/clinicaltrialversioning.pdf>;
<http://www.meddramsso.com/MSSOWeb/Docs/VCGuidesemiannual.pdf>) related to the timing of MedDRA updates in an attempt to clarify and harmonize the approach, particularly for regulatory reporting.

Updates to MedDRA have been on a twice yearly basis since 2001, and since then, there has been a general decline (and now a more or less steady rate) in the number of changes per MedDRA release. Nonetheless, users still need to account for the changes between each MedDRA version and make decisions on applying such changes to an ever-growing body of legacy MedDRA-coded data.

Over the past several years, MedDRA subscribers have asked for guidance on how to approach the challenge of assimilating and applying the changes made to MedDRA from one release to the next. The MSSO proposes a classification system that defines the extent to which an organization changes its legacy and real-time coding with each MedDRA release. It is hoped that these defined implementation “levels” will enhance communication of MedDRA-related information between organizations. This document also provides organizations – especially those new to MedDRA – with a series of options for new version implementation, including the benefits and limitations of these options.

There may be different approaches to the scope of version updates for clinical trial data vs. postmarketing safety data. For example, there may be no need to update clinical trial data from older trials if the data are not presently used or will not be used in the future. On the other hand, postmarketing safety data may be required to be reported in the current (or near-current) version of MedDRA, and version update recommendations then apply.

Scope of MedDRA Version Update

Extent of implementation

The effort involved in implementing MedDRA version updates relates primarily to changes to the coding level (Lowest Level Term – LLT) of MedDRA. When an organization states that it has implemented the latest version of MedDRA, it is important for the recipient of that information to understand to what extent the

new version has been applied so that the data shared between parties can be properly integrated or interpreted.

Because MedDRA LLTs are not deleted, an organization could simply apply the latest version without any legacy data changes. In other words, when a new version is available, an organization may simply begin to code all new data using the new version while leaving all prior legacy data in the MedDRA version in which they were originally coded.

However, an organization may wish to utilize the changes in the new version of MedDRA in varying degrees. For example, verbatim terms coded to LLTs that have become non-current in the new version could be re-linked to current LLTs.

Example:

Verbatim Term	Previous Version LLT	Version Change	New Version LLT (Re-coded)
RPGN (weeks duration)	Glomerulonephritis rapidly progressive chronic	LLT <i>Glomerulonephritis rapidly progressive chronic</i> became non-current in new version	Glomerulonephritis rapidly progressive

Or, an organization may choose to re-code verbatim terms to newly added LLTs that are matches (direct matches or lexical matches) to those verbatim terms. This may be especially true for LLTs that were added as a result of an organization's specific Change Requests.

Example:

Verbatim Term	Previous Version LLT	Previous Version PT	Version Change	New Version LLT (Re-coded)	New Version PT
Testosterone, deficiency of	Androgen deficiency	Androgen deficiency	LLT <i>Testosterone deficiency</i> was added to new version	Testosterone deficiency	Androgen deficiency

Finally, an organization may choose to evaluate all of its stored verbatim term data against all newly added LLTs, including those that do not word match or autoencode but represent a better "medical" match.

Example:

Verbatim Term	Previous Version LLT	Previous Version PT	Version Change	New Version LLT (Re-coded)	New Version PT
Bleeding during delivery	Bleeding	Haemorrhage	LLT/PT <i>Intrapartum haemorrhage</i> was added to new version	Intrapartum haemorrhage	Intrapartum haemorrhage

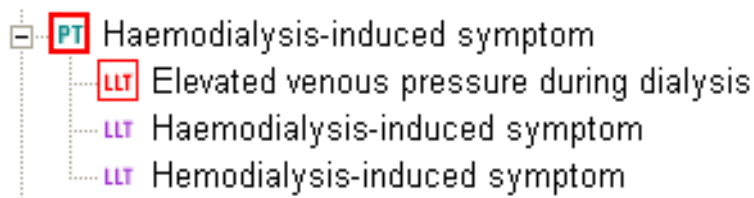
Not all options will apply to every organization's situation. For example, an organization may wish to apply one option to its regulatory (safety) database while keeping locked data from clinical trials in their original MedDRA versions. Decisions on which options to apply have impact on overall resource considerations, as described below.

Performing all three steps described above (i.e., recoding for non-current, LLTs, recoding for new matching LLTs, and recoding for medically better LLTs). makes the greatest use of the specificity of MedDRA, and assures that application of version-dependent queries, such as Standardised MedDRA Queries (SMQs), retrieve data optimally. For additional information, see *Impact of Version Changes on Data Presentation and Retrieval* below.

Resource considerations

The options noted above have varying degrees of resource requirements. The least resource requirements are when an organization simply begins to use the new version of MedDRA without addressing legacy coded data. The only resource considerations are generally the technical ones associated with loading MedDRA into various tools such as browsers and autoencoders.

There are additional resource considerations when identifying non-current LLTs for recoding. This involves identifying first the affected verbatim terms and then the appropriate new LLT for recoding. Some organizations may simplify (and automate) this step by recoding the verbatim term to the LLT that corresponds to the parent PT of the now non-current LLT. In the example below, LLT *Elevated venous pressure during dialysis* has become non-current in the new MedDRA version. Verbatim terms linked to this LLT could be automatically re-assigned to LLT *Haemodialysis-induced symptom*.



Others may opt to combine this step with a search for new direct matches and/or medically better matches; each of these latter steps entails more resources. In particular, the search for medically better matches is essentially a new term selection process involving adherence to coding conventions and QA review, both of which make this option the most resource intense of all.

Implementation levels

The options described above can be used to communicate to other parties the extent to which an organization has applied a new version of MedDRA. The MSSO recommends that organizations refer to their versioning practices by identifying their implementation “level”.

The table summarizes the types of version implementations (identified by level). Note that Level A is the most resource intense and Level D is the least.

Level	Description
A	Identify verbatim terms linked to non-current LLTs and recode existing data and Recode verbatim terms to new LLTs that are direct or lexical matches and Recode verbatim terms to new LLTs that are medically better matches
B	Identify verbatim terms linked to non-current LLTs and recode existing data and Recode verbatim terms to new LLTs that are direct or lexical matches
C	Identify verbatim terms linked to non-current LLTs and recode existing data
D	Begin to use new version for coding new data; no recoding of existing data

Practical Considerations of MedDRA Version Changes

Supplemental Changes

Approved change requests that are posted weekly on the MSSO site are called “supplemental changes”. These changes are incorporated into the subsequent version of MedDRA. A useful versioning strategy is to monitor these supplemental changes between releases of MedDRA; in particular, an organization may be keenly interested in supplemental changes resulting from its own Change Requests. By routinely reviewing the supplemental changes, an organization can assess the impact of these changes on their data and allocate

the necessary resources to deal with them. For example, if new LLTs are added that are better medical matches to verbatim terms stored in an organization's database, these can be assessed and flagged for upversioning in advance of the new version release.

Impact of Version Changes on Data Presentation and Retrieval

MedDRA users need to be aware that version changes potentially impact retrieval, presentation, and analysis of coded data. For example, if a PT is demoted to LLT status between versions, in the new version, that PT (and its associated verbatim data) may appear to have “disappeared” in standard outputs such as counts of events by primary SOC.

Additionally, for stored ad hoc queries used to retrieve MedDRA-coded data, the impact of term movements needs to be considered. For example, an organization may have a query to find cases of “compulsive behaviors” developed with terms from an older MedDRA version. Two new terms – LLT/PT *Compulsive sexual behaviour* and LLT/PT *Compulsive shopping* have been added to a more recent MedDRA version. If one were to search for potential cases of “compulsive behaviors” among data coded in the older MedDRA version but using a query developed in the more recent version, there is a potential to miss cases because the new PTs - PT *Compulsive sexual behaviour* and PT *Compulsive shopping* – are not part of the query.

For more information concerning the impact of version changes on data retrieval and presentation, please see the “*Data Retrieval and Presentation: Points to Consider*” document (<http://www.meddramsso.com/MSSOWeb/activities/PTC.htm>).

The complete impact of MedDRA version changes on maintenance of product labeling and on data reconciliation (i.e., serious adverse event reports jointly stored in clinical trial and safety databases) is out of the scope of this document. However, many of the same caveats regarding general presentation of data and the impact of MedDRA version changes apply to both of these processes. In addition, knowing the level of implementation used by each database may help to identify discrepancies based on version changes.

MSSO Recommendation

The MSSO advocates the use of standard descriptions of “levels” to define the extent to which an organization implements the new version of MedDRA. We believe this is very useful for communication and sharing of MedDRA-coded information, particularly in instances where this would occur over the span of more than one MedDRA version.