

Background and Blue Ribbon Panel Questions – Extent of Versioning Issue

Background

MedDRA “versioning” (i.e., the processing of updating with a new MedDRA release) has been an issue subscribers have had to address since the terminology was first made available to subscribers in 1999. Currently, MedDRA is released twice a year, and many subscribers have processes in place to deal with version updates.

Nevertheless, there is still a fundamental question that has not been fully addressed by the user community: “What does it *mean* to update to the next MedDRA version?”

Based on direct input from a subset of subscribers at a user group meeting in 2007,, the MSSO learned that to perform MedDRA “upversioning” means different things to different subscribers. Some subscribers may “upversion” by merely starting to use the new version of MedDRA without addressing legacy coded data, while other subscribers perform recoding of legacy data to various degrees to account for changes in the new MedDRA version.

Subscribers have expressed to the MSSO a need for a common and standard way to facilitate communicating the degree to which an organization applies the new MedDRA version; this is needed for transparency in data exchange between subscribing organizations.

Responding to this requirement, the MSSO drafted a document (“Defining the Extent of MedDRA Versioning Updates: MSSO Recommendation”). This document serves as the basis for discussion of BRP 6.

The “Defining the Extent” document – which contains a framework for communicating the extent of version updates – was initially posed to the MedDRA Management Board for their endorsement in May 2008. The Board recommended a number of edits and asked the MSSO to work with the Points to Consider Working group to revise the document. The revised version of the document is provided to the BRP members in a separate document.

Questions for the Panel to Address

During the course of the BRP meeting, the Panel will be asked to discuss and respond to the following questions:

1. Does the proposed system of versioning “levels” (page 4 of the document) adequately address the needs of users?

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

2. If the answer to No. 1 is “no”, or “partly”, please provide specific recommendations to improve the system
3. Does the MSSO’s document address the following points adequately?:
 - a. The differences for versioning between safety reporting and clinical trials databases
 - b. The variations of versioning steps used the industry and regulatory authorities
4. What other improvements could be made to the document?