

**Recommendations of Blue Ribbon Panel 6 –
Extent of Versioning and Feasibility of an Annual Release
13 May 2009**

Purpose

This document records the recommendations of a Blue Ribbon Panel (BRP) of MedDRA experts on the topics of extent of MedDRA versioning and the feasibility of an annual release.

Background

The BRP took place on 13 May 2009 at Schering-Plough Corporation in Kenilworth, NJ, USA. Panelists were: Barry Hammond (GlaxoSmithKline), JoAnn Medbery (Johnson&Johnson), Tom Paternoster (European Medicines Agency), Toni Piazza-Hepp (US Food and Drug Administration) and Yasuo Sakurai (Japanese Maintenance Organization). Facilitators were Patrick Revelle and Patricia Mozzicato of MSSO.

The meeting was attended by 38 observers from various subscriber organizations. Prior to the meeting, the MSSO had provided the Panelists and those registering on the MSSO Web site access to background documents, including the most current draft of the “Defining the Extent of MedDRA Versioning Updates: MSSO Recommendation” document.

Recommendations

During the meeting, the Panelists were presented with a series of questions (developed by MSSO) on each topic to serve as the framework for the discussions and their recommendations. Earlier comments by the ICH Points to Consider (PTC) Working Group on the “Defining the Extent of MedDRA Versioning Updates” document as well as results of a JMO survey of their subscribers about both versioning issues were also presented for discussion.

After further input and commentary from observers, the Panelists agreed on the recommendations presented below.

Extent of Versioning

The Panel supported use of the MSSO’s “Defining the Extent of MedDRA Versioning Updates” document to assist in communication between and among MedDRA users. In addition, they had these recommendations:

1. Content of the MSSO’s document to be added as an appendix to the “MedDRA Term Selection: Points to Consider” (TS: PTC). The PTC Working Group should further develop and refine the document content to align it with existing versioning language within the TS: PTC.

2. Add a recommendation that organizations should document their upversioning strategies for various projects and databases as appropriate (using the A-D levels as a framework, and noting any variations on this general approach).
3. The emphasis should be on *communication* of version extent, and it should not be interpreted as a regulatory requirement. Users should be encouraged to choose the most optimal approach based on their organization's characteristics.
4. Include the impact, positive and negative, of each method of version updates (e.g., recoding non-current LLTs). Specifically point out pitfalls, especially impacts on analysis of coded data.

Frequency of MedDRA release – Biannual vs. Annual

1. The Panel recommended that – for now – the release schedule for MedDRA remain biannual; it was further recommended to revisit the possibility of an annual release in 2011 (e.g., by MSSO survey).
2. However, it was noted that a significant number of MedDRA subscribers – particularly relatively new subscribers and those that are small organizations – favor an annual release based on a perception that resources needed to perform version updates may be out of their reach. The Panel was asked specifically for ideas on how to address this issue. The recommendations were as follows:
 - a. Related to the “extent of version update” discussion, the message should clearly be non-intimidating, and it should indicate that to implement a new version of MedDRA without recoding pre-existing data is acceptable for regulatory authorities.
 - b. MSSO should consider developing a software tool to help subscribers assess the impact of a new version on their data to facilitate the task of upversioning.
 - c. MSSO should explore additional ways for training subscribers on version update processes (e.g., downloadable broadcasts).
3. Include the MSSO's recommendation for the implementation date of a new version into the TS: PTC document to provide ICH endorsement of this approach.
4. The MSSO, in conjunction with the regulatory authorities, will develop a list of the versioning requirements for ICH regulatory authorities. The list will be published on the MSSO Web site and periodically updated.
5. Regulatory authorities should be asked to consider use of supplemental terms in the future. For transition to an annual release, there would be a longer period of time before new terms would be incorporated into MedDRA, thereby making use of supplemental terms more significant. Presently, regulatory authorities

could possibly consider allowing transmittal of supplemental terms in case safety reports for unusual circumstances, e.g., for a public health emergency.