BRP 6

Title/subject: Extent of MedDRA Versioning and Feasibility of an Annual MedDRA Release

Date/location: 13 May 2009, Schering-Plough Corporation, Kenilworth, NJ, USA

Purpose of BRP 6
To discuss an MSSO concept paper regarding the extent of MedDRA versioning (i.e., what an organization does to implement the latest version of MedDRA) and to discuss the feasibility of changing from a twice to once annual MedDRA release frequency.

Panel members/affiliations
Barry Hammond (GlaxoSmithKline)
JoAnn Medbery (Johnson&Johnson)
Tom Paternoster (EMA)
Toni Piazza-Hepp (FDA)
Yasuo Sakurai (JMO)

Panel recommendation
Regarding the extent of versioning issue, 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:

- Add content of the MSSO's document as an appendix to the "MedDRA Term Selection: Points to Consider" (MTS:PTC). Include a recommendation that organisations document their upversioning strategies for various projects and databases as appropriate (using the MSSO's proposed A-D levels as a framework)
- Emphasis on *communication* of version extent, and it should not be interpreted as a regulatory requirement
- Include impact, positive and negative, of each method of version updates (e.g., recoding non-current LLTs)

Regarding frequency of MedDRA's release (biannual vs. annual), the Panel had the following recommendations:

- For now, release schedule for MedDRA remains biannual; recommended to revisit the possibility of an annual release in 2011
- MSSO to consider developing a software tool to help subscribers assess the impact of a new version on their data to facilitate the task of upversioning

- MSSO to explore additional ways for training subscribers on version update processes (e.g., downloadable broadcasts)
- Include MSSO's recommendation for the implementation date of a new version into the MTS:PTC document
- MSSO to develop a list of versioning requirements for ICH regulatory authorities for publication on the MSSO Web site
- Regulatory authorities should be asked to consider use of supplemental terms in the future

Outcomes

The Panel's recommendations were reviewed and endorsed by the MedDRA Management Board. The MTS:PTC document was amended as recommended. It should be noted that the Panel's specific recommendation of "MSSO to consider developing a software tool to help subscribers assess the impact of a new version on their data to facilitate the task of upversioning" led to the development of the free online MedDRA Version Analysis Tool (MVAT) which became available to MedDRA subscribers in September 2012.