

MedDRA versioning and Clinical Studies

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Guidance available:

- How to Upversion?
 - Discussed at BRP May 2009
- When to upversion?
 - MSSO Recommendations For MedDRA®
Implementation and Versioning for Clinical Trials

Available on the MSSO website

Recommendations of Blue Ribbon Panel 6 – Extent of Versioning

The Panel supported use of the MSSO's "Defining the Extent of MedDRA Versioning Updates"

Recommendations:

1. Content to be added to "MedDRA Term Selection PtC"
2. Documentation of upversioning strategies for various projects and databases
3. The emphasis should be on *communication of version extent*
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.

MSSO Recommendations for MedDRA Implementation and Versioning for Clinical Trials

- **Option 1** – “Freeze” at the initiation and for the life of a project and report with same version of MedDRA.
- **Option 2** – “Freeze” at the initiation of a project and report with most recent version of MedDRA.
- **Option 3** – “Freeze” at the initiation of each trial within a project, and report with the most recent version of MedDRA.
- **Option 4** – Hold all coding to the completion of each trial and utilize the most recent version of MedDRA for coding and reporting

MSSO Recommendations For MedDRA® Implementation And Versioning for Clinical Trials

- **Option 5** – “Freeze” at the beginning of each trial within a project and optionally re-code data with the latest version at the conclusion of the trial based on criteria defined within project plan. Always output the data utilizing the most recent version of MedDRA.
- **Option 6** – Re-code the trial data for all trials in a project on an ongoing basis with the most recent version of MedDRA.

Recommendation:

- For clinical data, the MSSO recommends Option 5 or 6
- In each case the recommendation is to report in the latest version of MedDRA

Discussion 1

- What is the benefit in upversioning to the latest version of MedDRA for Clinical Studies?
- When to stop upversioning?
 - Following first (interim lock)?
 - At final lock?
 - What about survival studies with maybe just one or 2 subjects going on for many years?

Discussion 2

- How to handle changes in coding or hierarchy (SOC) when this has already been reported with an interim lock?
- How to account for the impact of upversioning on tables and listings?
- Would you send any queries as a result of upversioning?
- How to pool data from studies reported in various MedDRA versions?