



MedDRA MSSO User Group Meeting Versioning

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General

- Back by popular demand
 - MedDRA versioning continues to be a topic of interest to the MedDRA community
- Has multiple levels
 - Post-market/Safety reporting
 - Clinical trials
 - More recently, SMQs



Background

- MSSO developed a series of “best practice” papers
 - Goal was to provide guidance to harmonize the use of MedDRA with respect to version use
 - MSSO Management Board endorses as “best practice”
 - Regulators are starting to include in guidance



MSSO Recommendations

- Post-market/Safety reporting
 - Reporting done with the latest version of MedDRA
 - Not required to re-code all data with each release, but encouraged to understand impacts
 - New version of MedDRA becomes mandatory 2 months after release
 - MedDRA 7.0 released 1 March 2004 becomes the official version on the first Monday after the second month of release at midnight GMT (Sunday to Monday)
 - Provides time to load and understand changes



MSSO Recommendations (cont.)

- Clinical Trials
 - Paper considered 6 options
 - “Freezing versions” for a trial or set of trials
 - MSSO recommendations
 - “Freeze” version at the beginning of each trial and optionally re-code at the conclusion of each trial based on study criteria (Option 5)
 - Re-code all trial data with each version as each version is released (Option 6)
 - Most organizations implementing Option 6
 - Easier to have a single version active company-wide



Impacts of New Versions

- MedDRA key point – Coding terms (LLT, PT) are never deleted in MedDRA
- Types of LLT/PT changes
 - Currency changes
 - Moved (hierarchy change)
 - Gain/lose a multi-axial link
 - Change primary SOC
 - New terms added



Other Best Practices

- Periodically review Supplemental terms
 - Available on MSSO core web page
 - Easier to review a small number of changes rather than complete release
 - Identify terms that will be utilized by your organization
 - Identify impacts of upcoming changes
 - Avoid submitting redundant change requests

Discussion points

- Frequency of version releases – past, present and future
- What is an “upgrade”?
- Lessons learned...



Discussion