



# MedDRA Versioning: What Does it Mean to You?

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Pharmaceutical Manufacturers and Associations (IFPMA)



# Versioning Background

- An issue to be addressed by all users of MedDRA
- Most organizations have processes in place
- Goals of versioning
  - Implement the current version of MedDRA
  - Stay current with regulators and partners
  - Harmonize the use of MedDRA to optimize the communication of data



# Components of Versioning

- Tools and processes for updating
- Resources for updating
- Timing of update
- Scope of Update



# Timing of Update



# Timing of Update

- MSSO “Best Practice” document
  - “The MedDRA MSSO’s Recommendations for Single Case Reporting using Semi-annual Version Control”
  - Recommendations
    1. MedDRA should be used for spontaneous post-market single case reports and pre-market single case reports for serious adverse event reports
    2. All reporting should be done using the most recently released version of MedDRA. The version number of the MedDRA release used to code the report data should be included in all reports.



## Timing of Update (cont)

- Recommendations (cont)
  3. The decision to re-code historical data is an organizational decision
  4. The newly released version of MedDRA should become the reporting version on the first Monday of the second month after it is released. To synchronize this event over the three ICH regions, the MSSO recommends midnight GMT, Sunday to Monday, for the switchover



## Timing of Update (cont)

- Recommendation 4 applied to MedDRA 11.0
  - MedDRA 11.0 released 1 March 2008
  - First Monday in May is 5 May 2008
  - MedDRA 11.0 becomes the reportable version on 5 May 2008 at 00:01 GMT



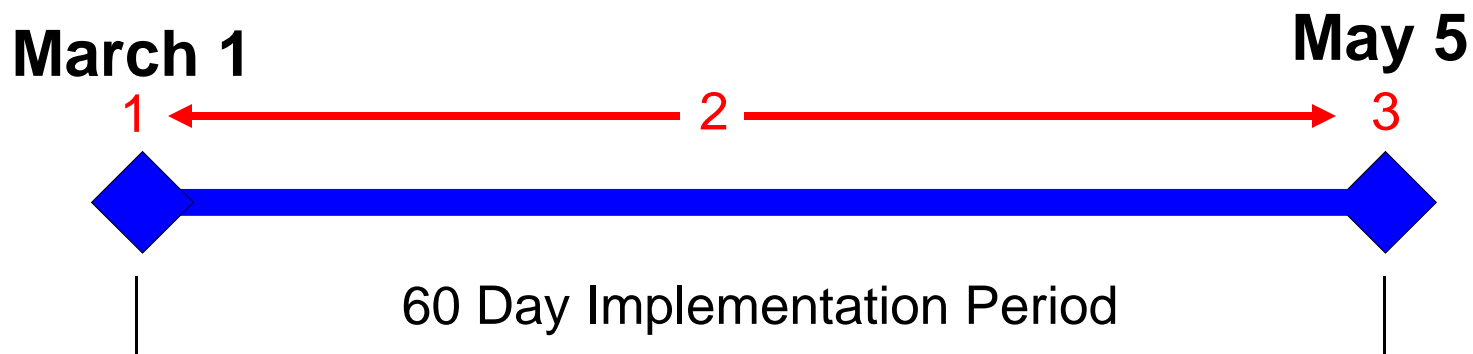
## Timing of Update (cont)

- Recently, the Danish Medicines Agency implemented the recommendation
  - “Electronic reports submitted prior to 7 May 2007 using version 10.0 will be rejected by the Danish Medicines Agency.”
- EMEA will accept the current version plus the previous version
- MHLW ?
- FDA has no requirement



# Issues with Timing

- Currently, organizations are implementing on different dates
  1. On the release date
  2. During the implementation period
  3. At the end of the implementation period





## Issues with Timing (cont)

- The differences in the implementation date negatively impact the communication of ICSRs
- Should the MSSO work with regulators to coordinate the implementation for all MedDRA users?



# Scope of Update



# Scope of Update

- What does it mean to implement latest version of MedDRA?
  - Since coding terms in MedDRA (LLTs) are not deleted, an organization could simply apply latest version with no data changes
  - What does your organization do?
    - Data coded to LLTs that become non-current
    - Data that have direct matches to new terms
    - Medically “better” terms available in new version



## Scope of Update (cont)

- Many approaches to versioning by industry and regulators
- No real regulatory mandate
- MSSO is drafting a versioning “Best Practice” document
  - Currently under review by MedDRA Management Board



# Versioning “Best Practice”

- Purpose
  - Augments existing “best practices” papers drafted by MSSO
  - Addresses question: what does it mean to update to the next version?



# Versioning “Best Practice” (cont)

- Addresses:
  - Extent of implementation
  - Resource considerations
  - Implementation levels
  - Supplemental changes
  - Impact of version changes on data presentation and retrieval
- Finally, provides an MSSO recommendation



# Versioning “Best Practice” (cont)

- Implementation levels

Level	Description
A (Preferred)	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



# MSSO Recommendation

- Adopt standard descriptions of “levels” to define extent of new version implementation
- Useful for communication and sharing of MedDRA-coded information
- Next step: Management Board endorsement; posting for subscribers



# Discussion