

Recommendations for Single Case Reporting using Semi-annual Version Control

Purpose

The purpose of this document is to provide the MedDRA Maintenance and Support Services Organization's (MSSO) recommendations regarding the issue of MedDRA versions and their implementation for spontaneous single case reports and pre-market single case reports.

Overview

The updated versions of MedDRA are both the strength of the terminology and one of its greatest challenges. Earlier terminologies were not properly maintained nor were there timely releases of these terminologies to address errors or medical advances. The MedDRA MSSO was created to address both of these issues. MedDRA is currently provided to subscribers on a semi-annual basis utilizing a rigorous medical and technical review for each change request. MedDRA versioning is an issue that affects the reporting of spontaneous single case reports and pre-market single case reports. Based on comments the MSSO has received on this issue from users of the terminology, the MSSO is making the following recommendations. These recommendations should not be viewed as official guidelines approved by regulatory authorities, however the MSSO hopes that these recommendations are taken into consideration when regulatory agencies draft guidelines regarding this issue in the future.

Recommendation:

The MedDRA MSSO makes the following recommendations to the users of MedDRA in the reporting of spontaneous single case reports and pre-market single case reports:

- 1) MedDRA should be used for spontaneous post-market single case reports and premarket 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.
- 3) The decision to re-code historical data is left to the discretion of each individual company.
- 4) A new release 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. For example :

- 2 September 2002 – MedDRA released

- October 2002 – first month after release
- November 2002 – second month after release
- 4 November 2002 – the new release of MedDRA becomes the reporting release.

The stated change over date and time are used to allow all users enough time to prepare their systems to switch to the new MedDRA version. Subscribers who are able to quickly update and validate their systems with each release of MedDRA need be aware that if they submit a report using the updated MedDRA release prior to the receiving party switching to the update version, the submission may be rejected or at least kicked out of automated processing and into a manual process and potential recoding, which will slow the processing of the submission.

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