

BRP 4

Title/subject: CTCAE (Common Terminology Criteria for Adverse Events) to MedDRA Mapping

Date/location: 6 April 2006, Northrop Grumman, Fair Lakes, Virginia, USA

Purpose of BRP 4

This BRP meeting was intended to address the following questions:

- Does the updated mapping of CTCAE base terms with a proposed six month maintenance schedule meet the needs of MedDRA users?
- Is there a need for a standardized mapping of CTCAE grades to MedDRA?
 - If yes, what are the options for mapping?
 - If no, what guidance should be provided for users?

Panel members/affiliations

Ruthann Giusti (FDA)

Carmen Kreft-Jais (AFSSAPS)

Michelle Mahoney (Mayo Clinic Comprehensive Cancer Center)

JoAnn Medbery (Johnson & Johnson)

Bob Pratt (FDA)

Yasuo Sakurai (JMO)

Ann Setser (CTEP)

Philippe Thouvay (Roche)

Panel recommendations

- A standardized mapping of CTCAE grades is important for consistency
 - A guidance document for consistent use is also needed
- The stakeholders involved (industry, regulators, cooperative groups, CTEP, MSSO and others) should begin a dialogue to address the optimal use of both terminologies
 - A collaborative working group should be formed
 - Optimal data collection practices and conventions could also be addressed
 - If needed, both terminologies could be modified to achieve harmonization and create an optimal mapping
 - Provide guidance for dealing with legacy data
- Current mapping:
 - Address the laboratory terms in CTCAE so that they consistently map to MedDRA investigation terms

Outcomes

After review of the recommendations by the MedDRA Management Board, the above described cooperative working group was formed by stakeholders involved with both terminologies. The ultimate product of these discussions was a revision of CTCAE (CTCAEv4.0 released in May 2009) in which the CTCAE adverse event terms were reconciled to MedDRA LLTs while still supporting a revised grading system.