

BRP2

Title/subject: MedDRA Modifiers

Date/location: 18 June 2004, MSSO offices, Reston, Virginia, USA

Purpose of BRP 2

The Panel met to consider potential options for accommodating requests for and uses of “modified” MedDRA concepts (e.g., terms for conditions that are “aggravated”, “acute”, “post-operative”). The core of the MSSO’s proposal included the use of a “base” term (e.g., *Confusion*) paired with a “modifier” (e.g., *Acute*). A list of “modifier” terms would be maintained along with “base” terms. The MSSO’s proposal included a change to MedDRA files with the potential for significant impact on users and their systems (e.g., E2B). The potential benefits and risks of this approach were outlined in a background/proposal document.

Panel members/affiliations

Christina Winter (GlaxoSmithKline)
Hilary Vass (AstraZeneca)
Yasuo Sakurai (JMO)
Kostas Kidos (Bristol-Myers Squibb)
Sabine Broche (EMEA)
Andrea Feight (FDA)
Greg Gribko (Pfizer)

Panel recommendations

During the course of the Panel meeting, the MSSO’s initially proposed approach was replaced by a different tactic that arose from discussions between the Panel and attending observers from the user community. The ultimate Panel recommendation was for the MSSO to propose a set of useful “modified” MedDRA terms that would be entered in a single MedDRA version after consultation with the entire user community. The idea was to allow users to agree on the most useful modified terms in MedDRA and also allow for controlled growth of the terminology.

Outcomes

The MedDRA Management Board endorsed the Panel’s recommended approach. After collecting feedback on a set of posted proposed modified terms, the MSSO added the terms to MedDRA Version 9.1.