

BRP1

Title/subject: Scope and Specificity of MedDRA

Date/location: 15 May 2003, MSSO offices, Reston, Virginia, USA

Purpose of BRP1

The purpose of this BRP was to provide the MedDRA Management Board with information to support the Board's oversight and policy formation regarding MedDRA. At this particular meeting, the BRP was asked to review, discuss and make recommendations on MedDRA's general scope and level of specificity.

Panel members/affiliations

Dr. I. Sanford Smith, (Merck Research Laboratories)

Sarah Singer (FDA)

Dr. Sidney Kahn (formerly of BMS, former ICH M1 working group member)

Dr. Philippe Thouvay (Hoffmann-La Roche Ltd)

Dr. Norbert Paeschke (BfArM)

Mr. Yasuo Sakurai (JMO)

Panel recommendations

The Panel's recommendations focused first on a specific MedDRA SOC (SOC *Investigations*) and then on all other SOCs collectively.

The recommendations for SOC *Investigations* were:

- Placement of general "serology" terms at the PT level with immunoglobulin class terms at LLT. A similar approach for DNA analysis terms was recommended
- No internal MSSO change requests simply to produce a full complement of qualitative investigation results
- Compelling regulatory need must be present to add esoteric investigation terms to MedDRA
- For requests for terms of the same metabolite in different specimen types (e.g., blood, CSF), there needs to be a different clinical interpretation of the results

The recommendations for the other MedDRA SOCs were:

- Compelling regulatory need must be present to add "normal" investigation terms to MedDRA
- Requests for new "prophylaxis" terms are evaluated on an individual basis for medical significance
- MedDRA can expand into new areas of medicine based on user input

Outcomes

The recommendations listed above were endorsed by the MedDRA Management Board and were implemented by the MSSO during MedDRA Version 7.0.