

BRP5

Title/subject: Proposed Terminology Changes to Facilitate the Analysis of MedDRA-Coded Data

Date/location: 16 November 2006, Boehringer Ingelheim Pharma GmbH & Co. KG, Mainz, Germany

Purpose of BRP 5

In response to subscribers' requests, the MSSO conducted a feasibility study in 2005 on MedDRA hierarchy structure modifications to improve its support of statistical analysis and reporting. The existing MedDRA rules and conventions, such as primary SOC allocation, were reviewed in this context.

The MSSO originally drafted 7 proposals, 4 of which were referred to this BRP for further discussion. These 5 proposals were:

- Review "NEC" HLTs and HLGs
 - Explore alternative namings for clearer indication of their content
 - Review large sized HLT groupings for possible reduction of the number of subordinate PTs
- Allow multi-axiality of SOC *Investigations*
- Allow multi-axiality of SOC *Social circumstances*
- Eliminate multi-axial HLTs (i.e., an HLT that is linked to more than one SOC) in cumulative data outputs when only the primary paths are displayed

Panel members/affiliations

Gottfried Kreutz (CIOMS)
Jürgen Kübler (Subject Expert)
Reiji Tezuka (JMO)
George Rochester (FDA)
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Panel recommendations

The BRP5 recommendations were as follows:

- "NEC" HLTs
 - No revision of "NEC" group names unless there is a more medically meaningful name within the hierarchy
 - Large-sized "NEC" groupings should be analysed for possible new groupings with the following priority:
 - Oversized HLTs (≥50 PTs)
 - Medium or large HLTs with higher frequencies in a regulatory authority database
 - Use regulatory risk assessment areas for prioritisation

- HLT re-grouping should be based on medicine (pathology, pathophysiology):
 - Avoid force fitting of PTs for the purpose of reducing HLT size
 - Avoid over-granularity at the HLT level
 - Consider use of age and gender criteria
- Consider implementation in a short timeframe
- Consider possible consecutive complex releases
- *SOC Investigations*
 - Pilot study on concept attribute approach recommended
 - MSSO to develop a sample set of investigation terms with concept attributes to be tested by regulatory authorities and industry volunteers
- *SOC Social circumstances*
 - Request PTC Working Group to provide additional guidance on SOC *Social circumstances*, specifically, addict/dependence/abuse terms
 - No change to current SOC structure
 - Review “abuse” related LLTs
 - Clarify PT/LLT wording to differentiate terms in SOC *Social circumstances* from those in SOC *Psychiatric disorders*:
 - Move “abuse” terms to SOC *Psychiatric disorders* and keep them as independent PTs from “dependence” counterparts
 - Keep terms that refer to people, such as PT *Drug abuser*, in SOC *Social circumstances*
- Multi-axial HLTs in cumulative data output
 - Create separate HLTs for cyst and polyps terms
 - Consult expert pathologists and oncologists
 - Review all multi-axial HLTs to ensure primary SOC are appropriate

Outcomes

Regarding the “NEC” HLTs, the Management Board endorsed this recommendation, and these were addressed over subsequent versions of MedDRA.

The Panel's recommendation of conducting a pilot study on implementing concept attribute relationships in MedDRA terminology was approved by the MedDRA Management Board. The MSSO conducted the pilot program (see below). For detailed information, please refer to the “Concept Attribute Pilot Plan” document.

In the pilot study, the MSSO analyzed the cost and level of effort for the *de novo* approach to establish diagnosis-test relationships, compared to those by exploiting existing relationships in National Library of Medicine's Unified Medical Language System (UMLS). In conclusion, both approaches are cost- and resource-intensive. Therefore, concept attributes for MedDRA are not feasible at present.

Regarding the Panel's recommendations for SOC *Social circumstances*, these were endorsed by the Board and implemented in MedDRA v10.1.

Finally, regarding the Panel's recommendation for multi-axial HLTs in cumulative data output, the Board also endorsed these recommendations which were implemented in MedDRA Version 11.0.