Blue Ribbon Panel Summary on Proposed HLGT/HLT Changes

The fifth Blue Ribbon Panel (BRP) meeting was held on 16 November 2006 in Mainz, Germany, hosted by Boehringer Ingelheim. The focus of the BRP was the proposed HLGT/HLT changes to improve MedDRA data retrieval and analysis.

There were 20 observers from the user community and 5 panel members in attendance. For many attendees, this was their first BRP experience; they found that it was informative and helpful. The BRP panel included the following:

- Dr. Gottfried Kreutz (CIOMS)
- Dr. Jürgen Kübler (EU Industry)
- Mr. Reiji Tezuka (Japan)
- Mr. George Rochester (US regulator)
- Dr. Greg Gribko (US Industry)

Meeting facilitators were Dr. Eva Rump and Dr. Anna Zhao-Wong from the MSSO.

For each topic, the MSSO facilitator presented background information, MSSO analysis, a proposed solution, user feedback, and questions to the panel members. All BRP participants, including the observers, were encouraged to voice their opinions. The final recommendations were based on the consensus among the panel members:

- "NEC" HLTs
  - "NEC" naming should not be revised unless there is a more medically meaningful name within the hierarchy
  - Large-sized "NEC" groupings should be analyzed for possible new groupings with the following priority:
    - Oversized HLTs (≥50 PTs)
    - Medium or large HLTs with higher frequencies in a regulator's database
    - Utilize regulatory risk assessment areas for prioritization
  - HLT re-grouping should be based on medicine, such as pathology or physiology:
    - Avoid force fitting of PTs for the purpose of reducing HLT size
    - Avoid over-granularity at the HLT level
    - Consider the use of age and gender criteria
  - Consider implementation schedule that completes the implementation in a short timeframe:

    - Consider the potential of consecutive complex releases
- SOC *Investigations*
  - Recommend a pilot study on concept attribute approach:
    - MSSO to develop a sample set of investigation terms with concept attributes
    - Tested by regulators 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 System Organ Class structure
  - Review “abuse” related LLTs:
    - Clarify the PT/LLT wordings 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 SOCs are appropriate

MedDRA Management Board approval will be obtained before proceeding with Blue Ribbon Panel 5 recommendations.