

## MedDRA User Group Meeting

4 March 2003

Rome, Italy

MAG Break-out Session

Dr. Eva Rump and Pat Revelle provided a current status and plans for MedDRA Analytical Grouping (MAGs) as well as the cooperative effort with the CIOMS working group. The break-out session was a good exchange of ideas about the initial efforts of the MSSO, CIOMS initiatives and the interests of the MedDRA user community regarding data analysis for safety issues. The following points were raised during the meeting for consideration in these efforts:

- When defining a SSQ/MAG include the official source of the definition in the definition.
- Recommended that the filtering mechanism of SSQ/MAGs includes a separate list of obligate vs. facultative terms.
- Recommended that algorithms be developed that would utilize the SSQ/MAGs (not necessarily built into the structure of SSQ/MAGs). This may be included in a PTC-like document that could be developed that would address specific SSQ/MAGs. The details would identify a series of PT combinations which, when taken as a group, provide a strong correlation to the concept of interest.
- Recommended that SSCs be archived in the future to avoid confusion. The attendees said that they don't use the SSCs and given the work being done for SSQ/MAGs, they don't see a benefit of keeping the SSCs.
- Recommended that the distributed files provide an indication when the PTs of an HLT or HLGT are included in their entirety in a SSQ/MAG.
- Strongly supported the concept of testing the SSQ/MAGs within real safety databases with both industry and regulators.
- Recommended that the introductory letter provide a discussion of the current status and intended scope of SSQ/MAGs. For instance, it would describe the expected development of new SSQ/MAGs or potential use of MAGs for labeling.