



# MedDRA MSSO User Group

MedDRA Modifiers Update

Lisbon, Portugal

10 March 2005



# Blue Ribbon Panel on MedDRA Modifiers

- Blue Ribbon Panel convened on 18 June 2004 in Reston, Virginia, USA
- Topic was MedDRA Modifiers
  - MedDRA code, term (e.g., aggravated) and description; distributed with terminology
  - Could be used in conjunction with any existing MedDRA term at user's discretion
  - Increases the flexibility of MedDRA
  - Many significant issues to consider for implementation



# Blue Ribbon Panel on MedDRA Modifiers (cont)

- Panel members represent ICH regions with MedDRA and E2B expertise
  - Mix of regulators and industry
- Approx. 40 subscriber/observers also present
- General conclusion - Modifier concept, as proposed, has more issues than benefits
- Focus shifted to alternative ways to accommodate modified terms in MedDRA
  - Planned process
  - Subscriber input



# Initial Recommendations

- Recommended approach
  - Add additional modified terms to MedDRA under a controlled, planned process
  - MSSO to work with user community to identify the most useful terms to add
  - Schedule the release of new modified terms in a specific version so all new terms are added to MedDRA in the same release



# Scope of New Terms

- Aggravated
- Acute
- Chronic
- Subacute
- Progression of
- Prophylaxis of
- Recurrent
- Procedure associated terms (Pre-, peri- and post-procedural)



# Recommendations

- Limited to LLTs/PTs
- MSSO to develop definitions of modified terms to include in Introductory Guide
- MSSO to proactively solicit input from subscribers
  - Meetings/conference calls with interested organizations



# Recommendations (cont)

- MSSO will review previously rejected change requests of modified terms
- After collecting input, proposed terms made available for comment to subscribers
- MSSO will identify a future release for implementation
- Subsequent requests could be considered but within the same scope



# Discussion

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