

UPDATE

MedDRA Term Selection:
“Points to Consider”

MedDRA Working Group

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- **The Points to Consider Working Group is pleased to announce:**
 - Completion of Release 2.0 – Application to Adverse Drug Reactions and Adverse Events
 - A companion document to “MedDRA Introductory Guide Version 3.2”
 - Endorsed by the ICH Steering Committee

How We Accomplished It!

- Reviewed ALL Comments to MSSO/JMO
- Modified to best meet global user needs
- Brainstormed among ourselves
- Added more and better examples
- Thought about how input affects output

What We Expect Next

- Continue “living document” format
- Joint release by MSSO/JMO (post translation)
- Publication date: mid-December, 2000
- Posted on JMO/MSSO websites
- Comments to be addressed to MSSO/JMO
- Comments received by x date will be addressed at the x date Working Group meeting.
- Management Board to convey to the ICH SC the continued success of the Working Group

Working Group Continued Activities

- Address changes needed due to MedDRA 4.0
- Respond to ongoing worldwide user comments
- Write guidance for Medical history, Laboratory, Indications, Output strategies, and use of Social Circumstances and Procedures SOCs
- Update “Points to Consider” following future “complex changes” to MedDRA

Issues “out of scope”

Referred to MSSO/MB

- Version control
- “Complex changes” –
 - Similar LLTs mapping to different PTs
 - “Aggravation” type terms
 - Age related terms – fetal, geriatric, etc
 - Make Social Circumstances SOC multi-axial

Other Areas Needing Clean-up

- Investigations SOC –
 - Hi and Lo qualifiers LLT to Increased Decreased PTs
- Introductory Guide needs to address reference ranges
- Need to define Overdose/toxicity/poisoning
- Therapeutic effect vs Drug effect terms

Recommendation to ICH

- ICH needs process to monitor/cross-link all working on MedDRA related issues
- We need to understand who they are and what they are charged with, and whether it impacts on our activities.

THANK YOU

to the Working Group

- EFPIA – B. Hammond, R. Fescharek
- EU – D. Montero
- FDA – A. Neal, T. Piazza-Hepp
- JMO – R. Tezuka
- JPMA – Y. Sakurai
- MHW – T. Yasukawa
- MSSO – J. Medbery
- PhRMA – S. Kahn
- TPP Canada – H. Morrison