



# Proactive MedDRA Maintenance Model

MedDRA MSSO User Group Meeting  
Chicago, USA  
23 June 2011

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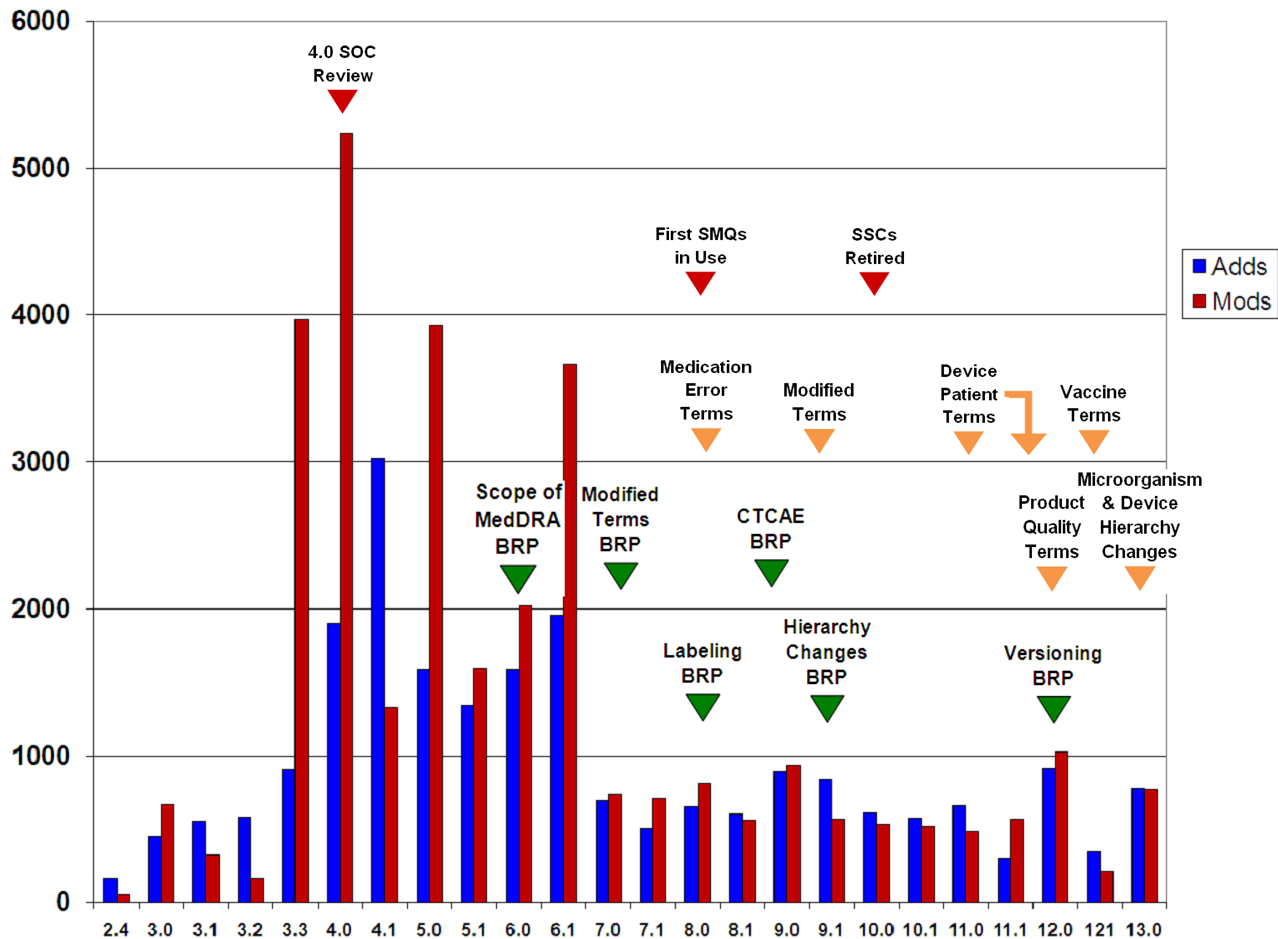


# Background

- MedDRA is successful because it is user-driven
- Early days of MedDRA – filling in “gaps”
- More recently, changes of two types have become more prominent
  - Changes that increase scope (e.g., medication errors, product quality terms)
  - “Fine-tuning” of existing terms



# Change Requests and MedDRA Initiatives





# What is Proactive MedDRA Maintenance?

- Corrections/improvements made internally by the MSSO
  - Without need for specific subscriber Change Requests
  - May be term by term or more regional changes (consistency, etc.)
- General changes suggested by users outside the Change Request process



# Submission of Ideas

- Submit your ideas to the MSSO Help Desk: [msohelp@ngc.com](mailto:msohelp@ngc.com)
- Justification for submitted ideas is appreciated
- Example:
  - “Please identify all HLTs with only one PT and determine if the PT can be consolidated into other existing HLTs. Consolidating these ‘single’ PTs into existing HLTs could work to improve safety signal strength.”



# Evaluation of Proposals

- MSSO will evaluate all input received
- Idea **may** be implemented in a future MedDRA version
- Things to keep in mind:
  - Not a substitute for Change Request process
  - MSSO not obligated to respond to suggestions
- Ideas posted on MSSO Web site  
[http://www.meddramsso.com/subscriber\\_proactive\\_maintenance.asp](http://www.meddramsso.com/subscriber_proactive_maintenance.asp)



# Proactivity Proposals as of 1 June 2011

Description	Subscriber or MSSO	Complex Changes?	Version to Implement	Status
Add bleeding LLTs to haemorrhage PTs	MSSO	No	15.0	In review
Create authorized HLT abbreviations/truncated words of around 20 to 25 characters	Subscriber	Yes	TBD	In review
Harmonize use of hyphen in "Non-" terms	Subscriber	No	15.0	In review
Addition of death and injury resulting from terrorism	Subscriber	Maybe	TBD	In review
Reconcile SDTM/CDISC terms into MedDRA because of an increasing interest	Subscriber	Maybe	TBD	In review
Add terms specific for indication that would differentiate the cause of medically-induced abortion	Subscriber	Maybe	TBD	In review



# Proactive MedDRA Maintenance

- MSSO will communicate with users when making major proactive changes
  - Expert Panel
  - Complex change proposals
  - Special broadcast e-mails seeking feedback
  - Blue Ribbon Panel



# Questions?