



MedDRA MSSO User Group Meeting

US – DIA San Antonio, Texas

19 June 2003



Agenda

Opening Remarks

Liz d'Alelio

MedDRA/MSSO Overview

Jim Mundell

Regulatory Update

Andrea Feight, FDA

Networking Break

Breakout session:

1. Points to Consider
2. SMQs
3. Versioning

Joann Medbery

Patty Mozzicato

Pat Revelle



MSSO Update Overview

- Transparency
- Blue Ribbon Advisory Panel
- CIOMS/MSSO co-development agreement
- Translations
- Technical issues
- Change to Breakout session format



MSSO Update - Transparency

- What is going on
 - MedDRA 6.1 – Freeze 27 June; September 2003
 - Posting of rejected terms
 - Posting of terminology proposals
- Web site bulletin board – soon
- Subscriber involvement in BRP meetings
- Stability / without stasis
 - Investigation terms
 - NOS terms
 - Modified terms



MSSO Update - BRP

- Blue Ribbon Advisory Panel
 - Concept of the MedDRA Management Board (MB)
 - Need for expert recommendations to help form policy and guidance
 - Panelists from USA, EU, Japan both regulatory & industry
 - MedDRA subscribers as Observers
 - First meeting held in Reston, VA; 15 May 2003
 - General Scope & Specificity of MedDRA
 - Consistency maintenance activities
 - Report due to MB July meeting
 - Results to be posted after MB review
 - Future plan
 - Two meetings a year
 - Panel will change to fit topic and availability
 - Potential topic – MedDRA Translations



MSSO Update - CIOMS/MSSO

- MedDRA Analytical Groupings (MAGs) & Standardized Structured Queries (SSQs)
- CIOMS/MSSO co-development agreement
 - Two year collaborative process
 - New product name Standardised MedDRA Queries (SMQs)
 - IFPMA will own the rights
 - MSSO will maintain and distribute with each MedDRA release
 - First set of four SMQs scheduled for MedDRA release 6.1 (September 2003)
 - Will be part of the change request process



MSSO Update - Translations

- Currently available
 - French, German, Portuguese to the PT level
 - English, Japanese, Spanish to LLT level
 - Dutch to LLT Scheduled for September 2003
- Current issue regarding non-translatable terms
 - MedDRA rule on unique terms (no duplicates)
 - British / American spellings
 - Lexical variants
- Could one day lead to the need for a new MedDRA



MSSO Update - Technical Issues

- MSSO experienced a series of technical issues recently
 - Hacker attack on web server
 - No subscriber information was accessed or corrupted
 - Tightened web security required by merger
 - Hardware upgrade
 - Change in naming conventions (trw.com -> ngc.com)
- Result
 - Delay in processing change requests
 - Email failures
 - Web site off line
 - Staff workload increase



MSSO User Group - Breakout

- Change to Breakout session format
 - Response to comments cards
 - No longer separate breakout sessions
 - Will be done sequential
 - Points to Consider document
 - SMQ development
 - Version control (MedDRA and SMQs)



MSSO Contacts

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