



MedDRA MSSO User Group Meeting

Osaka Japan – ICH-6

12 November 2003



User Group Meeting - Agenda

- MSSO Overview of Activities
- JMO Overview of Activities
- US FDA – Regulatory Update
- EU EMEA- Regulatory Update
- JP MHLW – Regulatory Update

Coffee Break

- Points to Consider Update
- CIOMS/MSSO Data Analysis
- Panel Discussion



MSSO Update Agenda

- Transparency
- Blue Ribbon Advisory Panel
- CIOMS/MSSO co-development agreement
- Translations
- Technical issues



MSSO Update - Transparency

- Recent actions
 - MedDRA 6.1 – September 2003
 - MedDRA 7.0 – March 2004
 - Posting of rejected terms
 - Posting of terminology proposals
- Web site – MedDRA Forum
- Blue Ribbon Panel meetings
- Stability / without stasis
 - Investigation terms
 - NOS terms
 - Modified terms



Blue Ribbon Panel

- Blue Ribbon Advisory Panel
 - 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
 - Consistency maintenance activities
 - Results to be posted after MB review
 - Future plans
 - Two meetings a year
 - Panel will change to fit topic and availability



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
 - Will be part of the change request process



Translations

- Currently available
 - French, German, Portuguese to the PT level
 - English, Japanese, Spanish Dutch to the LLT level
- Recent policy change regarding EU LLT translations
 - MedDRA EU LLT translations will be revised to allow for duplicate translations
 - Currently only Spanish and Dutch are impacted
 - MedDRA/J will not be affected



MSSO Contacts

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