

Implementation of MedDRA/J from Pharmaceutical Industry's Point of View



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MSSO User Group Meeting

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Standardization of MedDRA/J Utilization

- **Data input; Coding rules**
- **Data retrieval & output**
- **Maintenance**
- **E2B/M2 Regulatory Implementation**
 - **ICH, MSSO-MB, PTC-WG**
 - **JPMA Task force, JMO-JMB, E2B/M2 Project**
 - **EMEA, FDA, CIOMS**




MedDRA Term Selection: Points to Consider

- **One of the ICH Activities**
- **PTC-WG under MSSO-MB**
- **2000.02; Release 1.0**
- **2000.11; Release 2.0**
- **2002.04; Release 3.0**
- **2002.09; Release 3.1 (under preparation)**



PTC Release 3.1

- **Revised according to User Comments**
- **Based on MedDRA 5.1**
- **Guide for Indication and Investigation added**
- **English version; completed**
- **Japanese version; under preparation**



JPMA Guide Book

(Green Book)

- **Based on PTC release 3.1**
- **PTC Japanese translation and additional Japanese Explanation**
- **Specific issues for Japanese terms**
- **Coding Guide for MedDRA/J**
- **Publish in March 2003 expected**



Coding rules in each company

- (Unified rule is preferable, but)
- (Reflect each company's circumstances)
- Based on PTC and JPMA guide
 - Choice of options in PTC
 - Rules according to objective or structure of database
 - Avoid organization-specific solution
 - User training is indispensable



MedDRA Version Control

- **Recommendations for Single Case Reporting using Semi-annual Version Control**
- **Recommendations for MedDRA Implementation and Versioning for Clinical Trials**
- **Recommendations for the Implementation of MedDRA Supplementation Terms**



Purposes of MedDRA

- **Terminology for Drug Regulatory Activities**
- **International Standard (ICH)**
 - Not developed as a scientific terminology
 - Suitable for database construction, some problems for signal detection
 - Not completely stabilized yet
 - Standardization for data retrieval and output as well as data input



Tool for Retrieval and Output

- **SSC (Special Search Category)**
- **HLGT, HLT:Multi-Axial**
- **MAG (MedDRA Analytical Group)**
- **SSQ (Standard Search Query)**



Concept of MAG (MSSO)

- **Not only grouping of PTs , but include HLTs, HLGTs**
- **Drug safety related topics**
QT prolongation, Rhabdomyolysis, Pancreatitis, Hepatotoxicity
- **MSSO will maintain responsive to user input**
- **Under discussion at MSSO**



Concept of SSQ (CIOMS-WG)

- Proposed as a part of CIOMS activities
- Participate regulators , Pharmaceutical companies in EU,US and WHO
- Different method for data retrieval in each company, Difficult for Standardization
- Not sufficient current SSCs
- Started in September 2002
- Similar function and contents to MAG



MedDRA Maintenance

- **Transparency of MSSO Maintenance**
(Maintenance rule, rejection report etc.)
- **Dealing with the current modified terms**
(aggravated, recurrent, progression)
- **“NOS” Terms**
- **British/American Spellings**
- **Complex changes in MedDRA6.0**



Maintenance of Japanese Terms

- **Consistency in Japanese Terms**
- **Translation related issues**
- **Collaboration of JMO and Users**
- **Management of Japanese synonyms**
- **Japanese disease names**

(MEDIS Disease Code or Standard Disease Code)

(English translation not available)



Implementation of E2B/M2 to Regulatory Reporting

- **Different stages among Japan,US & EU**
- **Relation to mandatory use of MedDRA**



EU

- **EMEA Initiative (Setting up a network among EMEA, Member States and Industries)**
- **Progressing in Some Member States**
- **Mandatory use of LLTs for E2BM defined items**
- **Require MedDRA LLTs for B.3.1c (Investigation)**
- **Require to start by January**
- **Require to convert the legacy data from 1995**



Situation in US

- **Plan for AERS Database (- 1997)**
- **Start of AERS Database ; 1997.11**
- **Public hearing for AERS; 1998.03**
- **Pilot test (Periodic report); 1998 -**
- **e-prompt (Expedited report); 1999 -**
- **Ready for receipt FDA (DTD2.0); 1999.11**
- **Memorandum(Docket 92S-0251): 2001.05**




US

- **Advance notice of proposed rulemaking on electronic reporting of postmarketing adverse drug reactions; request for comments, 63 FR 59746, November 5, 1998.**
- **Proposal of new Regulation for ANPRM not announced yet**
- **Guidance has been published**



Present Situation in US

- No new regulation but started to report as a substitute for paper reporting
- FDA confirmed each company availability of Electronic reporting.
- Several companies have started e-submission, 20% of reports FDA receiving are electronic
- Expedited report and individual case in Periodic report
- MedDRA is not mandatory requirement




Present Situation in Japan and it's characteristics

- **Notification of ICH Guide line; 2001.03**
- **Notification of implementation for PMS safety reporting; 2002.05**
- **Mandate MedDRA/J use after 2003.10**
- **(Notification of IND safety report soon)**

Indispensable condition for Pharmaceutical Companies for Standardized Utilization of MedDRA/J



**Great impacts from implementation of
E2B/M2 to regulatory reporting**



Management of MedDRA use in each Industry

- **Appointment of MedDRA Manager**
- **Knowledge of MedDRA and Medical knowledge**
- **Training for coders and case evaluators**
- **Global point of view**
- **Avoid organization-specific solution**



MedDRA User Training

- **Back ground of MedDRA**
- **Relation to legacy data**
- **Structure of MedDRA and Maintenance**
- **Purpose and Contents of MedDRA**
- **Concepts included and not included in MedDRA**
- **Characteristics and restrictions of Japanese Version of MedDRA**



Standardization of MedDRA Coding

- **Coding rules in each company**
- **Based on PTC document**
- **JPMA Guide Book available soon**
- **Esteem International and Local Standards**



Important Note

- **Sense of International Standard**
- **Understanding of Revision points in MedDRA new version**
- **Understanding of related documents such as PTC document**
- **Attention to Standardization of Tool for Retrieval and Output (MSSO, CIOMS, Japan)**
- **Standardization of signal detection and judgment of expectedness**
- **Information of MedDRA usage in E2B/M2 implementation**