

**MedDRA® MSSO International User Group Meeting
Washington DC – 17 June 2004**

The agenda for the meeting was as follows:

1. Opening Remarks
2. Regulatory Updates – FDA
3. Regulatory Updates _EMEA
4. JMO update
5. Networking break
6. Update on Standardised MedDRA Queries (SMQs)
7. Versioning
8. MedDRA Encoding by Investigators
9. Question & Answer Session

The MedDRA MSSO User Group meeting was held in Washington DC on 17 June 2004. Speakers included members of the MSSO, Dr. Andrea Feight of the FDA, Dr. Sabine Brosch of EMEA and Mr. Yasuo Sakurai of JMO.

1. Mr. Patrick Reville, Director of the MSSO, opened the meeting with an overview of the recent developments for MedDRA and the MSSO including a schedule of deadlines for upcoming versions 7.1 and 8.0. The process for the online distribution of MedDRA files via the MSSO website was explained to ensure subscribers take advantage of the files as they become available for all translations on 1 September 2004 for MedDRA 7.1.
2. Dr. Andrea Feight gave an overview current FDA updates. She briefly described the history of MedDRA implementation, versioning and current AERS submissions in MedDRA status at FDA. She discussed the status of the Proposed Rule Regarding MedDRA and that FDA is reviewing the 109 unique comments received from industry that addressed the MedDRA requirements for consideration as the final rule is prepared. She next gave an overview of the development of Health Human Services (HHS)-wide standards, covering the purpose of Health Level 7 (HL7), HL7 Regulated Clinical Research Information Management (RCRIM) organization, the Clinical Data Interchange Standards Consortium (CDISC) and its purpose. She discussed HHS support for SNOMED CT for Electronic Patient Medical Record and the status of its evaluation at FDA. She presented their plan for comparing SNOMED to MedDRA in premarketing and postmarketing activities and the problems that FDA has encountered to date. She next discussed the status of MedDRA and the various activities at FDA regarding the organization's moving forward efforts with the terminology.

3. Dr. Sabine Brosch gave an overview of MedDRA and the Eudravigilance system at the EMEA. She described events that have major impact on e-reporting in the recent month: EU enlargement from 15 member states to 25, the implementation of Directive 2001/20EC related to Clinical Trials conducted in the EU and the publication of the New Community Legislation. Dr. Brosch gave an overview of the Eudravigilance Data Warehouse project including MedDRA's role therein. She next provided a statistical overview by MedDRA System Organ Class (SOC) of the coded adverse reactions and indications reported to the Eudravigilance system. Next, Dr. Brosch described MedDRA's role in the Eudravigilance Web Application for small and medium size enterprises (SMEs), which supports the ability of these types of companies to perform electronic ICSR reporting using MedDRA by means of new MedDRA licensing categories.
4. Mr. Yasuo Sakurai presented a brief overview of the history of MedDRA mandatory regulatory use in Japan. He next discussed the status of the E2B/M2 implementation and the results of the pilot study and final test as conducted by MHLW. Mr. Sakurai also spoke about the current status of submission methods and the steady increase in number of companies and percentage of cases transmitted via the internet during the past year.
5. Networking Break
6. Dr. Patricia Mozzicato of the MSSO presented an update on the progress of Standardised MedDRA Queries (SMQs) including a schedule for the releases of the SMQs and MSSO plan for SMQs for the current year. The initial two SMQs for Phase II testing will be posted on the MSSO website for download on 10 May 2004 and five additional SMQs are nearing Phase II testing as they become approved by the CIOMS Working Group. Dr. Mozzicato then opened the floor up for discussion on the various topics regarding SMQs from the user community.
7. Mr. Patrick Revelle of the MSSO gave a presentation of the versioning issue regarding MedDRA updates. He briefly discussed the background of the MSSO development of a series of the "best practice" papers for subscribers. The recommendations address post-marketing/safety reporting and clinical trials requirements. He also spoke of other best practices that companies who are further along in their MedDRA implementation current use, such as periodic reviews of supplemental terms to lessen the versioning issue during update release. He then opened up the floor for discussion on the various topics on updates from the user community.

8. Dr. Patricia Mozzicato of the MSSO spoke about MedDRA and its use by investigators. She went over the importance of good quality data needed for the coding of clinical trial data and the benefits of such quality data. Dr. Mozzicato stressed that to take advantage of MedDRA's richness and specificity, the source data needed to be clear, concise, complete and accurate and general principles needed to apply to all clinical data. She went over samples of problems with coding data. She next opened up the floor for discussion on the various topics regarding strategies used, appropriate level of MedDRA knowledge, and such from the user community.
9. After a Question and Answer session, the meeting was adjourned.