



**MedDRA  
Maintenance and Support  
Services Organization  
Annual Report  
2004**

### MedDRA MSSO Mission

The MedDRA Maintenance and Support Services Organization (MSSO) is tasked with two functions:

- Establish and maintain a mechanism for international support and development of the MedDRA terminology
- Foster the use of MedDRA worldwide through communication, education, and services

The goal of the MSSO is to maintain the MedDRA terminology as a stable, consistent terminology to suit the needs of regulatory authorities and the regulated biopharmaceutical industry. The terminology is used through the entire regulatory process, from pre-marketing to post-marketing; and for data entry, retrieval, evaluation and presentation.

### Highlights for 2004

During 2004, the MSSO experienced a year of continued growth and development of MedDRA. The number of worldwide MedDRA subscribers was 1,227 by the end of 2004. Of the 1,227 worldwide subscribers, 830 were MSSO subscribers and 397 were JMO subscribers. Figure 1 provides the breakout of MSSO subscribers by region. The rate of new MSSO subscriptions increased 35% from 2003. Figure 2 provides the number of new MSSO subscribers in 2004 by each region.

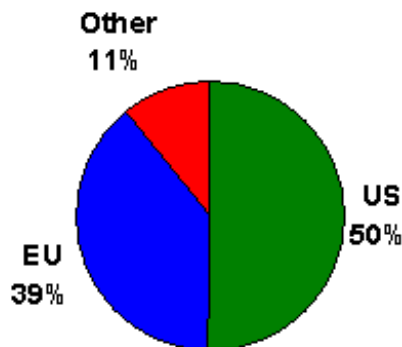
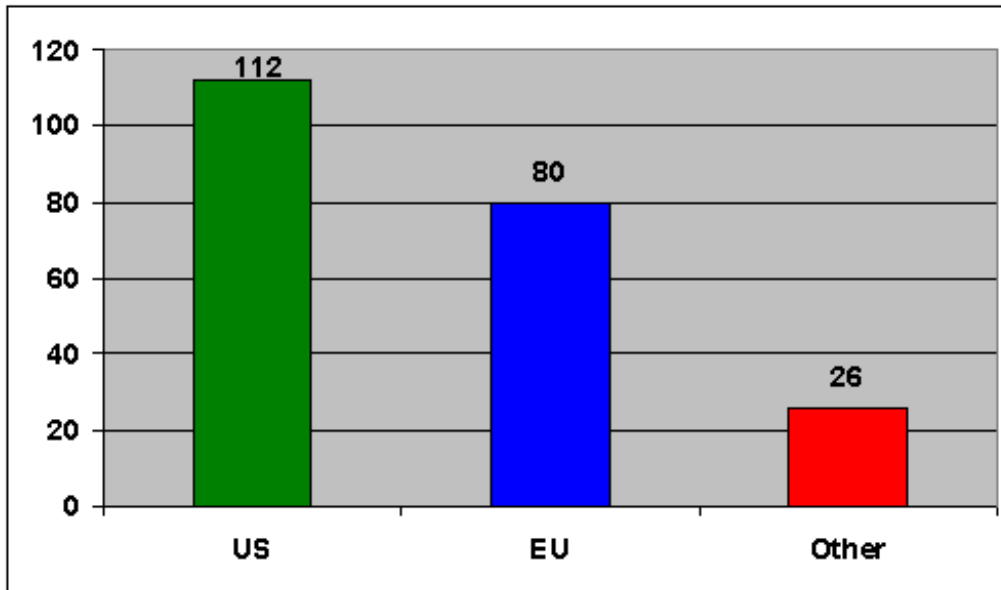


Figure 1. MedDRA MSSO Subscribers (830)



**Figure 2. Number of new MSSO subscribers in 2004**

The development of MedDRA continued as well. In 2004, the MSSO initiated several new development efforts to ensure MedDRA evolves to meet the needs of the subscribers.

**MedDRA Modifiers** – The MSSO held a “Blue Ribbon Panel” (BRP) on the topic of MedDRA modifiers. The BRP process was initiated by the MSSO to gather experts (regulators and industry) on a specific topic to advise the MSSO about what actions should be taken. For this BRP, the topic was MedDRA modifiers. The MSSO receives many requests to add terms containing modifiers (e.g., prolonged neutropenia). Modifiers, in this context, are terms that can be appended to any existing MedDRA term to create a new term. The MSSO developed a paper that described the possible implementation and impacts, and developed a series of recommendations.

The BRP panelists concluded that there is a need to accommodate terms with modifiers in MedDRA but not by a separate modifier term. The impacts to coding practices, coding tools (e.g., autoencoders), existing MedDRA coded data, E2B, and data analysis were considered to be too high compared to the benefit of implementing MedDRA modifiers as described in the concept paper.

The panelists then provided a series of recommendations for the inclusion of a defined scope of modifier terms in MedDRA. The recommendations were endorsed by the MedDRA Management Board and are part of the 2005 development efforts of the MSSO.

**Medication Errors** – To enhance information on medication events for better retrieval and analysis, FDA initially proposed the expansion of MedDRA with additional medication error terms. Led by the FDA, and with the participation of interested industry representatives and associations, the proposal was finalized in September 2004. In response to the regulatory need and with the active involvement of MedDRA subscribers, US FDA representatives, and the MedDRA Management Board, the MSSO undertook the expansion of medication error groupings in Version 8.0.

The medication error grouping terms (HLTs and HLGTS) in MedDRA were designed to facilitate accurate presentation of various types of medication errors and ultimately prevent them. The MSSO established a medical review team to evaluate the medication error change requests. The group included an FDA representative, JMO (Japanese Maintenance Organization) medical officers, and the MSSO medical review officers. A new HLGTS *Medication errors* was added in SOC *Injury, poisoning and procedural complications*.

**Standardised MedDRA Queries (SMQs)** – The MSSO participated in a working group tasked with the development of MedDRA Standardised MedDRA Queries (SMQs). The working group, formed under the auspices of the Council for International Organizations of Medical Sciences (CIOMS), is charged with development and initial testing of SMQs. The first products of this collaboration were made available to subscribers for production use in December 2004. This included two SMQs (Rhabdomyolysis/myopathy and Torsade de pointes/QT prolongation) as well necessary support documentation.

The production SMQs are considered part of MedDRA and will be maintained by the MSSO with each release of MedDRA. The release of the SMQs is a significant development for the MedDRA community. Just as MedDRA is a tremendous communication tool that is used to codify adverse events and communicate globally in clear, unambiguous terms, the SMQs provide the same capability to define standard queries. The SMQs have the added benefit that experts have developed queries that can now be used by the entire MedDRA community to provide a consistent data retrieval tool for MedDRA-coded data.

### **Internet Download**

The MSSO implemented an Internet download of the English version of MedDRA for subscribers. This service provides the most recent version of MedDRA to subscribers, including all support documentation, available for download on the scheduled MedDRA release date. Previously, subscribers received the English version of MedDRA on CD-ROM and had to wait until the product arrived in the mail. This upgrade in service was well received by the user community since it provides the users direct access to the latest version and allows for more time to review and incorporate the changes.

### **Outlook and Goals for 2005**

The MSSO looks forward to continued growth and development in 2005. The MSSO has several development efforts planned for 2005 that are intended to continue MedDRA's support for users. The following is a list of the planned development efforts:

- Conducting a Blue Ribbon Panel meeting to discuss MedDRA and Product Labeling
- Investigating the possibility of including additional medical device terms in MedDRA
- Conducting a feasibility study to review potential changes of HLT and HLTG groups to better support data analysis
- Implementing several more SMQs
- Soliciting input from clinical trial users to ensure MedDRA's utility
- Exploring the implementation of MedDRA for non-ICH regions

### **MedDRA Management Board and the Senior Members of the MSSO**

The activities of the MedDRA MSSO are overseen by the Management Board, which is composed of the six ICH parties, the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK, Health Canada, and The World Health Organization, and is chaired by the IFPMA. The individual members of the MedDRA Management Board are listed with their organizational affiliation.

Dr. Peter Arlett – European Commission  
Dr. Barry Arnold – EFPIA  
Dr. Christina Winter – EFPIA (Alternate)  
Mr. Barry Hammond – EFPIA (Alternate)  
Dr. Andrea G. Feight – FDA  
Dr. Ann Gaines – FDA (Alternate)  
Dr. Christopher Turner – Health Canada  
Ms. Shelley Gandhi – MHRA  
Mr. Hiroshi Moriguchi – MHLW

Mr. Kenichi Tamiya – MHLW (Alternate)  
Dr. Masahiko Yokota – MHLW (Alternate)  
Ms. Chie Kojima – MHLW (Alternate)  
Dr. Yo Tanaka – JPMA  
Mr. Takayoshi Ichikawa – JPMA (Alternate)  
Dr. Paul Lagarenne – PhRMA  
Ms. Janet Jenkins-Showalter – PhRMA (Alternate)  
Dr. Odette Morin – IFPMA  
Dr. Lembit Rägo – WHO Observer  
Dr. Mary Couper – WHO Observer (Alternate)

The MedDRA MSSO team is also international in nature with team members who were educated in Germany, Spain, China, India, and the United States. In addition to the MSSO Medical Team, the MSSO has an ongoing partnership in Japan with MedDRA Japanese Maintenance Organization (JMO.) The following is a list of the senior staff members and their role in the MSSO.

Patrick Revelle, Director  
Marvin Meinders, D.V.M., M.P.V.M., Manager of Terminology Maintenance  
Patricia Mozzicato, M.D., Medical Officer USA  
Eva-Beate Rump, M.D., Medical Officer Germany  
Tomás Moraleda Garcia, M.D., Medical Officer Spain  
Anna Zhao-Wong, M.D., Ph.D., Medical Analyst  
Nandini Mehorthra, M.D., Medical Analyst  
Maya Nair, M.D., Medical Analyst

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