



**MedDRA  
Maintenance and Support  
Services Organization  
Annual Report  
2006**

### MedDRA MSSO Mission

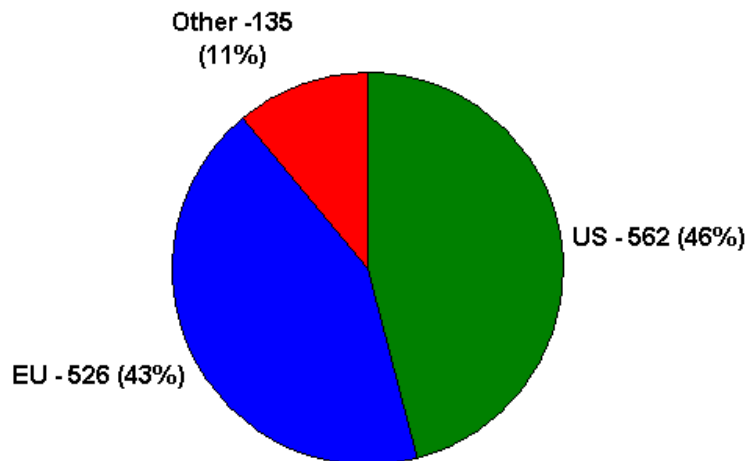
The MedDRA Maintenance and Support Services Organization (MSSO) is tasked with two functions:

- 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

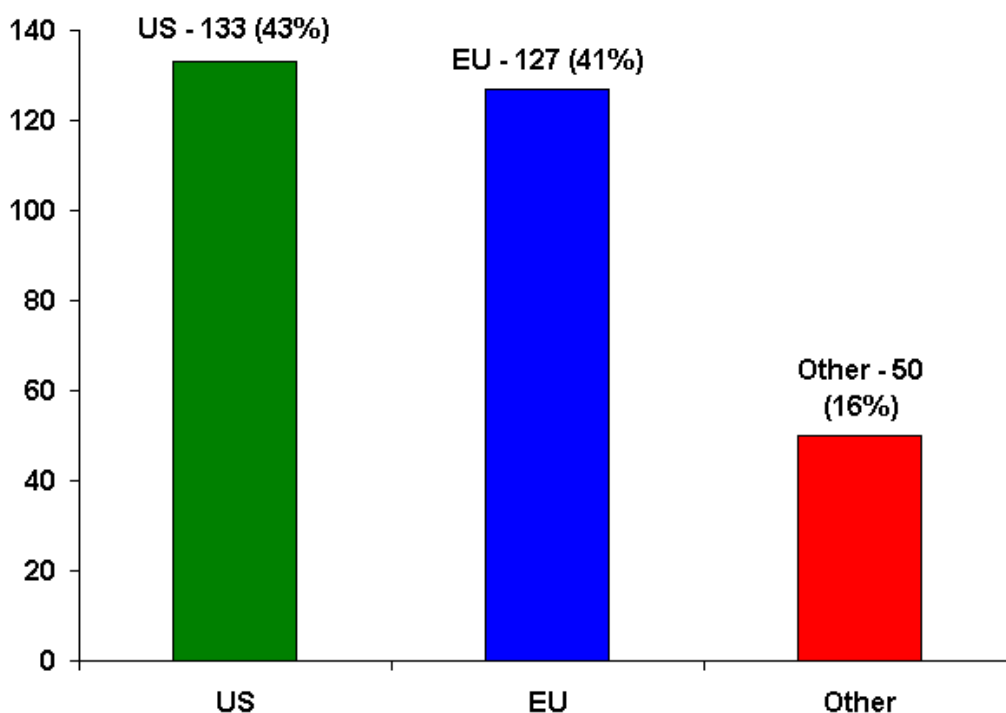
The goal of the MSSO is to maintain the MedDRA terminology as a stable, consistent terminology to suit the needs of regulatory authorities and the regulated biopharmaceutical industry. The terminology is used through the entire regulatory process, from pre-marketing to post-marketing; and for data entry,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

### Highlights for 2006

During 2006, the MSSO experienced a year of continued growth and development of MedDRA. The number of worldwide MedDRA subscribers was 1,665 by the end of 2006. Of the 1,665 worldwide subscribers, 1,223 were MSSO subscribers and 442 were JMO subscribers. The 1,223 MSSO subscribers represent a 24% growth in subscribers in 2006 over 2005. Figure 1 depicts the distribution of MSSO subscribers by region (number of subscribers and overall percentage). Figure 2 provides the number of new MSSO subscribers (310) in 2006 by each region.



**Figure 1 - MedDRA MSSO Subscribers (1223)**



**Figure 2 - Number of new MSSO subscribers (310) in 2006 by region**

The development of MedDRA continued as well. In 2006, the MSSO initiated several development efforts to ensure MedDRA evolves to meet the needs of the subscribers. The following sections provide a description of the significant MedDRA activities in 2006.

**New Subscription Rates** – The MSSO, in conjunction with the MedDRA Management Board, revised MedDRA subscription rates for 2007. The key change was the elimination of the subscription fee for non-profit or academic organizations and the reduction of the subscription fee for all subscription levels (by as much as 85%) with an emphasis on the low revenue organizations. The MSSO anticipates that the reduced rates will encourage further MedDRA subscriptions.

**Standardised MedDRA Queries (SMQs)** – The SMQ 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. As members of this working group, MSSO personnel attended meetings in 2006 and have directly participated in the development of 28 SMQs.

A total of 23 new SMQs were made available to subscribers with the MedDRA releases in March and September 2006. The MSSO will participate in 18-24 month reviews for all SMQs to review implemented changes and consider the content of SMQs based on user feedback.

**MSSO MedDRA Training** – In 2006, the MSSO initiated a free training program to provide classes in the US and Europe for new Basic, Core 0, and Core 1 subscribers. For regulators, the MSSO provided the same training for classes in the US and Europe. These classes were very popular and well attended.

**Webinars** – The MSSO began offering several webinars in 2006, including topics on medication error concepts, “What’s New in MedDRA,” MedDRA Coding Basics, and MedDRA for Statisticians and Programmers. Each webinar is 1-2 hours in duration. The response rate has been high for all offerings.

**MedDRA Modifiers** – In 2004, the MSSO held a “Blue Ribbon Panel” (BRP) on the topic of MedDRA modifiers. The BRP panelists concluded that there is a need to accommodate terms with modifiers in MedDRA but not by a separate modifier term that would be combined with existing MedDRA terms. As a result, the MSSO collected modified terms (e.g., Acidosis aggravated, Deep vein thrombosis recurrent, Bursitis worsened) from subscribers and processed them through the normal change request process with the criteria for acceptance provided by the BRP. This effort was completed with the release of MedDRA Version 9.1.

**Implementation of MedDRA in Vigibase** – The MSSO participated in meetings with IFPMA and WHO to discuss a business plan to support the Uppsala Monitoring Centre’s MedDRA implementation in the WHO Global Database (Vigibase). The goal is to extend the current Vigibase system to support the input of MedDRA-coded data and provide all output (e.g., reports) in MedDRA and WHO-ART<sup>®</sup>. Once agreed upon by the MedDRA Management Board and WHO, the project will begin in 2007.

**Mapping of MedDRA and the Common Terminology Criteria for Adverse Events (CTCAE) v3.0** – The US National Cancer Institute’s (NCI) CTCAE codes are mainly used as an adverse event severity grading scale for oncology clinical trials. For several years, the MSSO has received feedback from subscribers regarding issues with using CTCAE codes and MedDRA. Generally, subscribers’ concern was the difficulty in using the existing mapping (developed by NCI) between the CTCAE and MedDRA.

In April 2006, the MSSO held the fourth BRP to address the need for an improved mapping of CTCAE terms to MedDRA. The BRP made a series of recommendations that were endorsed by the MedDRA Management Board. The recommendations include removing ambiguous or multi-concept CTCAE terms, mapping from CTCAE grades to MedDRA LLTs, and establishing a collaborative working group from industry and regulators that will provide feedback on proposed changes to the mapping.

**HLGT/HLT Feasibility Study** – The fifth Blue Ribbon Panel meeting was held on 16 November 2006 in Mainz, Germany. The focus of the BRP was the proposed HLGT/HLT changes to improve MedDRA for data retrieval and analysis.

The BRP in 2006 considered the review of “NEC” HLTs and HLGTS, the multi-axiality of HLTs in cumulative data output, the multi-axiality of SOC *Investigations*, and the multi-axiality of SOC *Social circumstances*. A series of recommendations from the panel will be briefed to the MedDRA Management Board at the May 2007 meeting.

**Version Reports** – At the request of subscribers, the MSSO introduced a series of reports in spreadsheet form to provide easy access for non-IT users to the changes in each MedDRA version. The Version Reports are generated from the ASCII files by the MSSO and made available for download from the MSSO Web site associated with each MedDRA release. The reports include new terms (LLTs and PTs), promotions, demotions, currency Changes, SMQ changes, and several other listings. The feedback from subscribers on this initiative has been very positive.

**CME for Medical Team Members** – In 2006, the MSSO implemented a continuous medical education (CME) requirement for the doctors on the MSSO Medical Team. This was partly based on the recommendation of the 2005 Taratec clinical audit, but was also recognized by the MSSO as adding value to the terminology itself and creating a more attractive recruitment milieu for the future.

## **Outlook and Goals for 2007**

The MSSO looks forward to continued growth and development in 2007. The MSSO has several development efforts planned for 2007 that are intended to continue MedDRA's support for users. The following is a list of the planned development efforts:

- Implement several (25) more SMQs
- Participate in the WHO project to implement MedDRA in Vigibase
- Investigate the possibility of including additional medical device terms in MedDRA
- Explore the implementation of MedDRA for non-ICH regions (e.g. China)
- Implement the HLT/HLGT approved recommendations to further extend MedDRA's data analysis capabilities
- Add the Czech translation to the list of MedDRA translations
- Implement the new MedDRA Expert Panel to support the MSSO
- Explore improving the change request submission process by adding a web-based data entry page for subscribers
- Expand the regulatory training by increasing the number of training classes and providing advanced topics
- Continue to produce – and increase the number of – scientific papers on MedDRA

## **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. Robert Wise – FDA (Alternate)  
Ms. Heather Sutcliffe – Health Canada  
Dr. Christopher Turner – Health Canada (Alternate)  
Mr. Morell David – MHRA  
Mr. Masanobu Yamada – MHLW  
Dr. Tetsuya Kusakabe – MHLW (Alternate)  
Dr. Tatsuo Kishi – MHLW (Alternate)  
Mr. Yo Tanaka – JPMA  
Mr. Takayoshi Ichikawa – JPMA (Alternate)  
Dr. Paul Lagarenne – PhRMA

Ms. Janet Jenkins-Showalter – PhRMA (Alternate)  
Dr. Odette Morin – IFPMA  
Dr. Dawn Ronan – IFPMA (Alternate)  
Dr. Lembit Rägo – WHO Observer  
Dr. Mary Couper – WHO Observer (Alternate)  
Mr. Yasuo Sakurai – JMO  
Mr. Hiromichi Satou – JMO (Alternate)  
Mr. Patrick Revelle – MedDRA MSSO  
Dr. Patricia Mozzicato – MedDRA MSSO (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 the 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., MSSO Chief Medical Officer  
Eva-Beate Rump, M.D., Medical Officer Germany  
Tomás Moraleda Garcia, M.D., Medical Officer Spain  
Anna Zhao-Wong, M.D., Ph.D., Manager of MedDRA Terminology Development and Services  
Nandini Mehrotra, M.D., Medical Analyst  
Maya Nair, M.D., Medical Analyst  
Judy Harrison, M.D., MSSO Consultant

MedDRA® is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). WHO Adverse Reaction Terminology (WHO-ART), Copyright © 1998 World Health Organization Collaborating Centre for International Drug Monitoring.