



**MedDRA
Maintenance and Support
Services Organization
Annual Report
2008**

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 2008

During 2008, the MSSO experienced a year of continued growth and development of MedDRA. The number of worldwide MedDRA subscribers was 2,407 by the end of 2008. Of the 2,407 worldwide subscribers, 1,917 were MSSO subscribers and 490 were JMO subscribers. The 1,917 MSSO subscribers represent an 18% growth in subscribers in 2008 over 2007. 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 (486) in 2008 by each region.

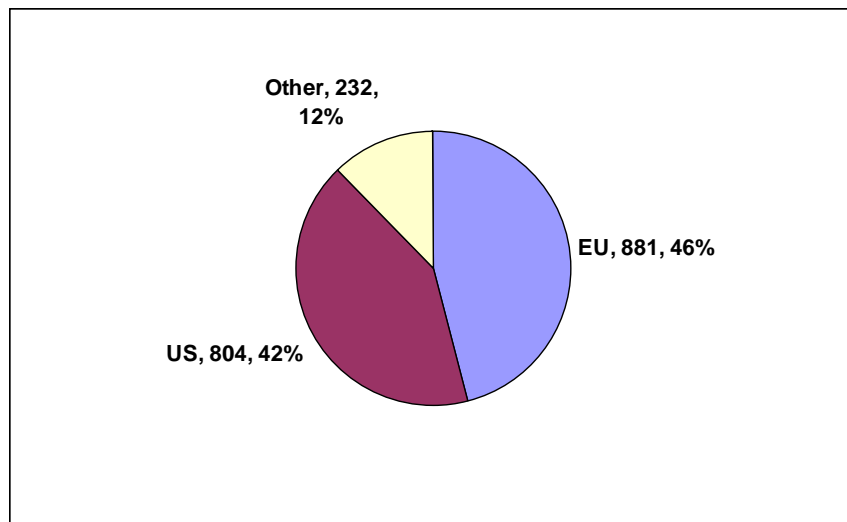


Figure 1 - MedDRA MSSO Subscribers (1917)

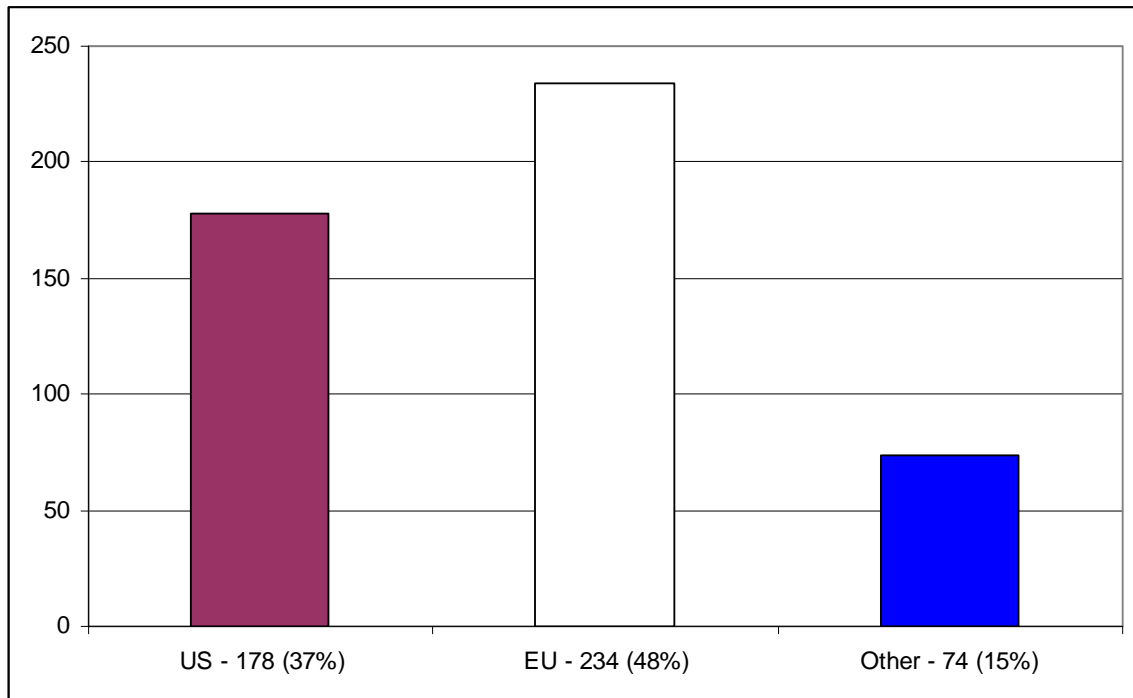


Figure 2 - Number of new MSSO subscribers (486) in 2008 by region

The development of MedDRA continued as well. In 2008, the MSSO initiated several efforts to ensure MedDRA evolves to meet the needs of the subscribers. The following sections provide a description of the significant MedDRA activities in 2008.

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 participated in the development and maintenance of SMQs. In 2008, 12 new SMQs (three in v11.0 and nine in v11.1) were released for use by subscribers bringing the total number of production SMQs to 67.

Subscription Rates - The Board approved the reduction of 5% for all Core levels and the Developer Sub-license for 2009 at the end of 2008. This reduction in subscription rates marks the fourth consecutive year MedDRA subscription rates have been reduced. The new rates are as follows.

2008 & 2009 Annual Subscription Rates		
Subscription Level	2008	2009
Basic	\$0	\$0
Core 0 (< \$1M)	\$200	\$190
Core 1 (\$1-10M)	\$850	\$804
Core 2 (\$10-500M)	\$5,850	\$5,529
Core 3 (\$500M – 1B)	\$12,270	\$11,600
Core 4 (\$1B – 5B)	\$50,243	\$47,600
Core 5 (> \$5B)	\$66,451	\$62,850
Developer	\$3,152	\$2,990
Regulatory Authority	\$0	\$0

EU Translations – The MedDRA translations for Czech, Dutch, French, German, Italian, Portuguese, and Spanish were made available to MSSO subscribers at no charge. The MSSO anticipates that this change will simplify the subscription process and will increase the utilization of the EU translations.

Gender and Pediatric Term Lists – At the request of the MedDRA Management Board, the MSSO developed a list and supporting documentation of Gender terms and Pediatric terms. The lists could be used to improve data quality of adverse event reporting and for specific pharmacovigilance practices (clinical trial study for male patients should not include MedDRA terms identified as female).

Unlike SMQs, these lists are not intended to identify a medical condition or area of interest. Similar to SMQs, these lists will be maintained by input from subscribers and updated with each version of MedDRA by the MSSO.

These lists are intended as recommendations only and are not part of any regulatory requirement. They provide the basis for a common understanding, and leave organizations the option to modify the lists – either adding or deleting terms – according to their own specific needs.

MSSO MedDRA Change Request (WebCR) - The MSSO implemented the change request submission software tool that allows MedDRA subscribers to enter change requests via a web-based user interface. The WebCR tool affords subscribers the ability to determine if there is a similar term in place or in process, provide justification for the request, and eliminates the need to create

and submit multiple documents such as a request spreadsheet and separate justification documents.

MedDRA Expert Panel - The MSSO organized an external MedDRA expert panel to provide feedback to the MSSO on MedDRA development ideas and provide a mechanism to review contested change requests. The MedDRA Expert Panel met on 23 May to discuss three issues raised by subscribers: the utility of MedDRA definitions, a possible annual release of MedDRA, and the fate of non-current terms. The MSSO held a webinar in July with the MedDRA Expert Panel to discuss the implementation of device terms in MedDRA and to discuss and prioritize proposed changes to the MedDRA Desktop Browser. The Management Board approved a review for implementation of a proposed set of Product Quality terms requested by the US FDA. The MSSO provided the Expert Panel with the list of terms and proposed hierarchy for their feedback. The MSSO worked with the US FDA to address the comments from the Expert Panel and the MSSO Medical Team before implementing the terms for MedDRA 12.0.

MSSO MedDRA Training - The MSSO continues its effort to train MedDRA MSSO subscribers and regulatory authorities on MedDRA. During 2008, the MSSO provided MedDRA training to 1,530 people. Of this number, 301 individuals were from regulatory authorities representing the following countries: Austria, Bulgaria, Canada, Croatia, France, Germany, Spain, Switzerland, Turkey, the United Kingdom, and the United States.

Since the original launch of the free training program in 2007, the MSSO has increased the number of classes taught, included introductory and advanced topics, added an online webinar, and taught classes in English, French, German, and Spanish). These classes have been very popular with MedDRA users and the MSSO will continue to diversify the training methods (e.g., face-to-face, webinar, downloadable modules) to provide a number of options.

Additional Medical Device Terms in MedDRA - The MSSO coordinated efforts with the FDA's Center for Devices and Radiological Health (CDRH) to discuss the status of the device terminology they have developed. The MSSO will continue this coordination and review CDRH terms for potential inclusion in MedDRA.

The MSSO formed the MedDRA device working group based on the recommendations from the Expert Panel members and MedDRA users. The working group is made up of volunteers from industry and regulatory agencies. The working group is reviewing the device problem codes from the CDRH and

those from the ISO-210 Working Group. Based on this review, the working group will develop recommendations on the level of detail and the type of device terms that should be incorporated into MedDRA, and develop recommendations on the future device hierarchical structure in MedDRA.

Scientific Papers on MedDRA - The following are papers written by MSSO staff on MedDRA during the 2008 year.

Rump, E. Medication error reporting and MedDRA. *Pharmacovigilance Review* 2008, 2:(2), 15 - 17

Outlook and Goals for 2009

The MSSO looks forward to continued growth and development in 2009. The MSSO has several development efforts planned for 2009 that are intended to continue MedDRA's support for users. The following is a list of the planned development efforts:

- Implement more SMQs and support the implementation of SMQs by subscribers
- Implement the product quality terms in MedDRA
- Complete the medical device term review
- Complete the initial MedDRA Chinese translation (including translation validation) and make it available to subscribers in Fall 2009
- Field the MSSO Desktop Browser and support the fielding of the Web-based MedDRA Browser
- Explore the implementation of MedDRA for non-ICH regions (e.g. China)
- Coordinate MedDRA development activities with the MedDRA Expert Panel
- Continue implementing a broader and more comprehensive free MedDRA training program for regulators and subscribers
- Proactively seek feedback from regulators on MedDRA translations
- 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. Matus Ferech - European Commission
Dr. Barry Arnold – EFPIA
Dr. Christina Winter – EFPIA (Alternate)
Mr. Barry Hammond – EFPIA (Alternate)
Dr. John (Jake) Kelsey - FDA
Dr. Marthe Bryant-Genevier – FDA (Alternate)
Dr. Robert Wise – FDA (Alternate)
Ms. Heather Sutcliffe – Health Canada
Dr. Christopher Turner – Health Canada (Alternate)
Mr. Morell David – MHRA
Mr. Kenji Kuramochi – MHLW
Ms. Wakako Horiki – MHLW (Alternate)
Mr. Daisaku Sato – MHLW (Alternate)
Mr. Yo Tanaka– JPMA
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. Shigeki Tsuda – JMO (Alternate)
Mr. Patrick Reville – MedDRA MSSO
Dr. Patricia Mozzicato – MedDRA MSSO (Alternate)
Dr. Anna C. Zhao-Wong – MedDRA MSSO (Alternate)

The MedDRA MSSO team is also international in nature with team members who were educated in Germany, Spain, China, India, UK, 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 Reville, Director
Brian O'Hare, 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., Deputy Director and Manager of MedDRA
Terminology Development and Services
Nandini Mehrotra, M.D., Medical Analyst
Marvin Meinders, D.V.M., M.P.V.M., Medical Officer USA
Judy Harrison, M.D., MSSO Consultant

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