



**MedDRA  
Maintenance and Support  
Services Organization  
Annual Report  
2009**

## 1 MedDRA MSSO Mission

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

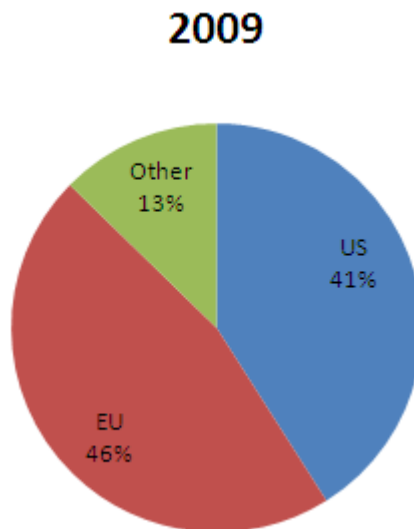
- Establish and maintain a mechanism for international support and development of the MedDRA terminology
- Foster the use of MedDRA worldwide through communication, education, and services

The goal of the MSSO is to maintain MedDRA 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.

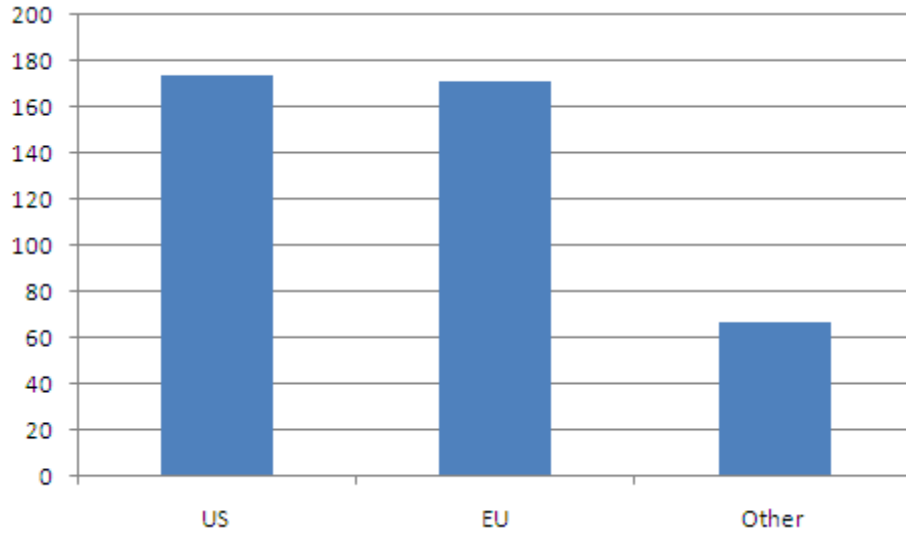
## 2 Highlights for 2009

### 2.1 Subscription and Subscription Rates

The year 2009 was a year of continued growth and development of MedDRA for the MSSO. MedDRA had 2,613 subscribing organizations worldwide by the end of 2009 (2,407 in 2008). Of the 2,613 worldwide subscribers, 2,108 were MSSO subscribers (1,917 in 2008) and 505 were JMO subscribers (490 in 2008). The 2,108 MSSO subscribers represent a 10% growth in subscribers in 2009 over 2008 (18% the year before). Figure 2-1 depicts the distribution of MSSO subscribers by region. Figure 2-2 provides the number of new MSSO subscribers (412) in 2009 (486 in 2008) by each region.



**Figure 2-1. MedDRA MSSO Subscribers (2108)**



**Figure 2-2 New MSSO Subscribers (412) in 2009**

At the end of 2009, the Board approved the MSSO's proposal for no changes in subscription rates from 2009 for 2010 (see Table 2-1). The 2010 rates are as follows.

Subscription Level	2009/2010
Basic	\$0
Core 0 (< \$1M)	\$190
Core 1 (\$1-10M)	\$804
Core 2 (\$10-500M)	\$5,529
Core 3 (\$500M – 1B)	\$11,600
Core 4 (\$1B – 5B)	\$47,600
Core 5 (> \$5B)	\$62,850
Developer	\$2,990
Regulatory Authority	\$0

**Table 2-1- 2009 and 2010 Annual Subscription Rates**

## 2.2 Major Development of MedDRA Terminology

In 2009, the MedDRA terminology including translations and SMQs continued to grow and evolve. A summary of major additions and modifications in the 2009 releases of MedDRA are listed in Table 2-2.

Activity	Version	Initiator
Product quality terms*	12.0	FDA
Divide large HLTs into smaller, medically meaningful groupings*	12.0	Blue Ribbon Panel
7 new SMQs	12.0	CIOMS SMQ Working Group
Vaccine terms	12.1	MSSO/CIOMS Vaccine PV WG
5 new SMQs	12.1	CIOMS SMQ Working Group
Chinese translation	12.1	MedDRA Management Board

**Table 2-2. Highlights in v12.0 and v12.1**

\* Some of the effort for these tasks was performed in 2008.

### Vaccine Terms

The MSSO mapped 22 available definitions of adverse events following vaccination published by the Brighton Collaboration to MedDRA terms and identified missing concepts as the potential additions to MedDRA to aid in vaccine pharmacovigilance.

### Chinese Translation

After the IFPMA received the MedDRA Chinese translation from Pfizer, the MSSO updated the translation from MedDRA v7.1 to MedDRA v12.1. In a cooperative effort with MedDRA subscribers, the translation was verified and found to be of good quality. The MedDRA Chinese translation was made available to subscribers on 15 September 2009.

Unlike EU translations, an additional fee is required to access the MedDRA Chinese translation. The MedDRA Management Board decided that the Chinese translation fee will not change in 2010. Table 2-3 provides the 2010 MedDRA Chinese translation subscription fees.

Subscription Level	2009/2010
Basic	\$100
Core 0 (< \$1M)	\$100
Core 1 (\$1-10M)	\$100
Core 2 (\$10-500M)	\$500
Core 3 (\$500M – 1B)	\$1,000
Core 4 (\$1B – 5B)	\$2,000
Core 5 (> \$5B)	\$3,000
Developer	\$1,500
Regulatory Authority	\$0

**Table 2-3. 2009 and 2010 Chinese Translation Subscription Fee**

### SMQs

Twelve new SMQs were added in 2009 bringing the total number of production SMQs to 79. Four existing SMQs with only broad scope terms – *Biliary disorders*, *Cardiac arrhythmias*, *Hepatic disorders*, and *Taste and smell disorders*– were reviewed by the CIOMS SMQ Working Group and the MSSO; changes were made so that each SMQ had both narrow and broad terms in v12.1. This effort will continue in MedDRA v13.0.

### Microorganism Identification Terms

The MSSO received a proposal from a regulatory authority to add additional microorganism identification test terms in SOC *Investigations* for MedDRA v13.0. The proposal included approximately 120 new PTs and 197 new LLTs, and it included the movement of existing PTs and LLTs. The new terms describe laboratory confirmation of a microorganism when there is no documented infection. These new terms facilitates the monitoring of contamination of biologics, medical devices, food supply, etc.

## 2.3 Significant MSSO Activities

### Blue Ribbon Panel

The Blue Ribbon Panel for the Extent of Versioning and Feasibility of Annual Release was held on 13 May 2009 in Kenilworth, New Jersey, USA. The panelists were Barry Hammond (GSK), JoAnn Medbery (J&J), Tom Paternoster (EMA), Toni Piazza-Hepp (FDA), and Yasuo Sakurai (JMO). Thirty-eight MedDRA subscribers also attended and participated in the discussions. The Board approved all of the Panel’s recommendations which included adding a versioning discussion to the ICH MedDRA Term Selection: Points to Consider

document, to retain the twice a year releases of MedDRA, and for the MSSO to investigate the scope and effort to develop a MedDRA versioning tool.

### **MedDRA Desktop Browser Upgrade**

The MSSO continued to maintain and support the MedDRA Desktop Browser. This included both a major and minor release that provided new features based on user requests. The MSSO will continue to support this tool in the future.

### **MSSO New Web Site**

The MSSO launched a revised MedDRA MSSO Web site in October 2009. The new site is a complete reorganization of the site based on feedback from MedDRA users. The MSSO has also included a Google™ search function within the site to provide users a familiar tool to find information within the MSSO Web site. The feedback from users on the revised site has been very positive.

### **MSSO MedDRA Training**

The MSSO continues its effort to train subscribers and regulatory authorities on MedDRA. Webinars were added to the free MedDRA training program in 2009. During 2009, the MSSO provided free MedDRA training to 1,753 people. Of this number, 680 individuals were from regulatory authorities representing the following countries: Abu Dhabi-United Arab Emirates, Belgium, Cameroon, Canada, Denmark, Egypt, Finland, France, Germany, Iraq, Ireland, Kenya, Kingdom of Saudi Arabia, Morocco, Nepal, Nigeria, Sierra Leone, Serbia, Singapore, South Korea, Sweden, Togo, and the United States.

### **MSSO Medical Team**

The MSSO Medical Team had its annual face-to-face meeting in February 2009. There were useful discussions of many MedDRA maintenance issues resulting in resolutions or additional actions. The discussion topics included: status of and activities related to the gender, pediatric and important medical events (IME), the potential of adding pharmacogenomic/pharmacogenetic terms to MedDRA, adding examples of practical applications of SMQs to MSSO training courses, and progress on addition of device-related terms to MedDRA.

### **MedDRA in non-ICH regions**

The MSSO participated the first DIA-China Annual meeting in Beijing and presented “MedDRA and MedDRA Chinese translation” at the Pharmacovigilance Workshop in November 2009. The MSSO will continue its effort to foster the use of MedDRA in China.

The MSSO conducted training on the use of MedDRA in the Uppsala Monitoring Centre’s Vigibase system to the attendees of WHO’s National Centre meeting in Rabat, Morocco. This was an important milestone since most of the training attendees had little experience with MedDRA.

One of the MSSO physicians attended the Latin American Congress of Clinical Research (LARC) in Mexico City. The goal was to learn more about the status and harmonization of regulatory practices in Latin America and to network with individuals who may be interested in furthering MedDRA’s use throughout the region. In 2010, we plan to conduct a MedDRA tutorial at this conference.

### **MSSO 2009 Outreach**

The MSSO met with a senior scientist with the Institute for Safe Medication Practices to discuss his comments on the utility of SMQs to mine the FDA’s AERS data. His comments and recommendations were helpful in improving a number of SMQs.

MedDRA was accepted as a standard terminology by the US National Cancer Institute (NCI) within the Cancer Bioinformatics Grid (caBIG).

### **MSSO ISO Certification**

In August 2009, the MSSO passed an independent audit for compliance with the ISO 9001:2008 standard for Quality Management Systems. The ISO certification reinforces to MedDRA users through an independent third-party, that the MSSO operates an effective quality management system that delivers a quality product.

## **2.4 Outlook and Goals for 2010**

The MSSO looks forward to continued growth and development in 2010. There are several development efforts planned for 2010 that are intended to continue and enhance the MSSO’s support for MedDRA users. The following is a list of the planned development efforts:

- Implement more SMQs and support their implementation by MedDRA users
- Provide the MedDRA Hungarian translation for initial release
- Provide training for non-ICH regions as endorsed by the ICH MedDRA Management Board / ICH Global Cooperation Group (e.g., ASEAN Workshop, Kuala Lumpur, March 2010).
- Update WebCR to provide more functions to MedDRA users

- Develop MedDRA Versioning Analysis Tool
- Continue MedDRA development in 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
- Continue proactively seeking feedback from regulatory authorities 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. Sabine Brosch - European Commission (Alternate)

Dr. Christina Winter – EFPIA

Dr. Barry Arnold – EFPIA (Alternate)

Mr. Barry Hammond – EFPIA (Alternate)

Dr. John (Jake) Kelsey - FDA

Dr. Marthe Bryant-Geneviev – FDA (Alternate)

Ms. Heather Sutcliffe – Health Canada

Dr. Christopher Turner – Health Canada (Alternate)

Mr. Morell David – MHRA

Mr. Daisaku Sato – MHLW

Mr. Yoshihiko Sano – MHLW (Alternate)

Ms. Wakako Horiki – MHLW (Alternate)

Mr. Yo Tanaka– JPMA

Dr. Paul Lagarenne – PhRMA

Ms. JoAnn Medbery – 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. Osamu Handa – JMO (Alternate)  
Mr. Patrick W. Revelle – 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 Canada, 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 Revelle, Director

Anna Zhao-Wong, M.D., Ph.D., Deputy Director and Manager of MedDRA Terminology Development and Services

Patricia Mozzicato, M.D., Chief Medical Officer

Brian O'Hare, Manager of Terminology Maintenance

Eva Beate-Rump, M.D., Medical Officer Germany

Tomás Moraleda Garcia, M.D., Medical Officer Spain

Savian Nicholas, M.D., Medical Officer USA

Nandini Mehrotra, M.D., Medical Analyst

Judy Harrison, M.D., MSSO Consultant

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