



**MedDRA
Maintenance and Support
Services Organization
Annual Report
2013**

1 MedDRA as an ICH Product

MedDRA was developed under the auspices of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). The activities of the MedDRA Maintenance and Support Services Organization (MSSO) are overseen by an ICH MedDRA Management Board, which is composed of the European Union (EU), European Federation of Pharmaceutical Industries and Associations (EFPIA), Ministry of Health, Labour and Welfare (MHLW) of Japan, Japanese Pharmaceutical Manufacturers Association (JPMA), the US Food and Drug Administration (FDA), Pharmaceutical Research and Manufacturers of America (PhRMA), the Medicines and Healthcare products Regulatory Agency (MHRA) of the UK, Health Canada, the World Health Organization (WHO), and the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA). See Section 3.5 for a list of the individual Management Board members.

2 MedDRA MSSO Mission

The MedDRA 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 throughout the entire regulatory process, from pre-marketing to post-marketing; and for data entry, retrieval, evaluation, and presentation.

3 Highlights for 2013

3.1 Subscriptions and Subscription Rates

The year 2013 was a year of continued growth and development of MedDRA. MedDRA had 3919 subscribing organizations worldwide by the end of 2013 (3606 in 2012). Of the 3919 worldwide subscribers, 3314 were MSSO subscribers (3035 in 2012) and 605 were JMO subscribers (571 in 2012). The 3314 MSSO subscribers represent an 8.4% growth in subscribers in 2013 over 2012 (16.1% the year before).

Figure 3-1 depicts the distribution of MSSO subscribers by region.

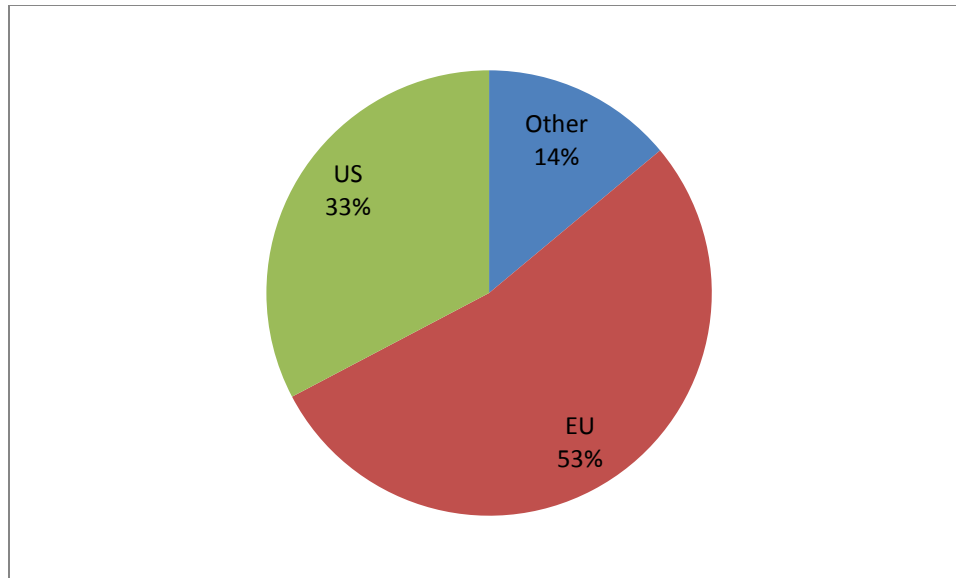


Figure 3-1. MedDRA MSSO Subscribers (3314)

At the end of 2012, the Board approved the 2013 subscription rates (including Chinese and Japanese translation subscription rates) that were unchanged from the rates in 2012; see Tables 3-1 and 3-2. MSSO's subscription rates have either been unchanged or decreased for the past 8 years (since 2006).

The 2013 rates are as follows.

Subscription Level	2013
Non-Profit / Non-Commercial	\$0
Commercial 0 (< \$1M)	\$190
Commercial 1 (\$1-10M)	\$804
Commercial 2 (\$10-500M)	\$5,529
Commercial 3 (\$500M – 1B)	\$11,600
Commercial 4 (\$1B – 5B)	\$47,600
Commercial 5 (> \$5B)	\$62,850
Developer	\$2,990
Regulatory Authority	\$0

Table 3-1. 2013 Annual Subscription Rates (in US Dollars)

Table 3-2 provides the 2013 MedDRA Chinese and Japanese translation subscription fees; the fees were the same as those for 2012. Users subscribing to the Chinese or Japanese translation must also have a MSSO subscription.

Subscription Level	Chinese Subscription Rate	Japanese Subscription Rate
Non-Profit / Non-Commercial	\$50	\$850
Commercial 0 (< \$1M)	\$50	\$850
Commercial 1 (\$1-10M)	\$50	\$850
Commercial 2 (\$10-500M)	\$150	\$850
Commercial 3 (\$500M – 1B)	\$300	\$850
Commercial 4 (\$1B – 5B)	\$600	\$850
Commercial 5 (> \$5B)	\$850	\$850
Developer	\$450	\$850
Regulatory Authority	\$0	\$0

Table 3-2. 2013 Chinese and Japanese Translation Subscription Fee (in US Dollars)

3.2 Major Developments of MedDRA Terminology

In 2013, MedDRA, including Standardised MedDRA Queries (SMQs), continued to grow and evolve. A summary of major additions and modifications in the 2013 releases of MedDRA is shown in Table 3-3.

Activity	Version	Initiator
Exposure terms, complex changes* resulting in 24 new exposure terms and 68 changes to existing terms	16.0	Discussions with ICH Points To Consider Working Group / MedDRA Expert Panel
Changes to SOC <i>Neoplasms benign, malignant and unspecified (incl cysts and polyps)</i> resulting in a total of 648 changes.	16.0	Blue Ribbon Panel meeting based on a MedDRA user request
SMQs – three new SMQs added	16.0	CIOMS SMQ Working Group /

Activity	Version	Initiator
and three SMQs renamed.		MedDRA user
Harmonization of the placement of Bruise, Contusion and Ecchymosis concepts resulting in 67 changes	16.0	MedDRA User Proactivity Request
Reviewed the placement of autoimmune disorder concepts resulting in 57 changes	16.0	MedDRA User Proactivity Request
SMQs – four new SMQs added	16.1	CIOMS SMQ Working Group
Removal of inactive PTs from Level 1 SMQs	16.1	MSSO / MedDRA user
Addition of 37 Catheter Site Terms	16.1	MedDRA User Proactivity Request
Reviewed the placement Neonatal terms which resulted in 37 changes	16.1	MedDRA User Proactivity Request
Addition of 216 missing American and British spellings counterparts ⁺	16.1	MedDRA user proactivity request.

Table 3-3. Highlights in MedDRA Version 16.0 and 16.1

* Some of the effort to complete these tasks was performed in 2011 and 2012 for MedDRA Version 14.1 and v15.0.

+ Completion of effort started in 2012

SMQs

The total number of production Level 1 SMQ topics is 94 as of MedDRA Version 16.1. Below is the list of the 7 SMQs added in the 2013 releases:

- *SMQ Arthritis*
- *SMQ Chronic kidney disease*
- *SMQ Hypersensitivity*
- *SMQ Malignant lymphomas*
- *SMQ Myelodysplastic syndrome*
- *SMQ Noninfectious diarrhoea*
- *SMQ Tumour lysis syndrome*

Exposure terms, complex changes

In MedDRA v16.0, 24 new exposure terms were added and 68 changes to existing exposure terms were implemented. These changes were the result of efforts by the MSSO, regulatory authorities and industry experts from the Points to Consider Working Group and the MedDRA Expert Panel to make exposure terms more self-explanatory and easier to use for pharmacovigilance purposes. This work builds upon earlier efforts to improve exposure terms in MedDRA and was performed in conjunction with the complex change review process.

Neoplasm SOC changes

In April 2011, the MSSO held its seventh Blue Ribbon Panel (BRP7) to discuss potential improvements to SOC *Neoplasms benign, malignant and unspecified (incl cysts and polyps)*. The MSSO implemented MedDRA Management Board endorsed recommendations which resulted in a total of 648 changes including 150 new terms and 498 changes to existing terms for MedDRA v16.0.

Proactive Maintenance

Proactive maintenance means the MSSO may make corrections or improvements to MedDRA that it identifies without receiving specific change requests from users. Certain important changes may require Board approval. MedDRA users may also request more general changes to MedDRA – perhaps correcting a series of outdated terms or addressing an area of inconsistency – outside the change request submission process.

Five proactivity proposals that originated from MedDRA users were implemented in 2013:

- Modifications to the placement of bruise, contusion, and ecchymosis terms to address some inconsistencies in how these terms were represented in MedDRA. A total of 67 changes were implemented based on this review.
- Addition of 216 missing American or British spelling counterparts to existing MedDRA terms to improve MedDRA for coding and consistency. This was a continuation of a proactivity request submitted in 2012.
- The MSSO reviewed the placement of autoimmune disorder concepts classified as “systemic”. The review focused on providing additional links, or in some cases reassigning the primary SOC, of existing terms from SOC *Immune system disorders* to a SOC representing the site of manifestation. A total of 57 changes were implemented based on this review.

- The MSSO added additional 37 catheter site PTs and LLTs in MedDRA v16.1 to improve coding and data analysis for these concepts.
- The placement of terms relating to the neonatal period such as “neonatal”, “neonatorum”, “perinatal”, “newborn”, “due to birth trauma” was adjusted to address inconsistencies in how these concepts were placed. A total of 37 changes were implemented based on this review.

3.3 Significant MSSO Activities

MedDRA Website

The ICH Secretariat and the MSSO worked closely together to launch the redesigned MedDRA website with a brand new logo on 23 July 2013. The new site and logo introduce a refreshed and revitalized visual identity for MedDRA. The new look and feel celebrates MedDRA as an ICH product and embodies aspects of ICH’s own visual identity. The website parallels the look and feel of the ICH website (www.ich.org) in its layout and navigation. The website is designed to maximize user-friendliness, and is geared towards supporting the needs of new and existing MedDRA users alike. The new site includes all MedDRA files and documentation, new automated features for subscriptions and event registration (e.g., training, User Groups), and an enhanced organization of the information on the site.

Web Based Browser Development

In 2013 the MSSO began development of a web-based browser (WBB) which will be made available to MedDRA users in place of the current web browser at the end of 2014. The WBB will add to the existing suite of tools which the Board has directed the MSSO to develop to support MedDRA users. The new WBB will have a similar look and feel as the current MedDRA Desktop Browser and will include similar functions such as a research bin, history feature, and support for browsing in multiple supported languages. It will also include some new features which will then be added in a second step to the Desktop Browser in an effort to keep both browsers consistent.

MSSO MedDRA Training

During 2013, the MSSO provided free MedDRA training to 1,710 people as part of their MedDRA subscription. There were 50 classes of face-to-face training with a total of 1,018 attendees. Of this amount, 347 were from regulatory authorities representing the following countries: Austria, Belgium, Canada, France, Ireland, Spain, the Netherlands, and the United States.

The 1,710 total trainees include 692 webinar connections for 13 free MedDRA user webinars. The MSSO will continue to provide webinars in 2014 on a variety of topics including Introduction to MedDRA, MedDRA Coding Basics, Introduction

to MedDRA Safety Data Analysis and SMQs for Physicians, and What's New with MedDRA Versions 17.0 and 17.1.

MedDRA in China

The MSSO was part of an ICH delegation that met with the China Food and Drug Administration (CFDA)/Chinese Pharmacopoeia in March 2013. The goal of the meeting was to address Chinese interest in MedDRA. Briefings included those provided by ICH delegates providing their experiences with the implementation of MedDRA in their regions (EU, Canada, Japan, and UK).

The MSSO also participated in a series of activities in Beijing, China. This included the following:

- Conducted MedDRA training (Coding With MedDRA and Safety Data Analysis and SMQs classes)
- Held a MedDRA User Group meeting
- Presented, with a representative of US FDA, at a workshop entitled “Applying MedDRA in Clinical Safety and Pharmacovigilance Practices: Regulatory Perspective” at the DIA China Annual meeting

The training classes and meetings were attended by a variety of participants including representatives of international and Chinese domestic companies, hospitals, CROs, and academics.

ICD-10 Mapping to MedDRA

In October 2012, the MSSO completed an ICD-10 to MedDRA mapping at the 3-digit level of ICD-10 which equates to approximately 2000 ICD-10 terms. While this level forms a major part of the various country-specific versions of ICD-10, it does not represent a fully common core. Some countries included many but not all of the 3-digit terms, while some also added their own 3-digit terms not in the ICD-10 version produced by WHO. This could limit the utility of the 3-digit level subset mapping across different countries.

At the Management Board meeting in November 2013, the MSSO informed the Board that it would continue to explore use cases for an ICD-10 to MedDRA mapping, but as a lower priority.

MSSO ISO Certification

In August 2013, the MSSO passed an independent surveillance audit for compliance with the ISO 9001:2008 standard for Quality Management Systems. The certification (also known as registration) period is from September 2012 to October 2015. The MSSO will have annual surveillance audits in August of the interim years to ensure continuing compliance with the standard. 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.

Collaboration with EU and US Poison Control Centers

The MSSO continues to participate in a meeting of the Alerting, Reporting and Surveillance System for Chemical Health Threats project in Phase III (ASHTIII). The ASHT project aims at improving health security from cross-border chemical health threats. ASHTIII seeks to further develop the functionality and sustainability of the Rapid Alerting System for Chemical Health Threats (RAS-CHEM) and promote the use and implementation of the project among EU Member States. MedDRA was selected for use with RAS-CHEM during the second phase of the ASHT project. The MSSO will work with the ASHTIII team to assist them with MedDRA changes that may be needed in this phase of the project.

The MSSO was in contact with the American Association of Poison Control Centers (AAPCC) which supports 59 poison control centers in the United States. It is interested in mapping its Clinical Effect Terms (CETs) to MedDRA.

Collaboration with US Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)

The MSSO was invited by the US NICHD to participate in an initiative to develop a pediatric terminology to enhance the conduct, dissemination and impact of child health research. The initiative is sponsored by NICHD of the National Institutes of Health (NIH). The organizers and the MSSO are committed to work to ensure compatibility between the future pediatric terminology and MedDRA (i.e., MedDRA serves as one of the term sources of the new terminology). This effort will continue over several years.

Cloud Distribution

The MSSO has continued to hold meetings with MedDRA users to gauge the impact of transitioning the MedDRA distribution method from internet file download to a cloud based approach. The goal of the discussions is to understand the impact of moving to a cloud distribution method and to understand the status of cloud approaches in place today with MedDRA users. The MSSO has contacted a variety of users (regulatory, pharmaceutical companies, software developers) of different sizes (i.e., Commercial 0-5, non-profits). In general, organizations have described a plan to move to the cloud but are at very different stages of implementation. The MSSO plans to continue these contacts to further understand the impact of the cloud approach.

APHA Annual Meeting

The MSSO delivered a MedDRA presentation at the American Public Health Association's (APHA) annual meeting on 4 November. The APHA is a 30,000 member professional organization for public health professionals in the United States.

EMA 1st MedDRA Information Day

The MSSO participated in the DIA EMA MedDRA Information Day on 22 October 2013 in London, UK, which focused on medication errors. It was a very informative and interactive meeting with about 80 people in attendance. Medication errors are an important patient safety issue and the MSSO plans to continue working with regulators, industry, and patient groups to facilitate the identification and reporting of medication errors.

Other MSSO Presentations

In addition to the two meetings mentioned above, the MSSO presented at several other professional meetings in the US, UK, China, France, and the Netherlands during the course of 2013. All of the presentations are available on the [MSSO Presentations](#) page on the MedDRA website.

3.4 Outlook and Goals for 2014

There are several development efforts planned for 2014 that are intended to continue and enhance the MSSO's support for MedDRA users. The following is a list of the planned development efforts:

- Add more SMQs into production and support their implementation by MedDRA users
- Begin implementation of MedDRA Management Board approved recommendations from the BRP meeting on the scope of MedDRA which will take place in early 2014
- Coordinate MedDRA development activities with the MedDRA Expert Panel
- Continue "proactive" approach to MedDRA maintenance. Gather input for broad changes from users, and, where practical, implement these proposals per existing MedDRA rules and conventions
- Deploy the MSSO's MedDRA Web-based Browser
- Continue researching cloud distribution and obtaining user inputs
- Continue collaborations with interested parties on medication error initiatives
- Continue implementing a broader and more comprehensive free MedDRA training program for regulators and industry, and respond to requests for training from beyond the ICH regions

- Continue to provide input to MHRA on a mapping between SNOMED-CT and MedDRA
- Continue the collaboration with EU and US poison control centers
- Continue the collaboration with US NICHD on the development of the pediatric terminology
- Continue to promote the use of MedDRA worldwide
- Develop new training offerings including a videocast and a half-day course on "Getting Started with MedDRA", and a training curriculum consisting of a series of videocasts that the MSSO recommends viewing in preparation for attending face-to-face training.

3.5 MedDRA Management Board and Senior Members of the MSSO

The individual members of the MedDRA Management Board are listed with their organizational affiliation.

Dr. Sébastien Goux - European Commission

Dr. Sabine Brosch - EU/EMA (Alternate)

Mrs. Hilary Vass – EFPIA

Mrs. Claudia Lehmann – EFPIA (Alternate)

Dr. Christina Winter – EFPIA (Alternate)

Dr. Omar De Mol – EFPIA (Alternate)

Mr. Mick Foy – MHRA - UK

Mr. Makoto Hirose – MHLW

Ms. Makiko Isozaki - MHLW (Alternate)

Mr. Daisuke Sato - MHLW (Alternate)

Mr. Yuhei Fukuta - MHLW (Alternate)

Mr. Yo Tanaka – JPMA

Mr. Hisaya Motojima - JPMA (Alternate)

Ms. MaryAnn Slack - FDA

Dr. Daniela Vanco - FDA (Alternate)

Ms. JoAnn Medbery – PhRMA

Ms. Heather Sutcliffe – Health Canada

Dr. Vicky Hogan – Health Canada (Alternate)

Mr. Kazuyuki Sekiguchi - JMO

Mr. Osamu Handa – JMO (Alternate)

Mr. Reiji Tezuka - JMO (Alternate)

Dr. Yutaka Nagao - JMO (Alternate)

Dr. Odette Morin – IFPMA

Dr. Lembit Rägo – WHO Observer

Mr. Patrick W. Revelle – MedDRA MSSO

Dr. Anna C. Zhao-Wong – MedDRA MSSO (Alternate)

Dr. Judy Harrison – MedDRA MSSO (Alternate)

The MedDRA MSSO is 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

Judy Harrison, M.D., Chief Medical Officer

Brian O'Hare, Manager of Terminology Maintenance

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

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

Savian Nicholas, M.D., International Medical Officer, USA

Nandini Mehrotra, M.D., Medical Analyst

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