MedDRA
Maintenance and Support Services Organization
Annual Report
2015
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 2015

3.1 Subscriptions and Subscription Rates

The year 2015 was a year of continued growth and development of MedDRA. There were 4,660 subscribing organizations worldwide by the end of 2015 (4,239 in 2014). Of the 4,660 worldwide subscribers, 3,987 were MSSO subscribers (3,601 in 2014) and 673 were JMO subscribers (638 in 2014). The 3,987 MSSO subscribers represent a 10.7% growth in subscribers in 2015 over 2014 (8% the year before).

Figure 3-1 depicts the distribution of MSSO subscribers by region.
At the end of 2014, the Board approved the 2015 subscription fees (including Chinese and Japanese translation subscription fees); see Tables 3-1 and 3-2. MSSO’s subscription fees are shown below. Fees have remained the same as the 2014 subscription level and fee.

The 2015 fees are as follows.

<table>
<thead>
<tr>
<th>Subscription Level</th>
<th>2015</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Profit / Non-Commercial</td>
<td>$0</td>
</tr>
<tr>
<td>Commercial 0 (&lt; $1M)</td>
<td>$190</td>
</tr>
<tr>
<td>Commercial 1 ($1-10M)</td>
<td>$804</td>
</tr>
<tr>
<td>Commercial 2 ($10-500M)</td>
<td>$5,529</td>
</tr>
<tr>
<td>Commercial 3 ($500M – 1B)</td>
<td>$11,600</td>
</tr>
<tr>
<td>Commercial 4 ($1B – 5B)</td>
<td>$47,600</td>
</tr>
<tr>
<td>Commercial 5 ($5B-20B)</td>
<td>$62,850</td>
</tr>
<tr>
<td>Commercial 6 (&gt; $20B)</td>
<td>$82,000</td>
</tr>
<tr>
<td>Developer</td>
<td>$2,990</td>
</tr>
<tr>
<td>Regulatory Authority</td>
<td>$0</td>
</tr>
</tbody>
</table>

Table 3-1. 2015 Annual Subscription Rates (in US Dollars)
Table 3-2 provides the 2015 MedDRA Chinese and Japanese translation subscription fees; the fees were the same as those for 2014. Users subscribing to the Chinese or Japanese translation must also have a MSSO subscription.

<table>
<thead>
<tr>
<th>Subscription Level</th>
<th>Chinese Subscription Rate</th>
<th>Japanese Subscription Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non-Profit / Non-Commercial</td>
<td>$50</td>
<td>$850</td>
</tr>
<tr>
<td>Commercial 0 (&lt; $1M)</td>
<td>$50</td>
<td>$850</td>
</tr>
<tr>
<td>Commercial 1 ($1-10M)</td>
<td>$50</td>
<td>$850</td>
</tr>
<tr>
<td>Commercial 2 ($10-500M)</td>
<td>$150</td>
<td>$850</td>
</tr>
<tr>
<td>Commercial 3 ($500M – 1B)</td>
<td>$300</td>
<td>$850</td>
</tr>
<tr>
<td>Commercial 4 ($1B – 5B)</td>
<td>$600</td>
<td>$850</td>
</tr>
<tr>
<td>Commercial 5 ($5B – 20B)</td>
<td>$850</td>
<td>$850</td>
</tr>
<tr>
<td>Commercial 6 (&gt; $20B)</td>
<td>$850</td>
<td>$850</td>
</tr>
<tr>
<td>Developer</td>
<td>$450</td>
<td>$850</td>
</tr>
<tr>
<td>Regulatory Authority</td>
<td>$0</td>
<td>$0</td>
</tr>
</tbody>
</table>

Table 3-2. 2015 Chinese and Japanese Translation Subscription Fee (in US Dollars)

### 3.2 Major Developments of MedDRA Terminology

In 2015, MedDRA, including Standardised MedDRA Queries (SMQs), continued to grow and evolve. A summary of additions and modifications in the 2015 releases of MedDRA is shown in Table 3-3.

<table>
<thead>
<tr>
<th>Activity</th>
<th>Version</th>
<th>Initiator</th>
</tr>
</thead>
<tbody>
<tr>
<td>Complex and related changes, including new terms requests, to better organize the placement of product use concepts such as medication errors, overdoses and underdoses, misuse, and off label use.</td>
<td>18.0</td>
<td>MedDRA Users</td>
</tr>
<tr>
<td>Scope of MedDRA revised in the MedDRA Introductory Guide to support the potential for</td>
<td>18.0</td>
<td>Blue Ribbon Panel</td>
</tr>
<tr>
<td>Activity</td>
<td>Version</td>
<td>Initiator</td>
</tr>
<tr>
<td>--------------------------------------------------------------------------</td>
<td>---------</td>
<td>-----------------------------------------------</td>
</tr>
<tr>
<td>expansion of the terminology into new topic areas.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Performed a review of existing drug utilization concepts</td>
<td>18.0</td>
<td>MedDRA User Proactivity Request</td>
</tr>
<tr>
<td>Added more ‘site’ (e.g., administration site) concepts to provide more coding options for MedDRA users.</td>
<td>18.0</td>
<td>MedDRA User Proactivity Request</td>
</tr>
<tr>
<td>Reviewed the specific choice of term and hierarchical placement of various MedDRA concepts relating to the anatomy of the back</td>
<td>18.0</td>
<td>MedDRA User Proactivity Request</td>
</tr>
<tr>
<td>Added medically relevant pharmacogenomics biomarker terms to MedDRA to provide more options for coding and analysis</td>
<td>18.0</td>
<td>MedDRA User Proactivity Request</td>
</tr>
<tr>
<td>Reviewed the primary SOC allocation for hemorrhage and hematoma PTs to ensure consistency in the primary SOC allocation</td>
<td>18.1</td>
<td>MedDRA User Proactivity Request</td>
</tr>
<tr>
<td>Reviewed the placement of “tinea” concepts for better and more accurate placement in MedDRA.</td>
<td>18.1</td>
<td>MedDRA User Proactivity Request</td>
</tr>
</tbody>
</table>

**Table 3-3. Highlights in MedDRA Version 18.0 and 18.1**

**SMQs**

The total number of production Level 1 SMQ topics is 98 as of MedDRA Version 18.1. Below is the list of the 2 SMQs added in the 2015 releases:

- **SMQ Respiratory failure**
- **SMQ Tendinopathies and ligament disorders**
In addition four SMQs related to central nervous system vascular disorders or conditions were renamed in MedDRA Version 18.0. to better reflect the anatomical areas covered.

<table>
<thead>
<tr>
<th>Previous SMQ Name</th>
<th>New SMQ Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cerebrovascular disorders (SMQ)</td>
<td>Central nervous system vascular disorders (SMQ)</td>
</tr>
<tr>
<td>Cerebrovascular disorders, not specified as haemorrhagic or ischaemic (SMQ)</td>
<td>Central nervous system vascular disorders, not specified as haemorrhagic or ischaemic (SMQ)</td>
</tr>
<tr>
<td>Ischaemic cerebrovascular conditions (SMQ)</td>
<td>Ischaemic central nervous system vascular conditions (SMQ)</td>
</tr>
<tr>
<td>Haemorrhagic cerebrovascular conditions (SMQ)</td>
<td>Haemorrhagic central nervous system vascular conditions (SMQ)</td>
</tr>
</tbody>
</table>

Table 3-4 Renamed SMQs

**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.

Six proactivity proposals that originated from MedDRA users were implemented in 2015. See Table 3-3 for details.

**3.3 Significant MSSO Activities**

**New SOC Product issues to be Implemented in MedDRA Version 19.0**

The ICH MedDRA Management Board confirmed the implementation of a 27th SOC in March 2016 for MedDRA Version 19.0 which will be called *Product issues*. This new SOC will include terms relevant for issues with product quality, devices, product manufacturing and quality systems, supply and distribution, and counterfeit products which are important as they may affect patient safety.

One of the goals of incorporating product quality terms into MedDRA is to support the recording of product quality issues and any associated adverse events using a single terminology. It is envisaged that the product quality terms, including those relating to manufacturing and distribution, may be used to report product defects to regulatory authorities and may also be used in organizations’ internal databases to track and trend quality issues or deviations.

The MSSO consulted the MedDRA Expert Working Group and asked MedDRA users’ for feedback via complex change posting regarding the new SOC. The
Expert Working Group agreed upon a limited set of moves of existing terms and new terms that are needed to populate the hierarchy of the new SOC in MedDRA Version 19.0. Further meetings will be scheduled in 2016 to review proposals for additional new terms submitted by users and to establish conventions for nomenclature and placement.

Scope of MedDRA: Revisions to Introductory Guide

Revisions were made to Section 1.5 (Scope of the Terminology) in the Introductory Guide for MedDRA Version 18.0. The revised wording pertains to the types of medical products and concepts that MedDRA supports and the potential for expansion of the terminology into new topic areas. These revisions are the result of the 2014 Blue Ribbon Panel recommendations on the scope of MedDRA which were endorsed by the MedDRA Management Board.

Updated MVAT

An updated MedDRA Version Analysis Tool (MVAT) was successfully launched on 28 May 2015. Improvements included:

- User interface available in all MedDRA languages
- Report output available in all MedDRA languages
- An improved history function
- An option to filter report output by SOC
- Improved report output related to MedDRA and SMQ changes

Additionally, the MSSO implemented an update to the MVAT data impact reports on 18 November. The update was made based on user feedback to provide better clarity on LLT changes.

Updated MedDRA Desktop Browser

The MedDRA Desktop Browser (MDB) version 4.0 was released for use by the MSSO subscribers 8 October 2015. The latest version of the MDB updates the user interface and the functions to be consistent with the Web-Based Browser (WBB). Additionally, the MDB includes an option to change the language interface to any of the currently supported MedDRA languages, multi-language term output in search results if selected, and hierarchy information is included in the export of search results and the research bin.

MSSO MedDRA Training

During 2015, the MSSO provided free MedDRA training to 2,372 people as part of their MedDRA subscription. There were 56 classes of face-to-face training with a total of 1,050 attendees. Of this amount, 124 were from regulatory authorities.
representing the following countries: Canada, the United Kingdom, and the United States.

The 2,372 total trainees include 1,322 webinar connections for 24 free MedDRA user webinars. The MSSO implemented a live, interactive polling feature in webinars to pose questions to and receive responses from the audience. The feature was welcomed by the webinar participants and the MSSO trainers. Based on user feedback, the MSSO will redesign its webinars in 2016 to offer shorter (one hour) sessions focused on specific topics and incorporating more interactive features and demonstrations. The MSSO will continue to present the What’s New with MedDRA Version webinars for MedDRA versions 19.0 and 19.1.

**MSSO ISO Certification**

In August 2015, the MSSO passed an independent re-certification audit for compliance with the ISO 9001:2008 standard for Quality Management Systems. The certification (also known as registration) period is from September 2015 to October 2018. 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.

**MedDRA’s Interoperability with Other Medical Terminologies**

There are other key medical terminologies besides MedDRA in the healthcare arena, such as CTCAE, WHO-ART, ICDs, SNOMED CT, etc. Mappings between MedDRA and other terminologies enable data exchange and facilitate communication between healthcare user communities. Through collaborations with other terminology maintenance organizations and research groups, the following terminologies have been mapped to MedDRA: CTCAE (collaboration with US Cancer Therapy Evaluation Program – CTEP), WHO-ART (collaboration with WHO Uppsala Monitoring Centre – UMC), ICD-9-CM (collaboration with Observational Medical Outcomes Partnership – OMOP), AAPCC National Poison Data System (NPDS) Clinical Effect Terms (CETs), and the Pediatric Adverse Event Terminology (collaboration with US National Institute of Child Health and Human Development – NICHD, and US National Cancer Institute - NCI).

The MSSO continues its effort to explore and develop mapping capabilities to bridge MedDRA with other medical terminologies, including SNOMED-CT and the ICDs.

**New Pharmacovigilance Initiatives**

In 2015, the MSSO became a partner in the WEB-RADR (Recognising Adverse Drug Reactions) project which is led by a consortium under the EU’s Innovative Medicines Initiative (IMI). WEB-RADR is exploring new technologies for
pharmacovigilance including the development of mobile applications to facilitate direct reporting of suspected adverse drug reactions by patients and healthcare professionals to regulatory authorities. The project is also investigating the potential for mining publicly available social media data such as Twitter, Facebook, and patient forums for identifying drug safety issues.

**MSSO Presentations**

The MSSO presented at several professional meetings during the course of 2015 as listed below. All of the presentations are available on the [MSSO Presentations](#) page on the MedDRA website.

| MedDRA: Coding Fundamentals and New Developments Anna Zhao-Wong, MD, PhD | Q1 Productions 3rd Annual Innovations in Clinical Data Management. Alexandria, VA, USA - 19-20 October 2015 |
| What Medical Writers Need to Know About MedDRA Judy Harrison, MD | Expert Seminar Series, 40th European Medical Writers Association Conference. Dublin, Ireland - 6 May 2015 |

**3.4 Outlook and Goals for 2016**

There are several development efforts planned for 2016 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
- Deploy an updated version of the WBB
- Develop a MedDRA user self-service application which will allow users to obtain and change information about their subscription
- 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
• Continue involvement in WEB-RADR and monitor new pharmacovigilance initiatives
• Continue implementing a comprehensive free MedDRA training program for regulators and industry, and respond to requests for training from beyond the ICH regions
• Continue to promote the use of MedDRA worldwide
• Develop mapping capabilities with other terminologies such as SNOMED-CT, ICDs
• Redesign webinars into shorter, more focused modules

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 - EU
Dr. Sabine Brosch - EU (Alternate)
Mrs. Hilary Vass – EFPIA
Mrs. Claudia Lehmann – EFPIA (Alternate)
Dr. Christina Winter – EFPIA (Alternate)
Mr. Mick Foy – MHRA - UK
Ms. Kiyomi Ueno – MHLW
Ms. Yasuko Inokuma - MHLW (Alternate)
Mr. Daisuke Sato - PMDA (Alternate)
Dr. Yuuki Miyatake - MHLW (Alternate)
Ms. Yuka Tamura – PMDA (Alternate)
Mr. Yo Tanaka – JPMA
Mr. Hisaya Motojima - JPMA (Alternate)
Ms. MaryAnn Slack - FDA
Dr. Daniela Vanco - FDA (Alternate)
Dr. Rajesh Ranganathan – PhRMA
Dr. Peter K. Honig - PhRMA (Alternate)
Dr. Vicky Hogan – Health Canada
Mr. Kazuyuki Sekiguchi - JMO
Dr. Mitsuru Takano - JMO (Alternate)
Ms. Tomoko Narita – JMO (Alternate)
Mr. Reiji Tezuka - JMO (Alternate)
Dr. Yutaka Nagao – JMO (Alternate)
Dr. Odette Morin – IFPMA
Dr. Lembit Rägo – WHO Observer
Dr. Daisuke Tanaka – WHO Observer (Alternate)
Mr. Patrick W. Revelle – MedDRA MSSO
Dr. Anna C. Zhao-Wong – MedDRA MSSO (Alternate)
Dr. Judy Harrison – MedDRA MSSSO (Alternate)

The MedDRA Management Board is supported by the MedDRA Secretariat (Dr. Dawn Ronan).

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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