

MedDRA
Medical Dictionary
for Regulatory Activities

MedDRA
Maintenance and Support Services Organization
Annual Report
2017

1 MedDRA as an ICH Product

MedDRA was developed under the auspices of the International Council for 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 Committee, which is composed of the European Commission (EC), European Federation of Pharmaceutical Industries and Associations (EFPIA), Ministry of Health, Labour and Welfare (MHLW) of Japan and Pharmaceuticals and Medical Devices Agency (PMDA) 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, and the World Health Organization (WHO). See Section 3.5 for a list of the individual Management Committee 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 2017

3.1 Subscriptions and Subscription Rates

The year 2017 was a year of continued growth and development of MedDRA. There were 5,179 subscribing organizations worldwide by the end of 2017 (4,827 in 2016). Of the 5,179 worldwide subscribers, 4,444 were MSSO subscribers (4,123 in 2016) and 735 were JMO subscribers (704 in 2016). The 4,444 MSSO subscribers represent a 7.8% growth in subscribers in 2017 over 2016 (3.4% the year before).

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

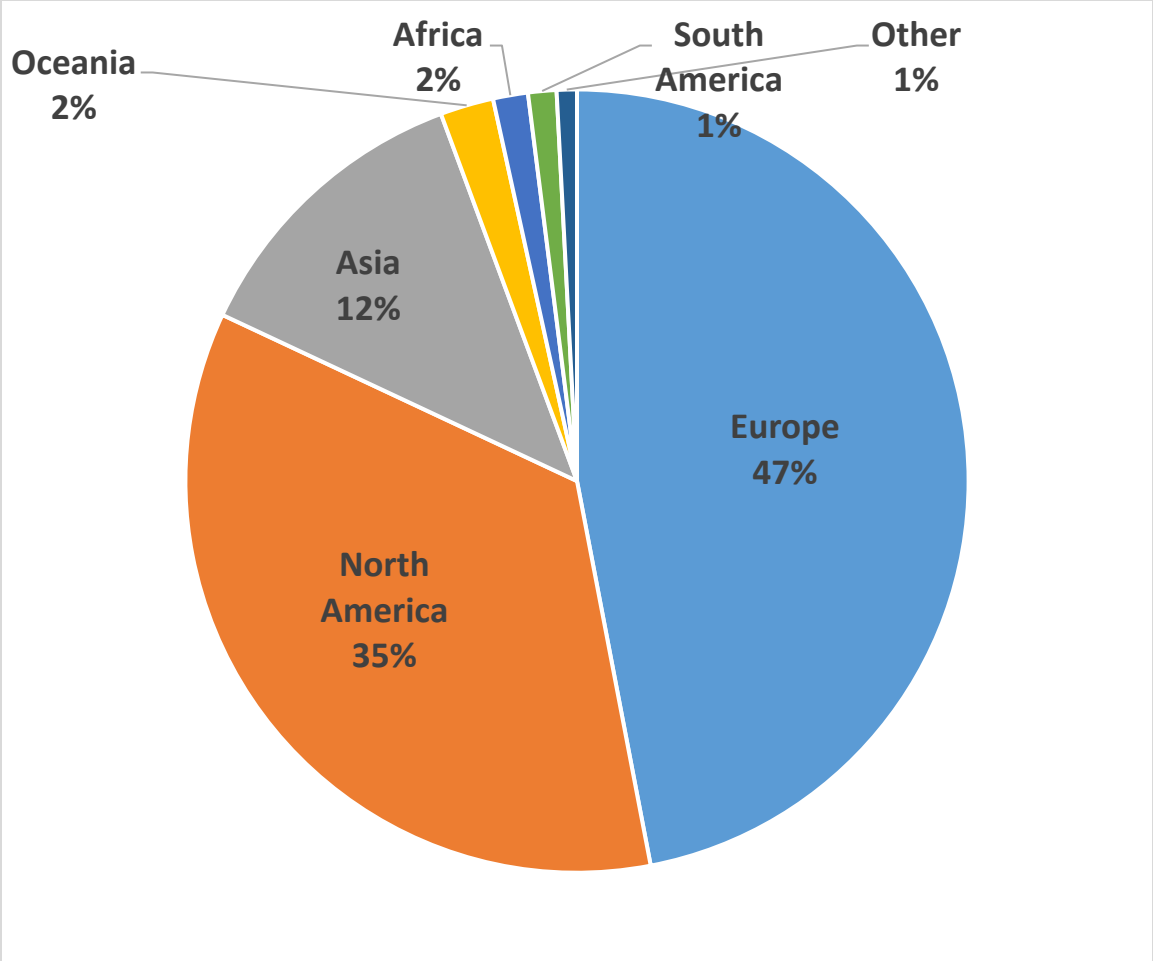


Figure 3-1. MedDRA MSSO Subscribers (4,444)

At the end of 2016, the Committee approved the 2017 subscription fees (including Japanese translation subscription fees). Rates for all subscription levels were reduced at least 9-10% compared to 2016 rates. The Chinese translation fee was removed. Like the other MedDRA translations, the Chinese translation became part of the MedDRA subscription. The most significant highlight was the Commercial 2 level being split up into 2 separate levels (10M-20M & 20M-500M) in response to users' feedback; see Tables 3-1 and 3-2. MSSO's subscription fees are shown below.

The 2017 fees are as follows.

Subscription Level	2017
Non-Profit / Non-Commercial	$0
Commercial 0 (< $1M)	$171

Commercial 1 ($1M-10M)	$724
Commercial 2 ($10M-20M)	$2,765
Commercial 3 ($20M - $500M)	$4,976
Commercial 4 ($500M - $1B)	$10,440
Commercial 5 ($1B-5B)	$43,316
Commercial 6 ($5B - $20B)	$57,194
Commercial 7 (>$20B)	$74,620
Developer	$2,691
Regulatory Authority	$0

Table 3-1. 2017 Annual Subscription Rates (in US Dollars)

Table 3-2 provides the 2017 MedDRA Japanese translation subscription fees; the Japanese fees were the same as those for 2016. Users subscribing to the Japanese translation must also have an MSSO subscription.

Subscription Level	Japanese Subscription Rate
Non-Profit / Non-Commercial	$850
Commercial 0 (< $1M)	$850
Commercial 1 ($1M-10M)	$850
Commercial 2 ($10M-20M)	$850
Commercial 3 ($20M – 500M)	$850
Commercial 4 ($500M – 1B)	$850
Commercial 5 ($1B – 5B)	$850
Commercial 6 ($5B - 20B)	$850
Commercial 7 (>$20B)	$850
Developer	$850
Regulatory Authority	$0

Table 3-2. 2017 Japanese Translation Subscription Fee (in US Dollars)

3.2 Major Developments of MedDRA Terminology

In 2017, MedDRA continued to grow and evolve. In addition to response to user change requests, the MSSO takes proactive measures to maintain MedDRA, which 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 Committee 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.

A summary of additions and modifications in the 2017 releases of MedDRA is shown in Table 3-3.

Activity	Version	Initiator
Revisions were made to the medication error and product use issues hierarchies to group them together under new HLGT *Medication errors and other product use errors and issues* avoiding the forced classification between these sometimes overlapping concepts.	20.0	MedDRA Users
Reviewed a request to consider adding a set of terms for gradation of chemical burns to MedDRA.	20.0	MedDRA User Proactivity Request
A set of terms that convey a reduction in visual ability were moved for better conceptual alignment in MedDRA	20.0	MedDRA User Proactivity Request
Revisions were made to represent several “drug use disorder” concepts at the PT level as these concepts, from a pharmacovigilance perspective, are distinct and important.	20.1	MedDRA Users
The placement of “foreign body” LLTs under PT Foreign body were moved to align them to more site specific PTs.	20.1	MedDRA User Proactivity Request

Table 3-3. Highlights in MedDRA Versions 20.0 and 20.1

SMQs

The total number of production Level 1 SMQ topics is 102 as of MedDRA Version 20.1 with the addition of new SMQ *Infective pneumonia*.

Additionally, in MedDRA Version 20.0, structural changes were made to the sub-search SMQs under level 1 SMQ *Malignancies* as the result of work by the CIOMS SMQ Implementation Working Group to further enhance specificity options for case identification of these sub-search SMQs.

3.3 Significant MSSO Activities

MSSO MedDRA Training

During 2017, the MSSO provided free MedDRA training to 4,442 people as part of their MedDRA subscription. There were 63 classes of face-to-face training with a total of 1,737 attendees. Of this number, 546 were from regulatory authorities representing the following countries: Brazil, Canada, Guatemala, Germany, Mexico, Ireland, Norway, Spain, the United Kingdom, and the United States.

The 4,442 total trainees include 2,705 webinar connections for 27 free MedDRA user webinars. With the increased capacity for webinars, registration numbers for these events has increased.

User Group Meeting in India

The MSSO held two MedDRA User Group meetings in India in coordination with the UMC WHO-Drug meetings in Bangalore on 6 February and Mumbai on 9 February 2017. This is the first time a MedDRA User Group meeting was held in India. The MedDRA portion of the agenda featured topics on maximizing the benefits of a MedDRA subscription, the change request process, and a presentation on coded data review. Both meetings generated overwhelming interest from local users with around 80 attendees at each event. The MSSO will plan to hold similar meetings in India in the future.

MSSO ISO Certification

In August 2017, the MSSO passed an independent surveillance audit for compliance with the ISO 9001:2015 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 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.

Self-Service Application

The MSSO deployed the Self-Service Application in April 2017. The application allows MedDRA users to perform routine tasks without the need to contact the Help Desk. Key features of this tool allow subscription points of contact access to their subscription information, authenticated users can confirm the subscription status of business partners, and users that attended in person training can obtain training certificates. A videocast explaining how to use the tool was developed and posted on the MedDRA website and the MSSO gave presentations on the application at the European and US User Group meetings.

MSSO Presentations

The MSSO presented at several professional meetings during the course of 2017 as listed below. All of the presentations are available on the MSSO Presentations page on the MedDRA website.

Supporting Public Health Globally via the use of Terminology Standards / Use of MedDRA in Adverse Event Reporting Brian O'Hare	American Public Health Association Annual Meeting Atlanta, Georgia, USA - 6 November 2017
MedDRA MSSO Update Patrick Revelle	US Industry MedDRA User Group Meeting Gaithersburg, MD, USA - 29 September 2017
MedDRA Self-Service Application & Planned Tools Brian O'Hare	US Industry MedDRA User Group Meeting Gaithersburg, MD, USA - 29 September 2017
Medical Dictionary for Regulatory Activities (MedDRA) Anna Zhao-Wong, MD, PhD	2017 Global Summit on Regulatory Science (GSRS) Brasilia, Brazil - 19 September 2017
Biological product concepts in MedDRA Judy Harrison, MD	DIA Clinical Safety and Pharmacovigilance Community Webinar - 20 April 2017
Introduction to MedDRA Anna Zhao-Wong, MD, PhD	14th Annual MCBIOS Conference Little Rock AR, USA - 24 March 2017

3.4 Outlook and Goals for 2018

There are several development efforts planned for 2018 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
- 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 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
- Continue work with the WHO Uppsala Monitoring Centre (UMC) on co-locating user group meetings and, where appropriate, coordinate on activities beneficial to both the MSSO and UMC
- Begin work on the MedDRA Korean translation
- Begin work on the MedDRA Russian Translation
- Continue to work with regulatory authorities seeking to establish special licenses
- In coordination with ICH, participate in the IMI mapping project
- Complete an update to the Web-Based Browser (WBB) in 2018
- Complete an update to the MedDRA Desktop Browser (MDB) in 2018
- Complete an update to the MedDRA Version Analysis Tool (MVAT) in 2018

MedDRA Subscription Rates in 2018 and Credit Card Payments

In November 2017, the MedDRA Management Committee approved the MSSO 2018 Subscription Rates. The Committee approved a 5% subscription rate reduction for the 2018 Commercial Level 0-2 subscription rates and the optional payment of Commercial 0-2 and Developer subscriptions via credit cards. The use of credit cards will offer a convenient method of payment for MedDRA subscriptions.

This reduction in rates is a reflection of the continued success of MedDRA as a global standard; with over 5,100 subscribing organizations worldwide, the costs of maintaining and developing the terminology can be distributed over a wider base, while still providing the same high standard of tools and services to MedDRA users.

3.5 MedDRA Management Committee and Senior Members of the MSSO

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

Dr. Georgios Balkamos - EC
Dr. Sabine Brosch – EC
Dr. Christina Winter – EFPIA
Mrs. Claudia Lehmann – EFPIA
Mr. Philip Tregunno – MHRA - UK
Mr. Mick Foy – MHRA - UK
Ms. Yuka Tamura – MHLW/PMDA
Mr. Hideo Eno – MHLW/PMDA
Ms. Yoko Hattori - JPMA
Mr. Yo Tanaka – JPMA
Ms. MaryAnn Slack – FDA
Dr. Barbee I. Whitaker - FDA
Dr. Peter K. Honig - PhRMA
Ms. Camille Jackson – PhRMA
Ms. Sophie Sommerer – Health Canada
Ms. Heather Morrison – Health Canada
Dr. Yutaka Nagao- JMO
Mr. Kazuyuki Sekiguchi – JMO
Dr. Mitsuru Takano - JMO
Ms. Tomoko Narita – JMO
Mr. Hisaya Motojima – JMO
Mr. Mike Ward – WHO Observer
Mr. Takahiro Goto – WHO Observer
Mr. Patrick W. Revelle – MedDRA MSSO
Dr. Anna C. Zhao-Wong – MedDRA MSSO
Dr. Judy Harrison – MedDRA MSSSO

The MedDRA Management Committee is supported by the MedDRA Secretariat (Dr. Dawn Ronan and Dr. Isabelle Güller).

The MedDRA MSSO is international in nature with team members who were educated in Canada, Germany, Spain, China, 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

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