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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

2018 saw an expansion of the global reach of MedDRA:
- The MedDRA Management Committee approved hiring additional staff for China, India, Latin America, and the Republic of Korea to provide local support (i.e., Help Desk, MedDRA training) to start in 2019.
- MSSO initiated the development of a Russian translation of MedDRA. The initial translation was performed by a medical translation vendor and then reviewed by a Russian Review group made up of the Roszdravnadzor, Russia and the Association of International Pharmaceutical Manufacturers (AIPM).
- MFDS, Republic of Korea developed an initial translation of MedDRA in Korean. The MSSO initiated a review and update of the translation and user documentation in 2018.

Outlook and Goals for 2019
- Continue implementing a comprehensive free MedDRA training program for regulators and industry, and respond to requests for training globally
- Add more SMQs into production and support their implementation by MedDRA users
- Continue the “proactive” approach to MedDRA maintenance
- Continue to promote the use of MedDRA worldwide
- Continue to work with the WHO Uppsala Monitoring Centre (UMC) on co-locating user group meetings and, where appropriate, coordinate on activities beneficial to users of both the MSSO and UMC
- Deploy a MedDRA Russian translation in March 2019, continue work on Korean translation, and begin work on Brazilian Portuguese MedDRA translation
- Continue work with regulatory authorities seeking to establish special licenses
- Under the direction of ICH, participate in the Innovative Medicines Initiative’s WEB-RADR 2 project
- Connect with users through various social media platforms
- Complete updates to the MedDRA Desktop Browser (MDB) and MedDRA Version Analysis Tool (MVAT) in 2019.
Training

In 2018 the MSSO provided more training than ever before to the global MedDRA user community. The training took place in the form of standard training, implementation training, and workshops. These training numbers are a positive indicator of interest in MedDRA as demand for training increases around the world.

**71** MedDRA subscribing organizations hosted free training classes, which were attended by **2,753** users from **46** countries.

**27** webinars were held with a total of **2,584** connections from **57** countries.

Countries of attendees of MedDRA training

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### Standard Training

The standard training consists of face-to-face classes and webinars that focus on applying MedDRA in coding and data retrieval and analysis.

### MedDRA Implementation Training

MedDRA is being adopted by a growing number of regulatory authorities, including: ANVISA, Brazil; COFEPRIS, Mexico; NMPA, China; MFDS, Republic of Korea; HSA, Singapore; and TITCK, Turkey. As such, the implementation training plays an increasingly integral role in new regions. In 2018, implementation training was provided for NMPA, China and MFDS, Republic of Korea, which made great strides in expanding MedDRA knowledge.

### MedDRA Workshops

Conducting MedDRA workshops at international pharmacovigilance conferences enables the MSSO to reach out to existing and potential users beyond the traditional training environment. Three such MedDRA workshops were conducted in 2018:

- Workshop at the XV International Pharmacovigilance Meeting of Americas on 8 October, in Santiago de Chile
- Workshop at the Conference of Pharmacovigilance, Challenges and Opportunities on 10 October, in Moscow, Russia
- Workshop at the Annual Meeting of Representatives of National Pharmacovigilance Centers Participating in the WHO Programme for International Drug Monitoring on 5 November, in Geneva, Switzerland
  - Presented with Health Canada, Canada. There were 150 attendees from 81 countries
MedDRA User Group meetings are a great way to meet other enthusiastic MedDRA users and enjoy presentations on MedDRA specific topics given by experts from regulatory authorities, industry, and the MSSO.

In 2018, the MSSO has held User Group meetings in Europe, the US, China, and India. In collaboration with the Uppsala Monitoring Centre (UMC), the MSSO held joint MedDRA and WHODrug meetings in India and China.

This year’s face-to-face training in India, co-hosted by the MSSO and UMC, was a first for MedDRA training in India. The MSSO and the UMC also held a joint MedDRA and WHODrug User Group meeting in Bangalore, India on 6 February.

The meeting generated overwhelming interest from local users with approximately 115 attendees. On 7 February, the day after the India User Group meeting, the MSSO provided face-to-face training on Coding with MedDRA and Safety Data Analysis and SMQs to over 90 users.
The MSSO continues to improve the features and functionality of software tools available to MedDRA users with many of the ideas and suggestions for updating coming from users. In October 2018 the MSSO deployed an update to the MedDRA Web-Based Browser (WBB). The update includes the following enhancements:

- An option to view supplemental updates
- SMQ analysis
- Hierarchy analysis
- More advanced searching via additional Boolean and string operators
- An option to include the secondary SOC path in exports of search results, the research bin, and hierarchy analysis reports

In 2019, the MSSO expects to deliver similar updates for the MedDRA Desktop Browser and MVAT, and to produce a mobile version of the WBB.

For more information, please visit the [WEB-RADR 2 website](#).
In 2018 the MSSO collaborated with two working groups on mapping:

- International Neonatal Consortium’s AE terminology
- International Medical Device Regulators Forum’s Patient Problem Codes

The MSSO will continue to focus on and respond to user requests to shape MedDRA for the benefit of all MedDRA users.

Visit the Support Documentation page on MedDRA website to see more.
The individual members of the MedDRA Management Committee are listed with their organizational affiliation.

- Dr. Georgios Balkamos – EC, Europe
- Dr. Sabine Brosch – EC, Europe
- Dr. Christina Winter – EFPIA
- Mrs. Claudia Lehmann – EFPIA
- Mr. Philip Tregunno – MHRA, UK
- Mr. Mick Foy – MHRA, UK
- Mr. Masahiro Inada – MHLW/PMDA, Japan
- Mr. Hideo Eno – MHLW/PMDA, Japan
- Ms. Yoko Hattori – JPMA
- Mr. Yo Tanaka – JPMA
- Ms. MaryAnn Slack – FDA, United States
- Dr. Barbee I. Whitaker – FDA, United States
- Dr. Peter K. Honig – PhRMA
- Ms. Maria Apostolaros – PhRMA
- Dr. Gayatri Jayaraman – Health Canada, Canada
- Ms. Heather Morrison – Health Canada, Canada
- Mr. Mike Ward – WHO Observer
- Mr. Takahiro Goto – WHO Observer

The following is a list of the senior staff members and their role in the MSSO:

- Mr. Patrick Revelle, Director
- Dr. Anna Zhao-Wong, M.D., Ph.D., Deputy Director and Manager of MedDRA Terminology Development and Services
- Dr. Judy Harrison, M.D., Chief Medical Officer
- Mr. Brian O’Hare, Manager of Terminology Maintenance
- Dr. Eva Beate-Rump, M.D., International Medical Officer, Germany
- Dr. Tomás Moraleda Garcia, M.D., International Medical Officer, Spain
- Dr. Savian Nicholas, M.D., International Medical Officer, USA