



MedDRA

Medical Dictionary
for Regulatory Activities

MedDRA MSSO Annual Report 2020

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Overview

5939 Subscribers in 2020

541 New Subscribing Organizations

10% Growth in subscribing organizations over 2019 (3rd consecutive year of 10% growth)

6806 Subscribing Organizations Worldwide (MSSO and JMO)

127 Countries with Subscribers

30% Growth in Subscribing Organizations in Asia (led by China, Republic of Korea, and India)

76% of Subscribers are Using MedDRA Free or Pay at Most \$654 Annually (Level 1)

- 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 through the entire regulatory process, from pre-marketing to post-marketing; and for data entry, retrieval, evaluation, and presentation
- The MSSO has successfully maintained its ISO 9001:2015 certification and achieved excellent results from a surveillance and audit. The ISO 9001:2015 standard is an internationally recognized quality management system standard developed by the International Organization for Standardization (ISO).
- 2020 provided significant challenges to respond to the worldwide pandemic and continue the support and development of MedDRA
 - The MSSO produced an out-of-cycle release of MedDRA to provide COVID-19 related terms to MedDRA to address the pandemic
 - The MSSO quickly shifted the delivery of training from primarily face-to-face training to webinars. At the same time, the MSSO increased the number of training events and extended content in response to user needs. Instructional videos were developed to facilitate self-learning
- Outlook and Goals for 2021
 - Expand the existing comprehensive free MedDRA training program for regulators and industry by providing more training options for users
 - Provide production versions of MedDRA Application Programming Interfaces (APIs) and the necessary validation documentation and support needed for users

Overview

- Add local support for MedDRA users in Russia and eastern European countries
- Continue work with regulatory authorities seeking to establish special licenses
- Launch the initial mappings between SNOMED CT and MedDRA and provide a change request process for users to propose changes
- Continue efforts for interoperability with other terminologies

Points to Consider

To support the uptake and implementation of MedDRA in new regions, translations of the full Points to Consider documents (MedDRA Term Selection and Data Retrieval and Presentation) in Chinese, Korean, and Spanish were completed by MSSO staff and were reviewed with the regulatory authorities in China, the Republic of Korea, and Spain, respectively. The documents were first posted on the MedDRA website in October 2020. They will be updated for MedDRA Version 24.0 in March 2021 along with the English and Japanese documents.

The Points to Consider Companion Document had two new releases in 2020. The first, Release 1.1, in July included extensive revisions and new examples in the medication errors section. Release 2.0 was made available to users in October and included a new section on product quality issues for distributed products in the clinical setting. The Companion Document is available in English and Japanese.

SSA

MedDRA Medical Dictionary for Regulatory Activities

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Select a language: English

Additional Points to Consider Documents and MedDRA Best Practices Document (click here)

Points to Consider Companion Document

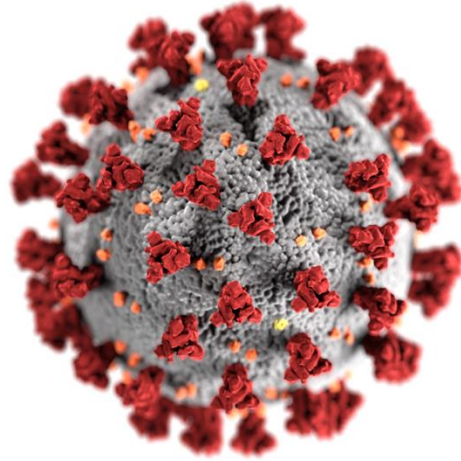
- Points to Consider Companion Document Release 2.0
- Points to Consider Companion Document Release 1.1
- Redline Changes to Points to Consider Companion Document Release 1.1
- Points to Consider Companion Document Release 1.0

Best Practices Document

- MedDRA Best Practices

COVID-19

The MSSO implements changes in MedDRA to meet the challenges of the COVID-19 pandemic



The ICH MedDRA Management Committee decided to provide new COVID-19 terms in an expedited fashion to ensure that any scientific and medical information from the COVID-19 outbreak could be captured, shared and analyzed appropriately.

In April 2020, the MSSO and JMO re-released the previously released version 23.0 of MedDRA to include new COVID-19 terms and revisions. The updated 23.0 release was available in all supported MedDRA languages and users were urged to implement it in their systems by 4 May 2020 in line with the established procedure for a global transition date for a new version of MedDRA.

A new SMQ *COVID-19* was developed in an expedited process with an international group of experts from regulatory authorities and industry; it went into production in MedDRA Version 23.1 in September 2021.

In anticipation that 2021 will be a rollout year for vaccinations for SARS-CoV-2 with a regulatory focus on monitoring the health and safety of patients receiving the vaccines, the MSSO proactively reviewed the vaccine related terms in MedDRA and solicited feedback from a group of regulatory and industry users on the MSSO's proposals for new terms for Version 24.0, as well as any other potential terms for additions.

Training

MedDRA Presentations

The MSSO continues to provide MedDRA presentations at virtual conferences, reaching large audiences in spite of the global pandemic. In 2020, the MSSO delivered 11 presentations. Of these presentations, 6 were delivered in Korea, 2 in India, 2 in China, and 1 for French speaking countries. These presentations were helpful in increasing knowledge in regions implementing MedDRA. Presentations also gave an opportunity to connect with current and potential users at a time when pharmacovigilance is of paramount importance.



Figure 1 Virtual NMPA Meeting

26 face-to-face classes attended by **1653** attendees from **10** countries. **163** webinars with **13,028** connections from **99** countries.



Countries of attendees of MedDRA training

MedDRA Training

The COVID-19 pandemic presented MSSO trainers with the challenge of maintaining levels of user interaction as training transitioned to solely online. In response to the cancellation of face-to-face courses, trainers increased the number of webinars offered to ensure the training demand of users was met. Additionally, the MSSO added webinars in Korean and French to reach more subscribers. Instructors began utilizing interactive polling tools during webinars to recreate elements of the classroom experience in a virtual setting. Further, trainers created new courses to meet varying user needs, including tool demonstrations (MVAT Demonstration), interactive coding sessions (Let's Code Together), and an open format panel discussion (MSSO Open Session).

MSSO developed instructional videos to guide self-learners to get trained on MedDRA and provide visual step-by-step instructions on how to submit an online subscription, download MedDRA release files, register for training classes, use the Self-Service Application, etc.

User Feedback

The new training initiatives of 2020 were met with encouraging user feedback, supporting the demand for interactive and in-depth sessions.

Open Session:



Figure 2 Open Session - May 2020

Training (cont.)

- “The MSSO has been forward thinking and innovative in their response to the pandemic and how to reach MedDRA users in a virtual fashion. Thank you.”
- “I appreciated the open responses to the questions and the panel members’ willingness to give a qualified opinion. There was a broad range of expertise on the panel.”

Let’s Code Together:

- “The session makes me feel coding is enjoyable and challenging work.”
- “Great examples with extensive explanations on search strategies.”
- “The examples are very practical and taken from real-life scenarios”

MVAT Demonstration:

- “Very clear and insightful presentation by a master teacher.”
- “Concise and clear, thank you!”

Other Training



Figure 3 Attendees at the National Drugs Authority, Uganda training session, July 2020

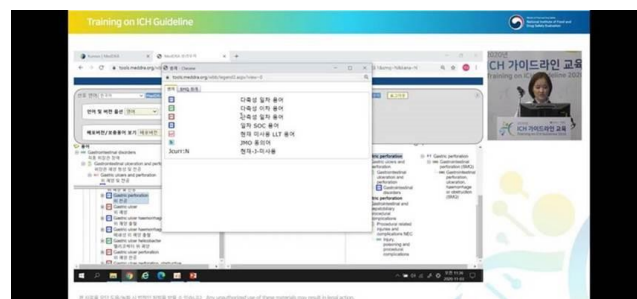


Figure 4 Virtual Training in the Republic of Korea

User Groups

MedDRA User Group meetings 2020

175 In-person User Group Attendees

85 India

90 China

842 Virtual User Group Meeting Attendees

242 U.S.

300 Europe

300 China

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 2020, the MSSO held virtual User Group meetings convenient for European, China, and U.S. time zones, and held in-person meetings in China and India.

The MSSO and the UMC held joint MedDRA and WHODrug User Group meetings in New Delhi, India on 20 and 21 February 2020. The meeting was well attended by approximately 85 users. Topics included an interactive coding workshop, coding challenges, quality control, and a presentation by the Indian Pharmacopoeia Commission about how they use MedDRA and WHODrug.



Figure 5 MedDRA User Group Meeting - India

The 2020 Chinese MedDRA User Group meeting took place on 14 October in Shanghai, China. The meeting was both in-person and virtual with 90 attendees onsite and over 300 attending virtually. Topics included an update on MedDRA and the MSSO, an update on the NMPA, China ICH Office M1 Group, the use of MedDRA in risk evaluation and management, experience sharing on building an in-house coding team, and a role-play coding workshop.



Figure 6 MedDRA User Group meeting - China

IT Tools Updates

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 January 2020, the Mobile MedDRA Browser (MMB) was updated with a multi-lingual user interface (UI). Users may choose any of the supported MedDRA languages as the UI language, including Brazilian Portuguese, Chinese, Czech, Dutch, English, French, German, Hungarian, Italian, Japanese, Korean, Portuguese, Russian, and Spanish. The mobile browser is a web-based application designed for mobile devices that has many of the features of the Web-Based Browser including:

- Search MedDRA terms and codes
- Browse the MedDRA hierarchy and SMQs
- Review term history
- Review term details



Figure 7 Mobile MedDRA Browser

MedDRA Application Program Interfaces

In February 2020, the MSSO deployed a set of MedDRA application program interfaces (APIs) for MedDRA user evaluation. The MedDRA APIs were developed in response to user requests and provide similar features as the Web-Based Browser and MedDRA Version Analysis Tool. These features include browsing and searching for MedDRA terms and SMQs, term detail information, term history, hierarchy and SMQ analysis, and data impact and version report information.

The MedDRA APIs are an open software model which allow users more flexibility in developing their own MedDRA tools or extending existing tools. The APIs accurately depict MedDRA and deliver access to all MedDRA versions and MedDRA translations. Presently the MedDRA APIs are in beta phase. The MSSO has begun work on extending and formalizing API information to align with “Good practice” (GxP) quality guidelines and regulations. Once this work is complete and the information is available to users, the APIs will move to the production phase.

WEB-RADR 2 Project

ICH and the MSSO as its subcontractor participated in the WEB-RADR 2 project (Web Recognising Adverse Drug Reactions) which is funded by the EU's Innovative Medicines Initiative (IMI). The project completed in June 2020.

For more information, please visit the [WEB-RADR 2 website](#)



In 2020, the MSSO and SNOMED International conducted an alpha test of two initial maps developed within the WEB-RADR 2 project:

- MedDRA to SNOMED CT
- SNOMED CT to MedDRA

The maps have been finalized to incorporate feedback from the alpha test and also to include relevant COVID-19 terms.

The first production release of the maps will be in April 2021 and will be made free of charge to licensed MedDRA and SNOMED CT users.

The MSSO began development on MapCR – a free online tool which will allow MedDRA and SNOMED CT users to submit requests for additions or changes to the production maps.

With the creation of the maps from the WEB-RADR 2 project, both ICH and SNOMED International have committed to their ongoing use and maintenance extending past the conclusion of the project.

Blue Ribbon Panel

Blue Ribbon Panel on MedDRA and Information Technology

The MSSO held a Blue Ribbon Panel (BRP) virtual meeting on 10 September from 10:00 to 11:30 US EDT on the topic of “MedDRA and Information Technology”. Blue Ribbon Panels (BRPs) are forums for MedDRA experts - in this case Information Technology experts - from industry and regulatory authorities to discuss and make recommendations on behalf of the user community. This BRP focused on the results of the Information Technology survey, distributed to MedDRA users between 29 June to 24 July 2020, with the goal to make recommendations on technologies the MSSO should consider as it plans for updates to existing software tools and potential new tools and services.

Ninety-four users attended the BRP. Panelists included experts from a broad spectrum including regulatory authorities and life science users. The panel discussed topics including off-cycle releases, machine learning, and the upcoming MedDRA APIs. The Panel’s recommendations on these issues were submitted to the MedDRA Management Committee for its review and consideration.



Figure 8 Blue Ribbon Panel (left to right in the screenshot): Patrick Revelle (MSSO), Nick Halsey (EMA/EC), Sameer Thapar (Oracle) Henry Chen (Thesis), Brian Perry (BKP Technologies), Kostas Kidos (Takeda), and Suranjan De (FDA, United States)

Social Media Growth

The MSSO's China local support team manages

5 WeChat Groups with a total of

2,109 members.

1 Official MedDRA MSSO WeChat Account with

4,703 followers.

LinkedIn is the largest English platform for the MSSO, surpassing

10,000 followers.

Help Desk Growth

9,362 tickets via email

3,929 online chats - a total of

13,291 inquiries.

This is up significantly from the year prior, before the implementation of online chat, where the total volume for 2019 was

8,958 tickets.

Social Media Growth

2020 saw the growth of MSSO on social media platforms like WeChat and LinkedIn. These platforms provide a new mechanism for the distribution of MedDRA news and updates to users.

In China, WeChat, a popular messaging and social media app, is a vital extension of the Help Desk, facilitating discussions and answering user questions, while disseminating news and training information.

The MSSO has also created WhatsApp groups in English, Spanish, and French as another option for users to get specialized updates for their region as well as general MedDRA news.

With followers across Asia, Europe, Australia, Africa, and the Americas, LinkedIn allows global users to receive updates at their convenience. From industry professionals to students, social media is quickly becoming many users preferred source for MedDRA news.

Help Desk Growth

As the global MedDRA user community continues to grow, the MSSO Help Desk has grown alongside, adding new members and methods to ensure users are assisted in a timely manner. Users are able to get in contact with a member of the Help Desk via email, social media, and online chat.

Online chat has allowed users to get immediate assistance from a member of the Help Desk team. The most popular online chat categories of assistance are subscription and training inquiries. Help Desk members provide immediate responses to questions about how to subscribe, registering for training, and where to find webinar connection information.