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MedDRA Version 23.0

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What’s New In MedDRA Version 23.0

Mr. Brian O’Hare
Terminology Maintenance Manager, MedDRA MSSO

MedDRA Version 23.0 was made available to MedDRA users on 1 March 2020 from the Downloads page on the MedDRA website.

MedDRA Version 23.0 is a complex change version, which means that changes may be made at all levels of the MedDRA hierarchy. There was a total of 2,083 change requests processed for this version; 1,850 change requests were approved and implemented, and 225 change requests were not approved. There are, in addition, 8 change requests suspended for further consideration and resolution beyond this version. See the table below for MedDRA Version 23.0 term counts.

<table>
<thead>
<tr>
<th>Level</th>
<th>Version 22.1</th>
<th>Version 23.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>System Organ Classes (SOC)</td>
<td>27</td>
<td>27</td>
</tr>
<tr>
<td>High Level Group Terms (HLGT)</td>
<td>337</td>
<td>337</td>
</tr>
<tr>
<td>High Level Terms (HLT)</td>
<td>1,737</td>
<td>1,737</td>
</tr>
<tr>
<td>Preferred Terms (PT)</td>
<td>23,954</td>
<td>24,289</td>
</tr>
<tr>
<td>Lowest Level Terms (LLT)</td>
<td>80,894</td>
<td>81,812</td>
</tr>
<tr>
<td>Total terms in MedDRA*</td>
<td>82,995</td>
<td>83,913</td>
</tr>
</tbody>
</table>

* Total LLTs include PTs which are included together in the LLT distribution file

There was a total of 12 complex changes implemented for MedDRA Version 23.0. The majority of these changes consisted of modifications in SOC Congenital, familial and genetic disorders to improve the hierarchical placement of gene concepts in MedDRA and to represent both acquired and congenital gene concepts in a single SOC. Note that the net result of the implemented complex changes did not affect the total number of terms at the HLGT and HLT level. Please see the What’s New Version 23.0 document for further details.

Two proactivity requests submitted by MedDRA users were implemented for MedDRA Version 23.0. The MSSO made 27 changes to the placement of existing terms containing “disseminated” or “systemic” to improve the consistency of their placement. A proactive review of existing “abrasion” concepts was performed to align these terms to a more appropriate representation in MedDRA and resulted in nine changes.

New SMQ Opportunistic infections was added in MedDRA Version 23.0. There are now 106 level 1 SMQs in production as of this version. Additionally, there were 499 approved changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA Version 23.0 Version Report.
At the MSSO Help Desk, we strive to provide accurate and comprehensive support for all MedDRA users, with timely responses. In order to enhance our support and make interactions quicker and more dynamic, we launched an instant ‘chat’ feature on the MedDRA website. During the hours that the global Help Desk team are online, the ‘Chat’ option will appear automatically on the website, giving users an opportunity to engage with one of the team in a live interactive text chat.

Users may provide their name and organization or remain anonymous and type a question, which we will endeavor to answer as quickly as possible. If the response requires consulting subject matter experts within the MSSO and/or more in-depth investigation, we will ask the submitter to provide an email address so that we can follow up with a detailed reply.

In addition to English, users may send us a question in Chinese, Korean and Spanish and the MSSO will respond as soon as practical in that language. If Help Desk staff are not online, the chat function will automatically forward the question to our mailbox and notify the sender that we will address the question as soon as possible.
The MSSO Accepts Credit Card Payments

Justin Ford
Business Operations Manager, MedDRA MSSO

In response to user requests the MSSO has provided the option to pay MedDRA subscriptions by credit card since April 2019. Subscribing organizations that are Commercial 0-2 or System Developer are provided this option.

Eligible subscribers receive instructions regarding the credit card payment option on their invoice. Subscribers are provided with the subscription amount in US dollars to pay and a link to a bank website that processes the payment and transfers it to the MSSO. MasterCard, Visa, and Discover credit cards are accepted.
ICH and the MSSO are participating in a project to develop maps between MedDRA and SNOMED CT, an international clinical terminology that is used by healthcare providers. The WEB-RADR 2 project (Web Recognising Adverse Drug Reactions) is funded by the EU’s Innovative Medicines Initiative (IMI) and it seeks to build upon mobile application technology to facilitate exchange of data between regulatory and industry databases (which use MedDRA) and healthcare databases/electronic health records (which use SNOMED CT).

In late 2019, a team from the MSSO, SNOMED International, and other consortium members from regulatory authorities and industry completed development of two initial maps based on a subset of key pharmacovigilance terms to support the data exchange within the application platform:

- MedDRA to SNOMED CT
- SNOMED CT to MedDRA

An alpha test of the maps will be conducted in 2020 with MedDRA and SNOMED CT users prior to the planned first production release in April 2021.

ICH and SNOMED International are developing agreements for licensing, publication, distribution, and continued maintenance of the maps in the future.

For more information, please view the recording of the European Industry MedDRA User Group webinar on the SNOMED CT – MedDRA Mapping.
MedDRA MSSO is on Social Media

Hannah Eaton
Project Coordinator, MedDRA MSSO

In April 2019, the MSSO began exploring social media as a means to enhance and expand communications with MedDRA users around the world. As e-mail use declines in certain regions of the world, supplementing e-mail content with various social media platforms is a vital tool to maintaining and increasing outreach to MedDRA users. The MSSO worldwide Help Desk team is communicating on several platforms around the globe.

Since the MSSO began its exploration into Facebook, LinkedIn, and Twitter, it has seen steady growth in interactions with users from around the world. LinkedIn has grown most notably, from 600 followers to now over 5,000. The platform has also been a helpful metric as MedDRA use grows in new regions. Following user training in Brazil, the platform gained over 100 followers from the São Paulo Area.

Regions that are new to MedDRA are greatly benefitting from the use of messaging apps to receive news updates and regional trainings. The MSSO Help Desk members are building localized WhatsApp groups to publish MedDRA news and facilitate discussions in Russia, India, and parts of Latin America and the Middle East. Training events have been the most successful way to gauge user interest in these groups. MSSO trainers can add interested attendees who can pass on updates or add their colleagues, expanding the network reach beyond traditional e-mail.

MedDRA users in China have been significant users of social media with the popularity of the platform, WeChat. New groups have been added as the existing MedDRA groups grew to the maximum number of participants. WeChat has allowed our Chinese Help Desk team member to build and moderate growing groups for members of the MedDRA user community to receive MSSO news, training updates, and discuss coding questions among chat group members. Training notifications on WeChat have helped to quickly fill classes and have given a useful indicator for training demand in the region. The platform has also become an integral extension of the MSSO Help Desk in China.

As MedDRA use grows, the MSSO is excited about the continued expansion of ways to reach as many users as possible. To read about other forms of MSSO communication, please see the article “” on the newly launched online chat tool at meddra.org website.

Follow us on Social Media

Español: +54 9 11 3862 1067
Chinese
MSSO Technology Updates

Shalini Gupta
IT Manager, MedDRA MSSO

The MSSO understands that MedDRA software tools enhance the utility of MedDRA for all users. The following is a summary of recent MSSO software tool updates and new releases.

WebCR

In October 2019, the MSSO deployed an update to the Web-based Change Request tool (WebCR) version 3.0. MedDRA users may now submit translation change requests using only their MedDRA ID and Password without requiring their Change Request ID (CRID). The change was made to allow more users to submit translation changes. Previously users were required to provide the CRID with proposed translation changes and this limited access since the CRID is frequently closely held within an organization. Translation change requests do not count against the monthly allotment of 100 change requests per month.

MedDRA Mobile Browser

In January 2020, the MedDRA Mobile Browser (MMB) was updated a multi-lingual user interface (UI). Users may choose any of the MedDRA languages as the UI language, including Brazilian Portuguese, Chinese, Czech, Dutch, English, French, German, Hungarian, Italian, Japanese, Korean, Portuguese, Russian, and Spanish.

MedDRA Mobile Browser in iOS.

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**APIs**

In the autumn of 2020, the MSSO plans to make available a set of application programming interfaces (APIs). This will allow software developers to create their own applications using MSSO-provided functions similar to the Web-Based Browser and MedDRA Version Analysis tool. API functions include searching, browsing, hierarchy and SMQ features. Currently, the MSSO is in the testing phase and if MedDRA users are interested to test and provide feedback, please contact the MSSO Help Desk.

Two webinars about the APIs were conducted in February. A recorded version of the webinar on the MedDRA website (Training / Training Materials / Tools) or viewed directly on the MedDRA MSSO’s YouTube channel, MedDRA MSSO, (February 11 version).

**MedDRA Points to Consider Documents**

Dr. Judy Harrison  
Chief Medical Officer, MedDRA MSSO

Beginning with MedDRA Version 23.0, the updates to the MedDRA Term Selection: Points to Consider and the MedDRA Data Retrieval and Presentation: Points to Consider documents will be released annually in March, instead of twice a year. This new schedule will make it easier for users to update their own internal coding and analysis conventions just once a year.

The MedDRA Management Committee and ICH have approved the translation of the full Points to Consider (PtC) documents into other selected languages to support the uptake of MedDRA in new regions. In addition to English and Japanese, translations of the PtC documents in Chinese, Korean, and Spanish will be available in the second half of 2020.

The ICH M1 Points to Consider Working Group is finalizing an update to the Companion Document section on medication errors which will be available on the MedDRA website in May 2020. A new section for the Companion Document on product quality issues is currently under development and will provide additional details, coding examples, guidance, and “Questions and Answers” to supplement the existing PtC documents.
The MSSO offers free training to MedDRA subscribers to support users’ implementation and their continuous use of MedDRA. Multiple forms of training are available for users to choose, including traditional face-to-face classroom training, web-based travel-free webinars, and self-directed training videos.

Face-to-face and webinar classes mainly focus on MedDRA fundamentals, coding principles, and data retrieval strategies, including the Standardised MedDRA Queries (SMQs). Training videos, on the other hand, cover a wide range of topics in addition to those of MedDRA terminology and can be found at the Training Materials Page (https://www.meddra.org/training-materials). They provide an excellent source for users to learn about the free tools that the MSSO offers – the MedDRA Web-Based Browser, MedDRA Desktop Browsers, MedDRA Version Analysis Tool, and Self-Service Tool.

In addition, all webinars are also recorded and posted on the Training Materials Page for users who would like a refresher training and who did not have the opportunity to attend a webinar. The recording of a recent webinar to software developers on Application Programming Interface (API) is now available for viewing. It explains the MedDRA related APIs that the MSSO is to release in later this year.

In 2019, the MSSO training team welcomed new trainers from Argentina, China, Germany, India, and South Korea. A detailed profile of each of MSSO 15 trainers can be found at https://www.meddra.org/msso-trainers. Together we conduct training in English, Chinese, Korean, Spanish, and upon request, French and German worldwide. A total of 6,885 attendees from 73 countries attended the face-to-face and webinar training in 2019.

The MSSO trainers also give MedDRA presentations and/or conduct MedDRA workshops at conferences, such as DIA, WHO Pharmacovigilance Centres meeting, Uppsala Monitoring Centre (UMC) International Pharmacovigilance Training, International Society of Pharmacovigilance (ISoP) meeting, and Pharmacovigilance training in China, India, and South Korea. We look forward to seeing you in future training classes or conferences.
MSSO Presentations From Around the World

MedDRA in India

Dr. Anamika Dutta
Medical Officer, MedDRA MSSO

The MSSO presented MedDRA training sessions at the Skill Development Programme on Pharmacovigilance for Medical Products (PvM) organized by the Indian Pharmacopoeia Commission in Ghaziabad, India on 26th September 2019 and 13th December 2019.

The objectives of this programme are to enhance pharmacovigilance knowledge and skills of health care professionals and to promote patient safety. Dr. Anamika Dutta of the MSSO (based in India) gave an overview of MedDRA as the international standard of global safety communication. The meeting attendees appreciated the MSSO’s outreach to them which offered future cooperative opportunities in increasing the user base in India as well as hosting MedDRA training classes. The MSSO conducted 10 face-to-face MedDRA classes in five major cities and trained over 170 users in India in 2019. We look forward to providing face-to-face training to many more users in India in future.

MedDRA Workshop at the Skill Development Programme on Pharmacovigilance for Medical Products on 13 December 2019
MedDRA in the Republic of Korea

Ms. Yunhui Do
Clinical Associate, MedDRA MSSO

I started to work for the MSSO in January 2019 as a local support staff person and trainer, based in the Republic of Korea. After 6 months, I was already able to represent the MSSO in front of more than 300 Korean and international MedDRA users from the biopharmaceutical industry. Dr. David Richardson and I were invited as guest speakers at an annual event called ‘Global Bio Conference¹ 2019’, hosted in Seoul by the Korean regulator, the Ministry of Food and Drug Safety (MFDS).

The two days of the MedDRA Training Workshop agenda were shared by the MFDS officers and the MSSO. It was a unique opportunity for the MFDS to announce their plan to mandate the use of MedDRA for submitting Individual Case Safety Reports in Korea. Following its acceptance as an ICH regulator member in 2016, the MFDS has been very supportive of the effort to implement M1 guidelines by 2021.

Using ICH standard terminology for the whole life cycle of drug development will certainly improve the pharmacovigilance data exchange between the biopharmaceutical industry and the MFDS. Dr. Yubin Lee (Deputy Director of the MFDS), who is also a member of the ICH M1 Points to Consider Working Group, told the audience that the topic of MedDRA implementation in Korea has been discussed within the Pharmaceutical Safety Bureau since 2012. She also commented that having a Korean translation of MedDRA would be one of the key elements of MedDRA implementation.

Dr. David Richardson and I presented not only a basic understanding of the scope, structure and characteristics of MedDRA, but we also discussed the role of MSSO and the maintenance of MedDRA. During my session, I briefly spoke about the plan for the release of the Korean translation of MedDRA in version 22.1. The next day’s session covered more specific topics related to the use of MedDRA for the coding of clinical information, the analysis of safety data and SMQs.¹ According to the event organizer, some of attendees commented that the MedDRA browser demonstration of coding practices was a great way of learning and Dr. David Richardson’s candid anecdotes from his clinical research experience were very engaging and relatable.

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With the release of Korean translation of MedDRA, the number of subscribing organizations based in the Republic of Korea grew 33% in one year. This demonstrates the utility of MedDRA translations and uptake of ICH guidelines in the Republic of Korea.

As a MedDRA trainer and Help Desk services member within the MSSO, I shall keep collaborating with the Korean regulator and communicating with users to support the use of MedDRA in the Republic of Korea.

1. https://www.gbckorea.kr
2. https://www.meddra.org/mss-presentations

**MedDRA in China**

Dr. Joy Zhu  
Medical Officer, MedDRA MSSO

The MSSO attended the 2019 China CDISC Interchange held on 19-20 September in Beijing. There were hundreds of attendees gathering to network, share their expertise, best practices, and lessons learned about implementing CDISC data standards. Within the CDISC standard, MedDRA serves as a standardized terminology for coding data elements such as adverse events and medical history.

On the first day of the conference, the MSSO presented an overview of MedDRA and the MSSO, as well as an introduction to the characteristics and applications of Standardised MedDRA Queries (SMQs) to the audience which included Biostatisticians, Clinicians, Data Managers, Medical Writers, Programmers, and Study Designers. Most of audience had never heard about SMQs previously, and they learned how these tools could effectively assist them in data analysis, especially on the identification and retrieval of potentially relevant individual case safety reports. They showed great interest and were glad to know the abundant training resources provided by the MSSO.

On the second day, there were a couple of topics regarding CDISC’s efforts in developing and maintaining a Controlled Terminology of Traditional Chinese Medicine (TCM). We had a productive discussion on the challenges of using TCM terms and MedDRA during the Q&A session. The MSSO appreciates the experiences shared by CDISC members and looks forward to hearing users’ ideas on the future development of MedDRA.

Dr. Joy Zhu of the MedDRA MSSO presenting at the 2019 China CDISC Interchange on 19 September in Beijing
Please visit us at the European MedDRA / WHO Drug Meeting

European MedDRA / WHODrug Meeting
Amsterdam, the Netherlands
1 – 2 April 2020

We want your Feedback! Please contact us:

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