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What's New for MedDRA Version 21.0



By Brian J. O'Hare
Terminology Maintenance Manager

MedDRA Version 21.0 was made available to MedDRA users on 1 March 2018 from the Downloads page on the MedDRA website.

MedDRA Version 21.0 is a complex change version which means that changes may be made at all levels of the MedDRA hierarchy. There was a total of 1,575 change requests processed for this version; 1,360 change requests were approved and implemented, and 203 change requests were not approved. There are, in addition, 12 change requests suspended for further consideration and resolution beyond this version. See the table below for MedDRA Version 21.0 term counts.

Number of Terms in MedDRA		
Level	Version 20.1	Version 21.0
System Organ Classes (SOC)	27	27
High Level Group Terms (HLGT)	337	337
High Level Terms (HLT)	1,738	1,737
Preferred Terms (PT)	22,774	23,088
Lowest Level Terms (LLT)	78,026	78,808
Total terms in MedDRA*	80,128	80,909

*Total LLTs include PTs as they are included together in the LLT distribution file.

There was a total of 10 complex changes implemented for MedDRA Version 21.0. The majority of these changes consisted of replacing existing HLTs with new more descriptive HLTs to better represent the underlying PT concepts. Examples include replacing HLT *Anaesthetic complications* with new HLT *Anaesthetic and allied procedural complications* and replacing HLT *Chest and lung injuries NEC* with new HLT *Chest and respiratory tract injuries NEC*. Please see the What's New Version 21.0 document for further details.

Other changes included the addition of new terms related to two terminology interoperability initiatives to map a set of device patient problem codes to MedDRA and a pilot study on the feasibility of mapping ICD 10 Chapter 1 infection terms to MedDRA. As a result of these initiatives, a total of 97 new terms were added. Please see the What's New Version 21.0 document for further details.

New SMQ *Dehydration* was added in MedDRA Version 21.0. There are now 103 level 1 SMQs in production as of this version. Additionally, there were 295 approved changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA Version 21.0 Version Report. 🗨️

Update from the Director



By Patrick Revelle
Director, MedDRA MSSO

2018 Subscription Rate Reductions

The MedDRA Management Committee (MMC) is responsible for overseeing the operations of the MSSO including responsiveness to users, MedDRA maintenance, ensuring MSSO services meet the needs of users, and setting subscriptions rates on an annual basis. In late 2017, the MMC directed the MSSO to reduce subscription rates for MedDRA users with annual revenue less than \$20M USD and for System Developers. The reduction of subscription rates for these users represents 77% of paying MedDRA organizations for 2018.

It should be noted that these reductions are possible due to the continued success of MedDRA as an international standard. With more users the cost of maintenance, development, and support of MedDRA is spread over a larger group which allows for a reduction in rates.

The MSSO plans to extend the benefits of a MedDRA subscription with more translations (e.g., Russian and Korean are in process), extended software tools (e.g., new features added to the Web-Based Browser), and extending MedDRA training to more users. 🗣️

New MedDRA Translations

The MSSO is currently in the process of providing two new translations of MedDRA to MedDRA users – Korean and Russian. As with other supported languages, these new translations will include all MedDRA terms (over 80,000 terms as of MedDRA Version 21.0) and all user documentation. The MedDRA tools that provide user interfaces in MedDRA languages (e.g., Web-Based Browser, MVAT, Desktop Browser) will also be available in these new languages.

Since all terms will be translated, users can easily code data with one translation and output the data in any other MedDRA language by simply using codes to link the terms together.

The MSSO will be working with the regulatory authorities of the Republic of Korea (MFDS) and the Russian Federation (Roszdravnadzor) to ensure the translation meets the needs of users.

The MSSO anticipates that these translations will be available to MedDRA users in late 2018 or early 2019. 🗣️

Patient-Friendly Term List



Judy Harrison, MD
Chief Medical Officer

The MSSO and partners from regulatory authorities and industry have developed a Patient-Friendly Term List for MedDRA. The list is available under [Related Links](#) on the [Support Documentation](#) page of the MedDRA website and it is maintained with each release of MedDRA.

The terms were selected from reports from patients and consumers in a variety of pharmacovigilance databases. The list includes approximately 1,400 Lowest Level Terms in English and is intended to aid in direct reporting of adverse events. The MSSO anticipates that the list will be used in data collection websites and mobile applications intended for patients and consumers. Reports collected with these terms can be immediately used for analysis without having to convert to MedDRA.

The Patient-Friendly Term List is incorporated in the YellowCard online form, which collects adverse events reported by patients and healthcare professionals for the Medicines and Healthcare products Regulatory Agency (MHRA) in the UK.

Users are invited to contact the [MSSO Help Desk](#) with any questions or comments about the Patient-Friendly Term List.

1	LLT	LLT code
2	Abdomen enlarged	10000045
3	Abdominal bloating	10048746
4	Abdominal cramps	10000057
5	Abdominal crampy pains	10000058
6	Abdominal discomfort	10000059
7	Abdominal hernia	10060954
8	Abdominal infection	10056519
9	Abdominal mass	10000077
10	Abdominal pain	10000081
11	Abdominal tenderness	10000097

Sample of Patient-Friendly Term List, MedDRA Version 21.0

MSSO Partnering with WHO and UMC



By Anna Zhao-Wong, MD, PhD
Deputy Director, MedDRA MSSO

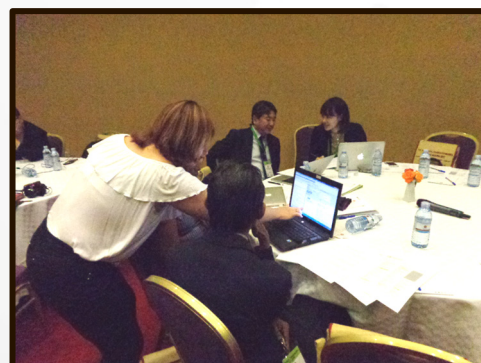
The MSSO has partnered with the World Health Organization (WHO) Medicines Safety and Vigilance Group, based in Geneva, Switzerland, and the Uppsala Monitoring Centre (UMC), based in Uppsala, Sweden, to provide training and support to countries transitioning from WHO-ART to MedDRA. In February 2015, UMC announced its decision to stop maintaining WHO-ART and to support MedDRA as its global terminology for regulatory and pharmacovigilance purposes.

Since then, UMC has collaborated with the MSSO/ICH to help regulatory authorities of member countries of the WHO Programme for International Drug Monitoring obtain MedDRA subscriptions and transition to use MedDRA in VigiFlow, the UMC's ICSR management tool, which is used by about 80 national centers. To promote the accurate use of MedDRA in VigiFlow, the MSSO, the WHO Medicines Safety and Vigilance Group, and the UMC are partnering to provide MedDRA training.

One recent example of such collaboration was the Preconference Workshop on MedDRA in Pharmacovigilance at the WHO 40th National Pharmacovigilance Centres Meeting in Kampala, Uganda on 6 November 2017. Over 130 representatives from 60 countries participated in the MedDRA workshop. MedDRA Management Committee members, Mr. Mick Foy (MHRA, UK) and Ms. Heather Morrison (Health Canada, Canada), conducted the workshop with presentations and hands-on exercises.



Mick Foy and Heather Morrison presenting at the MedDRA Workshop



Mick Foy and Heather Morrison assisting participants with Questions and Hands-on Exercises
(Photos were provided by Dr. Daisuke Tanaka, WHO Medicines Safety and Vigilance Group)

MSSO Partnering with WHO and UMC (continued)

In 2018, through this partnership, the MSSO will provide similar MedDRA training/workshops at WHO/UMC regional conferences to support the transition to MedDRA.

In addition to MedDRA training, the MSSO and the UMC also partnered to provide MedDRA and WHODrug joint user group meetings to better serve our shared user communities. In February 2017, we held joint user group meetings in Bangalore and Mumbai, India. For details, please see the India user group meeting article in the March 2017 Edition of the MedDRA Messenger. The MSSO and UMC will return to Bangalore in February 2018 for another joint User Group meeting.

On 6 September 2017, we held another joint MedDRA and WHODrug User Group meeting in Beijing China. The MSSO invited speakers to present the following topics: MedDRA and MSSO Update, MedDRA Coding Discussion, MedDRA Feasibility Study by Jiangsu ADR Center, and MedDRA and Traditional Chinese Medicine. Colleagues from the UMC presented WHODrug Introduction, Report from UMC, and Daily Challenges of Coding (WHODrug). The joint user group meeting was well attended with about 60 participants.



Speakers of MedDRA and WHODrug Joint User Group Meeting in Beijing: (from left to right) Dr. Qingna Li (Xiyuan Hospital), Dr. Lilin Zhu (Quintiles), Mr. Damon Fahimi (UMC), Dr. Anna Zhao-Wong (MSSO), Ms. Anna Mattsson (UMC), Ms. Mao Mao Söderberg (UMC), Ms. Danhua Ma (Jiangsu ADR Center)

We received positive feedback from users in India and China. Through the partnership, the MSSO and the UMC will continue to offer joint user group meetings worldwide 🌐

MedDRA Training in Mexico and Guatemala



By Tomás Moraleda, MD
International Medical Officer

In October 2017, the MSSO provided training to two Latin American countries. The interest in MedDRA as a medical terminology has steadily increased in Latin America over the last two years. Both the incorporation of MedDRA in the Uppsala Monitoring Centre's drug safety database, VigiBase, and the fact that many Latin American countries are striving to bring their regulations closer to ICH standards have played a role in that rising interest.

The Mexican regulator, Comisión Federal para la Protección contra Riesgos Sanitarios (COFEPRIS), asked the MSSO for two days of training for their staff on both coding and analysis aspects of MedDRA. An audience of approximately 100 participants comprising staff members from each of the 31 state regulatory centers met at the La Salle University of Ciudad de México on 17 and 18 October. COFEPRIS is implementing a new system of electronic transmission of safety reports to align with ICH requirements and has issued a new regulation, effective in January 2018, that will require public and private health care providers, MAHs, CROs, and other institutions working in clinical research to code medical information into MedDRA.



The audience in La Salle University

The same MedDRA coding and analysis courses were provided to approximately 150 members of the Mexican pharmaceutical industry and academia on 19 and 20 October. The impact of the new regulation requiring the use of MedDRA was discussed.

In addition to Mexico, the MSSO gave a one-day customized MedDRA training course in Antigua, Guatemala on 24 October that focused on the essential aspects of coding, analysis and SMQs.

The training was requested by the Spanish Agency (AEMPS₍₁₎), within the framework of the Spanish collaboration in the development of Central American countries. The Spanish Agency promoted a meeting with COMISCA₍₂₎ - an association created to solve common health problems of Central American countries - to help with the implementation of a common electronic transmission system.

This collaboration was a valuable opportunity for the MSSO to provide the first exposure to MedDRA to an audience of 16 regulators from Guatemala, El Salvador, Honduras, Nicaragua, Costa Rica, Panamá, Dominican Republic, and Belize.



Antigua and one of its surrounding volcanos

MedDRA Training in Mexico and Guatemala (continued)

The MSSO will participate in future periodic online meetings with this group to support their transition to electronic transmission of safety data using MedDRA.

All the courses were well-received and the MSSO plans to offer additional training in Latin America in 2018 and beyond to support the expanding use of MedDRA in this region.



- (1) AEMPS: Agencia Española de Medicamentos y Productos Sanitarios - Spanish Agency of Medicines and Health Products.
- (2) COMISCA: Consejo de Ministros de Salud de Centroamérica - Council of Ministers of Health of Central America

Web-Based Browser Access Available to JMO Users



By Brian J. O'Hare
Terminology Maintenance Manager

Organizations that subscribe to MedDRA through the Japanese Maintenance Organization (JMO) now have access to the MedDRA Web-Based Browser (WBB) application (<https://tools.meddra.org/wbb>) from the MSSO. The MedDRA Version Analysis Tool (MVAT) has been available to JMO users since 2015.

The WBB is a web-based application that allows MedDRA users to browse the MedDRA hierarchy and SMQs, search for terms and MedDRA codes, export term and SMQ information, and view up to three languages of the same version simultaneously. The WBB includes all English and Japanese MedDRA Versions from Version 2.1 to the present and all other MedDRA languages from the version they were introduced to the present. Note that access to Japanese MedDRA for users who subscribe through the MSSO requires an additional fee.

The WBB supports the unique features of the Japanese MedDRA including Kanji and Kana translations, Japanese synonyms, and J-currency.

For more information about the WBB, please go to the following link on the MedDRA website: <https://www.meddra.org/browsers>. All MSSO users have access to the WBB today by using your MedDRA User ID and password. If your organization subscribes to MedDRA through the JMO, please contact the JMO at info.jmo@pmrj.jp to obtain login credentials to access the WBB.

ICH M1 Points to Consider Working Group Meeting



By Judy Harrison, MD
Chief Medical Officer

The WG divided into sub-teams to work on the two sections planned for the first edition of the document: data quality and medication errors. Members all contributed to the lively discussions and provided relevant, practical examples from their regulatory and industry perspectives.

The MSSO participated in the ICH M1 Points to Consider (PtC) Working Group meeting in Geneva, Switzerland on 13-15 November 2017. The Working Group (WG) welcomed Dr. Won Im Do and Dr. Yong Seok Ko as new regulatory members representing MFDS, Republic of Korea.

The major accomplishment of the WG in this meeting was to complete the first draft of a Companion Document to the PtC documents. This document will provide more detailed guidance, examples, and “Questions and Answers” on topics of regulatory importance.

The Companion Document will be available in English and Japanese and the first edition is expected to be published on the MedDRA website in the first half of 2018. It is intended to be a “living” document with regular updates based on MedDRA users’ needs and feedback. New sections on other topics will be added in future editions.

The PtC Working Group invites MedDRA users to provide feedback on the main PtC documents as well as the Companion Document by sending an email to the MSSO [Help Desk](#).



ICH M1 PtC Working Group members in Geneva. November 2017

Did you Know?

By MedDRA MSSO

This article provides MedDRA users with useful information and answers to questions about MedDRA. Here is a set for you to consider:

1. Did you know there is a rate reduction and payment option change for 2018 Commercial 0-2 subscriptions?
2. Did you know that MedDRA MSSO has a YouTube channel?
3. Did you know that MedDRA.org has an explanation in Chinese on how to subscribe to MedDRA and pay for the subscription invoice?
4. The MSSO provides free MedDRA training to regulatory authorities and other users around the world. How many attendees participated in classroom and webinars in 2017?

Answers: 1- In Nov 2017, the MedDRA Management Committee approved a 5% subscription rate reduction for 2018 Commercial Level 0-2 subscriptions via credit cards. 2- The MedDRA MSSO has just created a YouTube channel called "MedDRA MSSO" where we have uploaded all the videocasts and recorded webinars. This will let MedDRA users, who are unable to view videos in the Windows Media Video (WMV) format, to view them from any system. Look for the links on the Training Materials page: 3- The explanation is posted at: <https://www.meddra.org/chinese-subscription-rates>. 4- Over 3,000.

**Please visit us at the
Drug Information Association
Annual Meetings**

Europe DIA 2018

Basel, Switzerland
17-19 April 2018

DIA 2018 Global Annual Meeting

Boston, Massachusetts USA
25-27 June 2018

**and the
MedDRA User Group Meetings**

European User Group Meeting

Basel, Switzerland
16 April 2018

U.S. User Group Meeting

Boston, Massachusetts USA
28 June 2018

We want your Feedback! Please contact us:

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