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**What’s New for MedDRA Version 21.1**

By Brian J. O’Hare
Terminology Maintenance Manager

MedDRA Version 21.1 was made available to MedDRA users on 1 September 2018 from the Downloads page on the MedDRA website.

MedDRA Version 21.1 is a simple change version which means that changes are made only at the PT and LLT levels of the MedDRA hierarchy. There was a total of 1,516 change requests processed for this version; 1,283 change requests were approved and implemented, and 229 change requests were not approved. There are, in addition, four change requests suspended for further consideration and resolution beyond this version. See the table below for MedDRA Version 21.1 term counts.

<table>
<thead>
<tr>
<th>Level</th>
<th>Version 21.0</th>
<th>Version 21.1</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>23,088</td>
<td>23,389</td>
</tr>
<tr>
<td>Lowest Level Terms (LLT)</td>
<td>78,808</td>
<td>79,507</td>
</tr>
<tr>
<td><strong>Total terms in MedDRA</strong>*</td>
<td>80,909</td>
<td>81,608</td>
</tr>
</tbody>
</table>

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

Three proactivity requests submitted by MedDRA users were implemented for MedDRA Version 21.1. The MSSO made four changes to PT and LLT terms under HLGT *Medication errors and other product use errors and issues* for better alignment and consistency of placement. A proactive review of all LLTs under PT *Procedural complication in SOC Injury, poisoning and procedural complications* was performed to align these terms to a more anatomically appropriate placement that resulted in 37 changes. In a separate request, the MSSO assessed the placement of existing prophylaxis/prevention terms in HLT *Prophylactic procedures NEC* and moved them to more specific HLTs to optimize their placement in MedDRA. Related to this request, the MSSO added 17 new terms that represent prophylaxis and prevention concepts pertaining to general disorder/disease categories, and moved 53 existing terms. Please see the What’s New Version 21.1 document for further details.

No new SMQs were introduced into MedDRA Version 21.1, however there were 307 approved changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA Version 21.1 Version Report.
Update from the Director

By Patrick Revelle
Director, MedDRA MSSO

Japanese Translation Fee Eliminated
Starting 2019

At the June meeting of the MedDRA Management Committee (MMC), the MMC agreed that, effective 1 January 2019, the additional subscription fee of $850 for the Japanese translation of MedDRA obtained through the MSSO will be eliminated. MSSO subscribers will receive all 11 MedDRA languages included with their subscription at no additional cost.


The Japanese translation of MedDRA is accessible from the Downloads page of the MedDRA website, and starting on 1 January 2019, the current version of MedDRA (Version 21.1 as of 1 January 2019) and all previous versions of MedDRA back to the initial version of MedDRA (Version 2.1) will be available.
On behalf of the ICH M1 Points to Consider (PtC) Working Group, the MSSO is pleased to announce that the first edition of the MedDRA Points to Consider Companion Document was made available to users on 27 June 2018. It is posted on the Support Documentation page of the MedDRA website and is available in English and Japanese in both Word and PDF versions.

The purpose of the Companion Document is to supplement the existing PtC documents by providing additional details, examples, guidance, and “Questions and Answers” on specific MedDRA-related topics of global regulatory importance. The first edition includes sections on data quality and medication errors. The Companion Document is intended to be a “living” document and will be updated frequently based on users’ needs. The PtC Working Group is already considering a new section to address product quality issues.

MedDRA users are invited to contact the MSSO Help Desk with any questions or comments about the Companion Document, which will be discussed with the PtC Working Group. We hope that the document will prove to be a useful resource and we look forward to your feedback.
ICH MedDRA Training

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

MedDRA is being adopted by an increasing number of regulatory authorities in countries and regions around the world, such as Brazil, Central America, China, Mexico, the Republic of Korea, Singapore, and Turkey. As an ICH standard terminology, MedDRA has been implemented by the EMA, Health Canada, MHLW, and US FDA. The experiences and lessons learned by these regulatory authorities are helpful to other regulatory authorities that are transitioning to MedDRA today.

Upon request, the MedDRA Management Committee, the ICH Secretariat, and the MSSO work together to provide training on the practical implementation of MedDRA, as well as coding and analysis to national regulatory authorities and industry to support their transition to MedDRA. In 2018, such training was provided to the regulatory authorities in China, the Republic of Korea, Colombia, and the Council of Ministers of Health of Central America and the Dominican Republic (COMISCA).

In February and March, through a series of webinars, the MSSO provided implementation training including demonstrations on downloading and installing MedDRA files to the regulators in Colombia and COMISCA.

On 10-13 April, the ICH training team, consisting of members of the MSSO and Health Canada, provided training to CFDA, China. The training agenda included MedDRA as an ICH product, MedDRA Introduction, MedDRA implementation in Health Canada, MedDRA Implementation Plan tasks and timeline, MedDRA Chinese translation, and the use of MedDRA in coding, data retrieval, and analysis based on the ICH MedDRA Points to Consider (PtC) documents. Over 200 CFDA staff attended the four-day training. An additional 200 industry and academia attendees joined the MedDRA coding and analysis training on 12-13 April (see the photograph below).

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On 29-30 May, the MSSO conducted MedDRA implementation training in the Republic of Korea. Approximately 30 members of the regulatory authority, MFDS, attended the first day’s session. Discussion topics included data conversion, IT implementation, translation quality assurance, and special licenses. Around 300 participants from local industry joined the second day’s session organized by MFDS for general MedDRA training (see the photograph below). Topics included an introduction to MedDRA and its maintenance process, demonstrations of the MedDRA website and the Desktop Browser, and coding and data analysis with MedDRA.
ICH MedDRA Training (continued)

Participants in all of these training sessions were enthusiastic learners and appreciated the training opportunities provided by ICH. The large number of attendees shows that the demand for training is high in new MedDRA communities. The MSSO is working with ICH to increase support in these new regions.

Meanwhile, the MSSO maintains a high level of free training services to existing users. In 2018, a total of 71 face-to-face classes are scheduled or were conducted - an 11% increase compared to the number of face-to-face classes conducted in 2017. Many regulatory authorities received or are scheduled to receive MedDRA training, including: Health Canada; SUKL, Czech Republic (see photograph below); EOF, Greece; COFEPRIS, Mexico; INFARMED, Portugal; TITCK, Turkey; MHRA, UK; and FDA, US.

MSSO Trainer Dr. Eva Rump (front row 3rd from the right) and training attendees at SUKL, Czech Republic

We hope to meet more MedDRA users at our training classes. To register for the MSSO free training, please visit the MedDRA website at: https://www.meddra.org/training/schedule.
Newly Updated Web-Based Browser

By Shalini Gupta
IT Manager

The MSSO is currently working to update the MedDRA Web-Based Browser (WBB) for version 3.0. We have collected ideas for new features and adjustments to existing functions from many users and we are anxious to deliver the new version. We have had a subset of users review a prototype and we are working now to apply their feedback in the 3.0 version.

These enhancements will include:

- **SMQ Analysis** – Users can upload a spreadsheet of MedDRA terms to apply their MedDRA coded data against SMQs that are selected by users.
- **Hierarchy Analysis** – Users can import a list of MedDRA terms and extract both the primary and secondary hierarchy of these terms up to the SOC level.
- **Research Bin Improvements** – When exporting terms from the Research Bin users have the option to include secondary SOC hierarchy information.
- **Supplemental View** – The supplemental view shows the most recent MedDRA supplemental data, which allows MedDRA users to see the changes (e.g., new terms and changes to existing terms) that will be available in the next MedDRA release.
- **Advanced Search** – More complex searches are available via Boolean operators and string operators (CONTAINS, NOT CONTAINS, BEGINS WITH, ENDS WITH) to perform more targeted searches.
- **Improved Term History** – The term history function has been upgraded to match the graphical term history available in MVAT which provides comprehensive history of how a term has changed over time.
- **User Specific Settings** – A user’s choice of the interface language, selection of MedDRA languages, and options to Show Codes, and Hide Non-Current LLTs are now saved so that at the next login, there is no need to reset these preferences.

The WBB will be available at [https://tools.meddra.org/wbb](https://tools.meddra.org/wbb) and accessible via your MedDRA ID and password in the Autumn.
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, the MSSO held joint MedDRA and WHODrug meetings in India, and China.

When possible we coordinate with the UMC to schedule MedDRA User Group meetings in conjunction with WHODrug meetings since many attendees use both terminologies. We are able to do this in Europe and India this year.
MedDRA User Group Meetings (continued)

MedDRA User Group Meeting in Basel Switzerland on 16 April 2018

MedDRA User Group Meeting in Beijing, China on 16 April 2018

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MedDRA User Group Meetings (continued)

Winners of the MedDRA trivia contest at the Boston User Group Meeting held on 28 June 2018

For details on the agendas and presentations of past meetings and information on upcoming meetings, please see the User Groups page on the MedDRA website.
The Japanese Maintenance Organization (JMO) and the MSSO have had a partnership in place since the very beginning of our organizations in 1998. Our shared goal is to meet the needs of MedDRA users with the highest quality maintenance, development, and support of MedDRA. The JMO focuses on MedDRA users headquartered in Japan by providing training and Help Desk support to Japanese users, and is responsible for maintaining the Japanese translation of MedDRA. The JMO plays an integral role in the MedDRA terminology maintenance process by reviewing and providing feedback on all change requests, and by participating in the development and maintenance of SMQs.

The JMO and MSSO initiated an exchange program in 2017 with the goal to deepen the understanding of the processes used by both organizations and look for efficiencies to share. Last year, Ms. Tomoko Narita from the JMO came to the MSSO sharing JMO functions, observing the functions of the MSSO, and reviewing software tools developed by the MSSO. This year, I traveled to the JMO for the same purpose and spoke at user group meetings in Osaka and Tokyo to update users on the global status of MedDRA and how the MSSO and JMO collaborate to support MedDRA users. The experience was a great success for both organizations and we look forward to a continued partnership for the benefit of MedDRA users.
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 that in 2019 all MedDRA translations, including Japanese, will be available to MSSO users as part of their MedDRA subscription?

2. Did you know which additional translations of MedDRA are in process?

3. Did you know that supplemental changes to the current MedDRA release will be available in the next version of the MedDRA Web-Based Browser?

4. Did you know how many people the MSSO trained in 2017?
Please visit us at the
Drug Information Association
Annual Meetings

DIA Europe 2019
Vienna, Austria
05-07 February 2019

DIA 2019 Global Annual Meeting
San Diego, California USA
24-26 June 2019

and the
MedDRA User Group Meetings

European User Group Meeting
Prague, Czech Republic
Date: TBD

U.S. User Group Meeting
San Diego, California USA
27 June 2018

India User Group Meeting
TBD

China User Group Meeting
TBD

We want your Feedback! Please contact us:

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