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Did You Know?

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MedDRA Version 22.0 was made available to MedDRA users on 1 March 2019 from the Downloads page on the MedDRA website.

MedDRA Version 22.0 is a complex change version which means that changes may be made at all levels of the MedDRA hierarchy. There was a total of 1,541 change requests processed for this version; 1,333 change requests were approved and implemented, and 207 change requests were not approved. There is, in addition, one change request suspended for further consideration and resolution beyond this version. See the table below for MedDRA Version 22.0 term counts.

<table>
<thead>
<tr>
<th>Level</th>
<th>Version 21.1</th>
<th>Version 22.0</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>
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<tr>
<td>Preferred Terms (PT)</td>
<td>23,389</td>
<td>23,708</td>
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<tr>
<td>Lowest Level Terms (LLT)</td>
<td>79,507</td>
<td>80,262</td>
</tr>
<tr>
<td>Total terms in MedDRA*</td>
<td>81,608</td>
<td>82,363</td>
</tr>
</tbody>
</table>

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

There were a total of 16 complex changes implemented for MedDRA Version 22.0. The majority of these changes consisted of replacing existing HLGTs and HLTs with new more descriptive terms to better represent the underlying PT concepts. Examples include replacing HLGT Cardiac disorder signs and symptoms NEC with new HLGT Cardiac disorders, signs and symptoms NEC and replacing HLT Aortic inflammatory disorders with new HLT Aortic infections and inflammations. 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 22.0 document for further details.

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Two proactivity requests submitted by MedDRA users were implemented for MedDRA Version 22.0. The MSSO made 14 changes to anesthesia terms for more optimal placement in MedDRA. A proactivity review to consider modifications to the placement of existing chemical burn and corrosive injury terms was also performed. Based on this review a total of six changes were made to existing terms for more consistent placement in MedDRA. Please see the What’s New Version 22.0 document for details.

New SMQ Hypokalaemia was added in MedDRA Version 22.0. There are now 104 level 1 SMQs in production as of this version. Additionally there were 389 approved changes to existing SMQs. To view changes to existing SMQs, please review the MedDRA Version 22.0 Version Report.
MSSO Subscription Updates

At the Charlotte, USA meeting in November 2017, the MedDRA Management Committee approved a 5% reduction in MedDRA subscription fees for all subscription levels, effective 1 January 2019. Details are available on the MedDRA website. This reduction is a reflection of the continued success of MedDRA as a global standard in public health. With an expanding user base, the costs of maintaining and developing the terminology can be distributed more widely, while still providing the same high standard of tools and services to MedDRA users.

Another change implemented on 1 January 2019 was the removal of the additional fee to access the Japanese translation of MedDRA. This change was approved by the MedDRA Management Committee earlier in 2018.

With this change, MedDRA users receive all MedDRA languages included with their MSSO subscription at no additional cost. This also means that all MedDRA translations are available in the Web-Based Browser and the MedDRA Version Analysis Tool.

By Patrick Revelle
Director, MedDRA MSSO
MedDRA was one of the topics of the keynote panel discussion that started the International Conference, “Pharmacovigilance: Challenges and Opportunities” in Moscow, Russia on 10 October 2018. Co-hosted by the Russian regulatory authority (Roszdravnadzor) and the Association of International Pharmaceutical Manufacturers (AIPM). The conference included presentations by experts from Roszdravnadzor; the Eurasian Economic Commission (EEC); national regulatory authorities of the Eurasian Economic Union (EAEU); European Medicines Agency (EMA); the Russian and European pharmaceutical industry; and the WHO.

The MSSO provided a presentation on MedDRA as the international standard of global safety communication and a MedDRA Workshop.

Implementing MedDRA in the EAEU Unified Database of Adverse Drug Reactions is an important step in implementing ICH guidelines in Russia and the greater EAEU. The announcement of an upcoming MedDRA Russian translation in March 2019, by Mr. Mikhail Murashko, Head of Roszdravnadzor, underscored the commitment of the Russian regulatory authority to MedDRA.

The MSSO’s presentation on MedDRA as an ICH product and its role in standardizing adverse event reporting and safety communication offered a direct dialogue between the attendees and the MSSO. The subsequent MedDRA Workshop provided detailed discussions of MedDRA basics, including structure, scope, characteristics, maintenance, coding adverse events and applying the MedDRA structure including SMQs in the analysis of MedDRA-coded safety data. The meeting attendees appreciated the MSSO’s outreach to them which offered future cooperative opportunities in hosting MedDRA training classes. The MSSO looks forward to providing additional training to users in Russia.
Russian Review Team Plays Key Role in MedDRA Translation in Russian

By Patrick Revelle
Director, MedDRA MSSO

With the release of MedDRA version 22.0 the MSSO is pleased to announce the availability of the Russian translation of MedDRA. With Russian, MedDRA is now available in 12 languages including Chinese, Czech, Dutch, English French, German, Hungarian, Italian, Japanese, Portuguese, and Spanish. The translations of MedDRA include all of the terms (roughly 80,000 terms currently) and MedDRA user documentation.

The MSSO contracted with a medical translation firm to develop the initial Russian translation of Russian. A key element to any MedDRA translation is to ensure that the translation is accurate, consistent, and meaningful to the native speakers of the language.

The MSSO worked with the Russian regulatory agency, Roszdravnadzor, and the Association of International Pharmaceutical Manufacturers (AIPM) to form a Russian Review team to support this goal. The Review Team was led by Elena Obernikhina and consists of regulatory authorities and industry representatives with over 30 participants. The effort required a broad range of expertise to be able to review and provide feedback on all of the MedDRA’s 27 SOCs. The Russian Review team performed extremely well under tight timeframes and provided detailed feedback including revised translations. The MSSO held weekly meetings with the Russian Review team to discuss translation changes and translation conventions to support accuracy and consistency.

The MSSO is greatly appreciative of the effort made by Elena and the Russian Review team to review the Russian translation and to meet demanding timelines. We are pleased to be able to provide this new translation of MedDRA.

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Expanding MSSO’s Help Desk Support and Training Services

For users in non-English speaking countries, how about getting MSSO Help Desk support in your local time zone and in your native language? How about having training slides translated and training classes taught in your native language too? These are the new initiatives that the MSSO is committed to implement in 2019 to enhance our services to our global user community.

The new initiatives are being implemented by establishing MSSO local support in selected countries. The MedDRA subscriber base expanded by 10% in 2018 compared to 2017. The fastest growing area was Asia (41% increase), driven mostly by China and the Republic of Korea.

The large number of new users in these countries leads to high demand for Help Desk support and MedDRA training in their native languages because English is not commonly spoken.

Additionally, the Eastern Standard Time Zone of the United States and European time zones where most of the MSSO staff reside makes it challenging to provide assistance during the business hours in Asia. With the support of the MedDRA Management Committee, local support staff are being hired in China, India, Latin America, and the Republic of Korea to provide Help Desk service and MedDRA training in the local time zone and in local languages.

The local support staff are the MSSO representatives in their respective geographic regions. They will respond to Help Desk inquiries in local languages and local time zones, translate the MSSO training materials, and conduct training in their corresponding local language. Ms. Yun Hui Do, based in Seoul, Republic of Korea, and Ms. Ana García Rubio, based in Buenos Aires, Argentina, have already joined the MSSO early this year. They look forward to meeting users and supporting the use of MedDRA.

Ms. Yun Hui Do
Ms. Ana García Rubio
WEB-RADR 2 Project: MedDRA/SNOMED CT Mapping

ICH and the MSSO are participating in a project to develop a bi-directional mapping between MedDRA and SNOMED CT, an international clinical terminology that is used by healthcare providers to exchange information. 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 the mobile application technology that was developed in the original WEB-RADR project. A major goal is to use the enhanced functionality of the application to facilitate exchange of data between regulatory databases (which use MedDRA) and healthcare databases/electronic health records (which use SNOMED CT).

For example, SNOMED CT-coded data in a health record could be converted to MedDRA for the purpose of adverse event reporting to regulatory authorities. In the opposite direction, MedDRA-coded data such as adverse events and regulatory information could be converted into SNOMED CT so that the information is available in the patient’s record to aid in clinical decision-making.

A bi-directional mapping between MedDRA and SNOMED CT is therefore being developed to support the data exchange within the application platform. By the end of the project in February 2020, the mapping work package members will deliver an initial mapping of a subset of about 7,000 key pharmacovigilance terms. In parallel, they will develop agreements between the two terminology maintenance organizations (MedDRA MSSO and SNOMED International) for licensing, publication, distribution, and continued maintenance of a mapping in the future. For more information, please visit the WEB-RADR 2 website.
MedDRA Points to Consider Companion Documents and MedDRA Best Practices Document

Condensed versions of the MedDRA Term Selection and Data Retrieval and Presentation Points to Consider documents were made available to users on 9 November 2018. They are posted on the Support Documentation page of the MedDRA website.

Developed by the ICH M1 Points to Consider (PtC) Working Group, the Condensed versions focus on the fundamental principles of term selection and data retrieval, and are intended to support the implementation and use of MedDRA in the ICH regions and beyond. They are available in all MedDRA languages except for English and Japanese; the English and Japanese PtC documents will continue to be maintained and updated as the full reference documents. Please select the relevant language to navigate to the specific translation of the document.

In addition, the MedDRA Best Practices document has been posted on the Support Documentation page. The purpose of the document is to provide the recommendations of the MSSO for the implementation and use of MedDRA. Topics include primary SOC allocation rules, versioning, and use of supplemental terms. It is available in all MedDRA languages.

MedDRA users are invited to contact the MSSO Help Desk with any questions or comments.
Did You Know?

By MedDRA MSSO

Did you know…

1. How many new SMQs were added with version 22.0?
2. Which MedDRA translations are available in the Web-Based Browser and the MedDRA Version Analysis Tool?
3. Which locations where additional support staff are being hired?
4. Which languages the Condensed versions of the MedDRA Term Selection and Data Retrieval and Presentation Points to Consider documents are offered in?

Answers:

1. One new SMQ term was added with version 22.0 – Hypokalaemia
2. All MedDRA translations are now available at no additional cost to subscribers.
3. Additional support staff are being hired in China, India, Latin America, and the Republic of Korea.
4. The Condensed versions of the MedDRA Term Selection and Data Retrieval PtC documents are offered in all languages EXCEPT English and Japanese, which are updated and maintained as the full reference documents.
Please visit us at the
Drug Information Association
Annual Meetings

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

and the
MedDRA User Group Meetings

India User Group Meeting
Hyderabad, India
12 March 2019

European User Group Meeting
Prague, Czech Republic
10 April 2019

U.S. User Group Meeting
San Diego, California, USA
27 June 2019

China User Group Meeting
TBD

Be sure to check our Training Registration page for information on upcoming webinars and face-to-face training!

We want your feedback! Please contact us:

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