Messenger

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What's New for MedDRA Version 18.0

By Brian J. O'Hare
Terminology Maintenance Manager

MedDRA Version 18.0 was made available to MedDRA users on 1 March 2015 from the Downloads page on the MedDRA website**.**

MedDRA Version 18.0 is a complex change version which means that changes may be made at all levels of the MedDRA hierarchy. There were a total of 2,069 change requests processed for this version; 1,758 change requests were approved and implemented, and 280 change requests were not approved. There are, in addition, 31 change requests suspended for further consideration and resolution beyond this version. Below are highlights of Version 18.0 changes. Please see the What's New Document included with the Version 18.0 release package for details:

- A new HLGT *Product use issues* was added to SOC *Injury, poisoning and procedural complications* to group related product use concepts (medication errors, misuse, off label use, overdoses, and underdoses) in one location to facilitate coding and retrieval. This new HLGT contains four new HLTs – HLT *Product use issues NEC,* HLT *Overdoses NEC*, HLT *Underdoses NEC*, and HLT *Off label uses*.

- Four proactivity requests were implemented which resulted in the addition of new drug utilization, administration site, and pharmacogenomics terms. Additionally, twelve changes were made to more consistently represent the placement of concepts relating to the anatomy of the back with respect to bony structures or to nervous/soft tissues.

Two new level 1 SMQs were released into productionin MedDRA Version 18.0: *SMQ Respiratory failure and SMQ Tendinopathies and ligament disorders.* There are now 98 level 1 SMQs in production as of this version. Please see the MedDRA Version 18.0 SMQ Introductory Guide for more information about the new SMQs including their inclusion and exclusion criteria.

For more detailed information on MedDRA term additions and changes, users may wish to use the MedDRA Version Analysis Tool (MVAT) – https://mssotools.com/mvat – which is an online tool that compares any two MedDRA versions – including non-consecutive versions – to identify changes. The output of MVAT is similar to the Version Report. MVAT is free to MedDRA users as part of their subscription.

Number of Terms in MedDRA Version 18.0	
System Organ Classes (SOC)	26
High Level Group Terms (HLGT)	335
High Level Terms (HLT)	1,721
Preferred Terms (PT)	21,345
Lowest Level Terms (LLT)	52,884

The MSSO encourages MedDRA users to consider submitting change requests to help us maintain MedDRA as a rigorous terminology that is responsive to your needs. Change requests can be submitted to the MSSO via the online change request application WebCR – (https://mssotools.com/webcr).

MSSO Services Surveys

By Patrick Revelle
Director, MSSO

In September 2014 the MSSO sent a survey to all MSSO subscribing organizations and those individuals included on the MSSO's email distribution list. The goal of the survey was to collect feedback on all MSSO services. The MSSO routinely surveys users after training classes and meetings but it had been several years since users were surveyed on all MSSO services including change requests, MSSO events (e.g., User Group meetings, Blue Ribbon Panel meetings), Help Desk support, subscription processing, training, and software tools provided by the MSSO.

The overall results from the 187 responders to the survey are shown below:

Survey Question	Agree or Strongly Agree
I receive change request responses from the MSSO in a timely fashion.	91%
I receive satisfactory explanations from the MSSO on the outcome of change requests.	94%
The online change request submission application – WebCR – is easy to use.	91%
I am satisfied with the quality of the MSSO events.	98%
MSSO events inform me about MedDRA related issues.	97%
It is easy to register for MSSO events.	97%
The MSSO Help Desk answers my question in a helpful manner.	98%
The MSSO Help Desk responds to me in a timely fashion.	98%
I can easily request new and/or renewal subscriptions.	93%
The training (e.g., Face-to-face, webinar, videocast) that I received from the MSSO is of good quality.	99%
The MSSO instructors are knowledgeable.	99%
Registering for MSSO training is easy.	96%
I find the MSSO software tools (e.g., MVAT, Browsers) are of good quality.	97%
The MedDRA.org website provides a good experience.	93%
I find it easy to navigate the MedDRA.org website.	86%

The MSSO is pleased with the results but also sees areas for improvement. The MSSO plans to solicit input from users on MedDRA.org navigation improvements, interview frequent users on MVAT and WebCR for improvements or added features, and meet with system developers to discuss MedDRA user issues with their systems (e.g., no Secondary SOC outputs, SMQ implementation).

The MSSO thanks the survey responders for their feedback and we look forward to continuing to improve our services for MedDRA users worldwide.

ICH M1 Points to Consider Working Group Meeting

By Judy Harrison, MD
Chief Medical Officer

The MSSO participated in the ICH M1 Points to Consider (PtC) Working Group meeting at the European Medicines Agency in London on 10-12 November 2014. The Working Group discussed updates to the PtC documents for MedDRA Version 18.0 including the addition of preferred options for coding maternal exposures and medication errors without clinical consequences in the *MedDRA Term Selection: Points to Consider* document.

A major focus of the meeting was on the complex changes for MedDRA Version 18.0 (see also "What's New for MedDRA Version 18.0" in this edition of the Messenger). MedDRA users had requested changes to better organize the placement of product use concepts including medication errors, overdose and underdose, as well as misuse and off label use concepts. The PtC Working Group reviewed the proposals and collaborated with the MSSO to develop a new structure for these concepts which includes a new HLGT *Product use issues*. For detailed information, please see the What's New document in the MedDRA Version 18.0 release package. Revisions were made to the relevant sections *MedDRA Term Selection: Points to Consider* document to reflect the reorganization of product use concepts.

ICH M1 Points to Consider Working Group at EMA, November 2014
Mr. Tezuka is fourth from right, front row

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ICH M1 Points to Consider Working Group Meeting

The PtC Working Group and medication error experts from EMA, FDA, and Health Canada also continued to consult with the EU on its "Good Practice Guide for Recording, Coding, Reporting and Assessment of Medication Errors" and provided input on sections that reference the PtC documents. Please see the article on the Good Practice Guide in this edition of the Messenger for more details.

The PtC Working Group members wish to acknowledge the tremendous contribution of Mr. Reiji Tezuka of the Japanese Maintenance Organization (JMO) to the Group and to the support of MedDRA worldwide. Mr. Tezuka will be retiring from the JMO in March 2015. As a member of the original MedDRA Expert Working Group (M1) in 1995, Mr. Tezuka was involved in the creation of MedDRA as an international standardized medical terminology. He has been a member of the PtC WG since its inception in 1999 and has been instrumental in providing guidance to MedDRA users through the English and the Japanese translation of the PtC documents. All PtC Working Group members wish Mr.Tezuka a happy and well-deserved retirement.

The PtC documents for MedDRA Version 18.0 are available in English and Japanese and were posted on the MedDRA and JMO websites on 1 March 2015. There are also Summary of Changes documents which help users identify the changes between the latest versions of the documents and the previous ones. The PtC Working Group invites MedDRA users to provide feedback on the documents by sending an email to the MSSO Help Desk.

27th SOC to be Implemented in MedDRA Version 19.0

By Judy Harrison, MD
Chief Medical Officer

The ICH MedDRA Management Board has endorsed the creation of an additional (27th) System Organ Class in MedDRA. The 27th SOC (which is yet to be named) is being created to accommodate non-clinical/non-patient related concepts. These terms cover issues related to medical products which are important from regulatory and public health perspectives as they may affect patient safety.

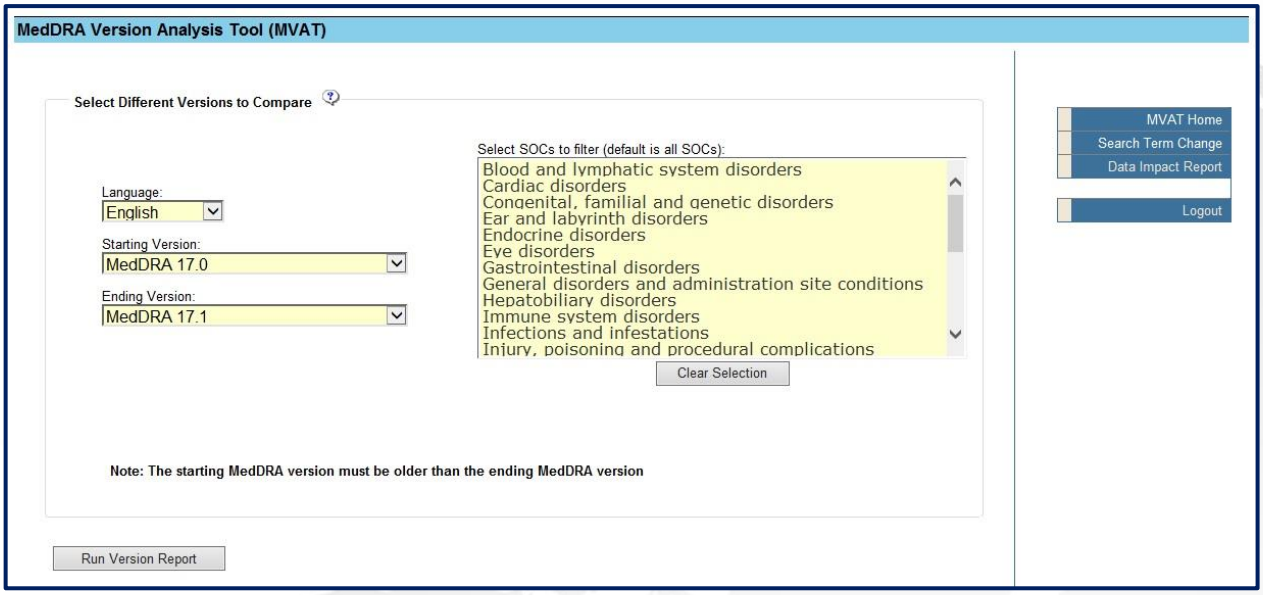
The 27th SOC will include product quality issue terms which are defined as abnormalities that may be introduced during the manufacturing/labeling, packaging, shipping, handling, or storage of medical products. The existing HLGT *Product quality issues* will be moved from SOC *General disorders and administration site conditions* to the new SOC and will be supplemented by new terms related specifically to the manufacturing process.

The 27th SOC is expected to be implemented in March 2016 in MedDRA Version 19.0. The MSSO will provide more detailed information on the 27th SOC through webinars, broadcast emails, and other communications, such as a dedicated web page on the MedDRA website well in advance of the planned implementation date in 2016. For questions on the 27th SOC, please contact the MSSO Help Desk.

MVAT Update Available in 2015

By Brian J. O'Hare
Terminology Maintenance Manager

The MSSO is currently working on an update to the MedDRA Version Analysis Tool (MVAT), which debuted in February of 2012. MVAT is a web-based tool designed to assist organizations by comparing any two versions of MedDRA – including non-consecutive versions – to identify changes.



MVAT is free to all MedDRA users as part of their subscription. The update will include the following enhancements.

- User interface available in all MedDRA languages
- Report output available in all MedDRA languages
- An improved history function
- An option to filter report output by SOC
- Improved report output related to MedDRA and SMQ changes

These updates are expected to be available by the spring of 2015. The MSSO will produce an updated videocast on how to use the MVAT, and will be holding webinars to explain the enhancements. For questions about the new MVAT, please contact the MSSO Help Desk.

Update on EU Medication Errors Good Practice Guide

By Judy Harrison, MD
Chief Medical Officer

The EU is developing a Good Practice Guide for Recording, Coding, Reporting and Assessment of Medication Errors covering pharmacovigilance obligations and good practice recommendations. During the course of 2014, the MSSO, the ICH M1 Points to Consider (PtC) Working Group, and medication error experts from EMA, the UK's National Health Service, FDA, and Health Canada have provided consultation in the development of sections that reference the PtC documents.

The Good Practice Guide underwent a round of consultation with the EU Member States in late 2014 followed by consultation with the European Commission's Patient Safety and Quality of Care Working Group (PSQCWG). A final draft will be produced after consultation with the EU regulatory network.

In the 2nd quarter of 2015, the final draft will be released for public consultation on the EMA website (News and Events/Public Consultations). It is expected that the Guide will be of interest to all MedDRA users involved with medication error pharmacovigilance activities and you are encouraged to submit your comments.

The Guide is projected to be finalized by the 4th quarter of 2015.

Further information can be found on the EMA website (Medication Errors).

New Web-Based MedDRA Browser Available

By Brian J. O'Hare
Terminology Maintenance Manager

The MSSO is pleased to announce that the new MedDRA Web-Based Browser (WBB) was launched on 1 December 2014. A MedDRA User ID and Password are required to use the application. The new WBB has similar features as the current MedDRA Desktop Browser plus a few new ones:

- Browse the MedDRA hierarchy and SMQs
- Search for MedDRA terms or codes and SMQs
- View multiple supported languages simultaneously
- Research Bin to collect terms for analysis and research purposes
- View term history
- View term detail information
- Export search results to a spreadsheet
- Support for unique features of the MedDRA Japanese translation

The WBB is free to all MedDRA users as part of a MedDRA subscription. Please view or download a videocast from the Training Materials section of the MedDRA website located under "Tools" to learn how to log in and use the WBB. Additionally, there is a user guide available. For questions about the new WBB, please contact the MSSO Help Desk.

We want your feedback! Please contact us:

Email: mssohelp@meddra.org
Website: www.meddra.org
Toll Free International: +1.877.258.8280
Direct: +1 703.556.2950
Fax: +1 703.556.1744

Please visit us at the Drug Information Association Annual Meetings

27th Annual EuroMeeting
Paris, France
13-15 April 2015

51st US DIA Annual Meeting
Washington, DC USA
14-18 June 2015

and the MedDRA User Group Meetings

MedDRA User Group Meetings

European MedDRA User Group
Paris, France
16 April 2015

Chinese User Group
Hangzhou, 310058 China
8 May 2015

US User Group
Washington, DC USA
18 June 2015