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MedDRA

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What's New for MedDRA Version 17.1

By Brian J. O'Hare
Terminology Maintenance Manager

MedDRA Version 17.1 was made available to MedDRA users on 1 September 2014 from the Downloads page on the MedDRA website**.**

MedDRA v17.1 is a simple change version which means that changes are made at the PT and LLT level only. There were a total of 1614 change requests processed for this version; 1214 change requests were approved and implemented, and 290 change requests were not approved. There are, in addition, 110 change requests suspended for further consideration and resolution beyond this version. Below are highlights of v17.1 changes. Please see the What's New Document included with the v17.1 release package for details:

- Promoting LLTs representing incarcerated, strangulated, and obstructive hernia terms (e.g., LLT *Incarcerated hernia* under PT *Hernia obstructive*) to PT level so that they are represented as medically distinct concepts.

- Changing the mapping of LLTs containing "pressure" to align them with PTs related to the concept of "discomfort," instead of "pain."

Two new level 1 SMQs were released into production in MedDRA v17.1: SMQ *Proteinuria* and SMQ *Tubulointerstitial diseases*. There are now 96 level 1 SMQs in production as of this version. Please see the MedDRA v17.1 SMQ Introductory Guide for more information about the new SMQs including their inclusion and exclusion criteria.

For more 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 17.1	
System Organ Classes (SOC)	26
High Level Group Terms (HLGT)	334
High Level Terms (HLT)	1720
Preferred Terms (PT)	20808
Lowest Level Terms (LLT)	73221

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 Maintains ISO 9001:2008 Certification

By Mike Burke
MSSO Quality Assurance Manager

The MedDRA MSSO is is pleased to announce that, effective 22 August 2014, it has successfully maintained its ISO 9001:2008 certification from BSi™, a quality management systems registrar. The MSSO achieved excellent results from a surveillance audit conducted 21-22 August 2014. The ISO 9001:2008 standard is an internationally recognized quality management system standard developed by the International Organization for Standardization (ISO).

To be certified to the standard, enterprises must implement a Quality Management System (QMS) encompassing the activities of the enterprise for controlled product planning, training on roles and responsibilities in the QMS, controlled development of products, controlled purchasing of materials and services, and controlled delivery of the products and services. Certification to ISO 9001:2008 reinforces to customers through an independent third-party that the MSSO operates a QMS in accordance with the standard. For example, the MSSO produces a release plan for each MedDRA Release; manages execution of the plan by monitoring and measurement through product and process verifications; and delivers the prescribed products on time with the correct resources.

Pat Revelle, MSSO Director, notes "We are extremely proud of our continuing certification to the ISO 9001:2008 standard. It demonstrates our commitment to MedDRA users that the MSSO is heavily engaged in continuing process improvement, world-class performance, and monitoring our terminology maintenance operations to ensure that we deliver on the commitments we make to our users, staff, and vendors."

The MSSO achieved its first certification to the ISO 9001:2000 standard on 14 November 2003. The MSSO achieved certification to the ISO 9001:2008 standard on 18 August 2009 and recertification on 31 August 2012. BSi will continue to conduct annual routine surveillance audits of the MSSOs business operations.

Blue Ribbon Panel 8 – Scope of MedDRA

By Judy Harrison, MD
Chief Medical Officer

The MSSO convened a Blue Ribbon Panel (BRP) meeting on 29 April 2014 at MedImmune's facilities in Gaithersburg, Maryland, USA. The purpose of this 8th BRP meeting was to discuss how the scope of MedDRA should be defined in its role as an international medical and regulatory terminology and how to address issues pertaining to the possible expansion of the terminology into new topic areas. Such issues included how to establish general criteria when considering potential areas for expansion (e.g., manufacturing product quality concepts and additional device-related concepts) and where new topic areas can be placed in MedDRA.

Panelists were: Barry Hammond (Terminologeze), Norbert Paeschke (BfArM), Stewart Geary (Eisai), Daisuke Sato (PMDA), Sonja Brajovic (FDA), and Lisa Lawrence-Miyasaki (Santen). Facilitators were Patrick Revelle and Judy Harrison of the MSSO.

Approximately 35 MedDRA users attended the meeting in person and had the opportunity to engage in discussions with the Panelists. For the first time for a BRP meeting, the MSSO provided a live webcast to approximately 80 individuals and groups worldwide, enabling them to view the proceedings. The webcast was welcomed by the MedDRA user community and the MSSO plans to use this approach for future meetings.

The Panel discussions yielded a set of recommendations which are summarized on the Blue Ribbon Panel 8 – Scope of MedDRA web page under "Documentation." At its recent meeting, the ICH MedDRA Management Board considered the Panel's recommendations and requested the MSSO to develop impact analyses, following which the Board will communicate its decisions to the MedDRA user community.

Blue Ribbon Panel 8

Patient Safety: Applying MedDRA in Pharmacovigilance

Swissmedic's experience switching from WHO-ART to MedDRA

By **Cordula Landgraf**
Head of Networking, Swissmedic

In September 2013, the Swissmedic Management Board adopted the decision to switch from WHO-ART to MedDRA. Within the following four months, all Swiss cases were analysed, mapped and recorded in close co-operation with the Uppsala Monitoring Centre (UMC). On 1 February 2014, all cases in the database VigiFlow were coded in MedDRA and Swissmedic staff started using the new terminology.

The use of an international standard greatly facilitates the exchange of data between Swissmedic and Marketing Authorisation Holders that were already using MedDRA terminology for some time. The cumbersome re-coding from WHO-ART to MedDRA and vice versa has become superfluous for both sides. Furthermore, the use of MedDRA provides for an easier processing of follow-up reports (FUPs). Additionally, on an international level, sharing of information and comparison of data is facilitated when using the same internationally accepted standard.

Thanks to an excellent co-operation with both the UMC and the MSSO (Maintenance and Support Services Organization) and the commitment by all parties involved, no problems were encountered in any phase of the project. First experiences reported by Swissmedic's reviewers and staff from the Regional Pharmacovigilance Centers (RPVC) in Switzerland are fully positive of the new terminology used as the ideal term can be found very rapidly when coding the report. This saves a great amount of time and allows for a much more efficient coding process.

It is expected that the quality of the cases can be enhanced thanks to more detailed coding possibilities and thus better detection of potential signals is envisioned.

The switch to MedDRA will provide the Agency with the optimal prerequisite to tackle future challenges like e.g. the increasing amount of ICSRs (Individual Case Safety Reports), a more proactive pharmacovigilance approach and last but not least, transparency and targeted communication of risks associated with the use of medicinal products.

Swissmedic Pharmacovigilance and IT staff. From left to right: Manuel Klaus, Martina Schaeublin, Guido Strack

Friend of MedDRA Award

By Anna Zhao-Wong, MD, PhD
Deputy Director

The 2014 Friend of MedDRA (FOM) was awarded to Dr. Catherine (Jun) Xie at the Chinese User Group meeting on 11 April 2014 in Chengdu, China. Dr. Xie is the Head of Product Safety Surveillance and Reporting for Pfizer in Shanghai.

When the MedDRA Chinese translation was first released in 2009, the concept of MedDRA was relatively new in China. As one of the pioneer MedDRA users in China, Catherine joined the Chinese MedDRA User Group (CMUG) and later became the secretary of the Group in 2011. She helps new members with their MedDRA questions and actively participates in group discussions via emails and teleconferences. She gave MedDRA presentations and led discussion at the MSSO face-to-face China MedDRA User Group Meetings. Catherine serves as the volunteer expert in neurology to assist the MSSO with questions regarding the MedDRA Chinese translation. She is a passionate supporter of the MSSO's free MedDRA training and offers logistical support for the face-to-face training sessions conducted in China.

The MSSO congratulates Catherine on receiving the FOM award.

Dr. Catherine Xie (left) receives the Friend of MedDRA award from Dr. Anna Zhao-Wong at the Chinese User Group meeting

Enhancing Translations at the LLT level

Due to language and culture differences, not every English LLT has a unique translation in other languages. For example, LLTs with British/American spelling and lexical variants (e.g., LLT *Haemorrhage* / LLT *Hemorrhage*, LLT *Back pain* / LLT *Pain back*) are often translated to the same term name. Additionally, synonymous LLTs may not have a unique translation in every language (e.g., LLT *Dry heaves* and LLT *Gagging* may not have different synonyms in the translated language.) For this reason, duplicate translations are permitted at the LLT level under the same PT for non-English languages.

This maintenance approach is not always optimal as it may reduce the number of terms in a translation. To enhance the MedDRA languages, the MedDRA Management Board has approved a modification of the translation maintenance rules to allow the use of language specific synonyms in place of duplicate translations where appropriate. See below for an example:

Code	English term	French term v17.0	French term v17.1
10063056	Faecal disimpaction	Désimpaction fécale	**Evacuation d'un fécalome**
10063058	Fecal disimpaction	Désimpaction fécale	Désimpaction fécale

These synonym translations must enhance the utility of the translation but retain the meaning of the original term. This enhancement has been applied proactively for many of the supported languages and will be part of any future translation review.

We want your feedback! Please contact us:

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New Free Face-to-Face Training Course: Getting Started with MedDRA

By Judy Harrison, MD
Chief Medical Oficer

Is your organization getting ready to implement MedDRA? You may have already seen the "Getting Started with MedDRA" videocast which provides an introduction to the terminology and covers basic implementation topics such as how to subscribe and how to obtain training and access other resources. The MSSO is pleased to announce that this "Getting Started with MedDRA" concept has now been expanded into a free, half-day, face-to-face training course.

This new addition to the MSSO's suite of face-to-face courses will be offered free of charge in locations around the world upon request. An experienced MedDRA instructor will provide a comprehensive overview of MedDRA and how to start using it effectively. The course is designed to be of interest to anyone involved with MedDRA including medical/clinical staff, clinical data managers, regulatory specialists, statisticians, programmers, and IT professionals.

Following an overview of the structure, scope and characteristics of MedDRA, practical implementation topics will be covered: downloading and installing MedDRA; versioning; procedures documentation and conventions; legacy data conversion; and IT considerations. As in all the MSSO's face-to-face courses, there will be a strong focus on interactive exercises and discussions, with ample opportunities to ask questions. Attendees will be able to engage in hands-on exercises with a MedDRA browser to learn about the applications of MedDRA in coding and data retrieval. Finally, there will be a summary of the many resources available to MedDRA users including further training opportunities, the MedDRA website, the Help Desk, and User Group meetings.

Please visit the Training section of the MedDRA website or contact the Help Desk for further information about the new "Getting Started with MedDRA" face-to-face course.

Drug Information Association (DIA) Meetings And MedDRA User Group Meetings

By Brian J. O'Hare
Terminology Maintenance Manager

The MSSO attends both the DIA EuroMeeting and the DIA Annual meeting in the US each year and often gives presentations on MedDRA-related topics at sessions and workshops. Attendance at the DIA provides the MSSO a way to connect with MedDRA users, understand their issues, and answer questions. If you attend either the EuroMeeting or Annual meeting, please stop by and see the MSSO at our booth in the exhibit hall.

Following both DIA meetings, the MSSO hosts a MedDRA User Group Meeting. These meetings provide an opportunity for MedDRA users to meet face-to-face and to discuss MedDRA related topics, to ask questions directly to the MSSO, and to share experiences with other users. In 2014, the MSSO conducted User Group meetings in Vienna, Austria (March), in Chengdu, China (April), and in San Diego, USA (June).

At the Vienna User Group meeting, presentation topics included text mining, medication errors, off label use, MedDRA in labeling and MedDRA versioning. On the agenda at the San Diego meeting were presentations on social media safety monitoring and investigator training to improve data quality. At the meeting in Chengdu, topics included practical experience in coding with the Chinese MedDRA translation and safety data management.

The MSSO encourages new and veteran MedDRA users alike to attend User Group meetings. Please visit the User Group section of the MedDRA website for information on past and future user group meetings, or contact the MSSO Help Desk at mssohelp@meddra.org. The MSSO hopes to see you at the next User Group meeting!

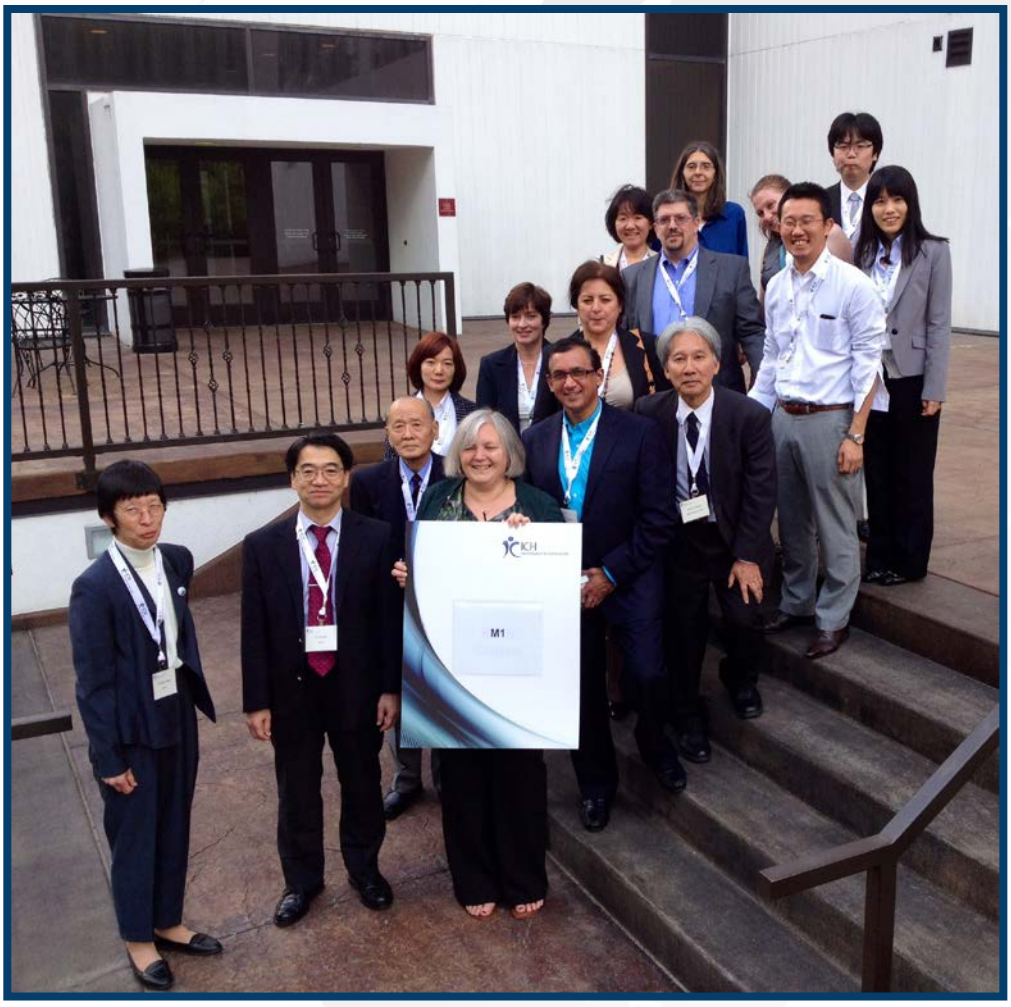
MSSO Staff at the DIA Annual Meeting in San Diego, June 2014. From left to right: Pat Revelle, MSSO Director; Dr. Judy Harrison, Chief Medical Officer; Dr. David Richardson, Medical Officer; Dr. Anna-Zhao-Wong, MSSO Deputy Director

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 in Minneapolis, USA on 2-5 June 2014. The Working Group discussed updates to the PtC documents for MedDRA Version 17.1 including changes to the Congenital Terms and Medication Monitoring Errors sections in the *MedDRA Term Selection: Points to Consider* document.

A major focus of the meeting was on medication errors since the EU is developing a Good Practice Guide on Coding and Reporting of Medication Errors and had requested the PtC Working Group's consultation in the development of sections that reference the PtC documents. Medication error experts from EMA, the UK's National Health Service, FDA, and Health Canada joined the meeting via teleconference and good progress was made on developing concept descriptions and examples of coding of medication errors.



ICH M1 Points to Consider Working Group Meeting

Further discussions are planned on medication errors and the related topics of misuse, abuse, overdoses, and off label use, and updated guidance and examples will be included in the MedDRA Version 18.0 release of the PtC documents in March 2015.

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ICH M1 Points to Consider Working Group Meeting

The PtC documents for MedDRA Version 17.1 are available in English and Japanese and were posted on the MedDRA and JMO websites on 1 September 2014. 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.

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

US Industry User Group
Newport Beach, CA USA
26 September 2014

European MedDRA User Group
Paris, France
16 April 2015

US User Group
Washington, DC USA
18 June 2015