

Published by MedDRA MSSO for our Users

September 2019

Special 20th Anniversary Edition

MedDRA has reached its 20-year anniversary and is a true international standard. The success of MedDRA is due to users of the terminology developing the content, driving the Maintenance and Support Services Organization to continue to extend support and services, and to the partnership with ICH and the MedDRA Management Committee. The following are a series of articles from current MedDRA Management Committee members offering their reflections on MedDRA's milestone achievement.

- Patrick Revelle, Director, MSSO

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Reflections on 20 Years of MedDRA

By: Claudia Lehmann
Boehringer-Ingelheim/EFPIA

When I started as a data manager in the pharmaceutical industry in the early 1990s, my first task was to review the coding of adverse events of several studies for a specific product and to compile product specific coding conventions to harmonize the coding and thus enable a meaningful analysis across studies. This included harmonizing the coding from different dictionaries into one and the definition of rules of how to code. This was an important step towards combined safety analyses based on good quality data. Some years later we reviewed the MedDRA terminology in a global working group across data management and pharmacovigilance and besides the easy transition, the most important point was the accompanying MedDRA Term Selection: Points to Consider (MTS:PTC) document, making all product specific coding conventions and their maintenance redundant. The advantages of a commonly accepted, known and used terminology were so apparent that after a short while, MedDRA was engraved in everyone's mind, no matter which role the colleagues had in the clinical development or pharmacovigilance processes. Data exchange with other companies or health authorities required no re-coding from a different terminology any more. And finally, the introduction of SMQs and their use also by regulators as well as market authorization holders ensured common and unbiased views on the data.

The introduction of MedDRA and the MTS:PTC document also enabled the set-up of central coding groups and –more recently - the use of machine learning and algorithms to augment automated coding. One thing though has never changed and will never change: coding is not a topic for specialty groups and tools only. The general understanding of the topic of coding, the value of coded data, the use of the data and the fundamental need to have good quality reported terms to achieve a reliable basis for analysis has to remain and has to constantly be re-enforced across all functions handling clinical data. No terminology or coding tool or artificial intelligence tool can replace the need for high quality data as the input for medical coding.

When I was given the opportunity to join the ICH MedDRA Management Board (now Committee) and also moved from Data Management to Pharmacovigilance I learned about the need for interoperability of terminologies for epidemiological studies and real-world data use. A lot of our discussions in the ICH MedDRA MC revolve around the need for enhancing global uptake of the terminology and what it takes to change the reporting of a whole country from one terminology to the other both on the side of the regulators and on the side of industry. The ICH MedDRA MC together with the MSSO have made it their mission to drive projects and worldwide training to ensure further uptake. The robust governance, maintenance and training process is an asset of MedDRA that might be rather unknown to the wider user community but is a crucial pillar in the success of MedDRA and its usage.

In summary, MedDRA is not just the provision of a terminology, but it has provided and will continue to provide major contributions to many process changes in the management and use of clinical data leading to higher quality and to a common “language” for the benefit of public health. ●



ICH MedDRA Management Committee, Amsterdam ICH meeting, June 2019. (Photo on ICH website - www.ich.org).

Congratulations on the 20th Anniversary From the Initial Release of MedDRA

By: Yo Tanaka
Chugai Pharmaceutical Co, Ltd/JPMA

Considering the development phase before its first release, MedDRA has a history of over a quarter of a century. The great achievements of those involved in the development phase, and the fact that 12 languages are continued to be maintained constantly at high quality every six months, and that MedDRA is rapidly spreading to all over the world beyond the initial ICH regions of Europe, US and Japan, MedDRA is now becoming as a true international standard terminology for pharmacovigilance activities.

We would like to express our utmost respect to the people who have accomplished the great work of MedDRA development and to the daily efforts of the MSSO and JMO.

In Japan, in addition to participating in the development of the MedDRA English version with ICH, we also created the MedDRA Japanese version (MedDRA/J). After translating MedDRA Version 1.0 into Japanese, repeated review was conducted with the cooperation of many Japanese doctors (including the MHLW research group). Then it was able to be released in March 1999 at the same time as the English version.

It must have been considerable work for the medical doctors and senior experts from industry who made efforts in a limited time to build MedDRA/J in parallel with the English version development with ICH.

Our JPMA's major contributions to MedDRA are: the initial translation of MedDRA Version 1.0 into Japanese; participation in the post-translation evaluation activities; and participation in the ICH M1 Points to Consider (PtC) Working Group to develop and maintain the PtC documents and translate them into Japanese working with the JMO.

Also, in order to better understand the MedDRA Term Selection: Points to Consider document, we drew up our own booklet "MedDRA/J Users' Guide; Term Selection Guide" (which is a supplemental description of points to use MedDRA/J for better understanding). Furthermore, we have worked to understand and disseminate the MedDRA Term Selection and MedDRA Data Retrieval and Presentation (PtC) documents, and SMQs through the MedDRA/J Taskforce with JMO for JMO users.

Moreover, it should also be remembered that JPMA fully supported providing a large amount of funds to establish JMO.

As a member of the MedDRA Management Committee, ICH M1 Points to Consider Working Group, and the Japanese Management Board (JMB) which supervises JMO, I have been involved in MedDRA issues for over 15 years since 2003.

The environment surrounding MedDRA has been changing significantly due to recent technological innovations, and it is expected that more useful information for using medicines more safely and effectively will be able to be provided soon by the use of artificial intelligence and integration of MedDRA data with those in terminologies other than MedDRA.

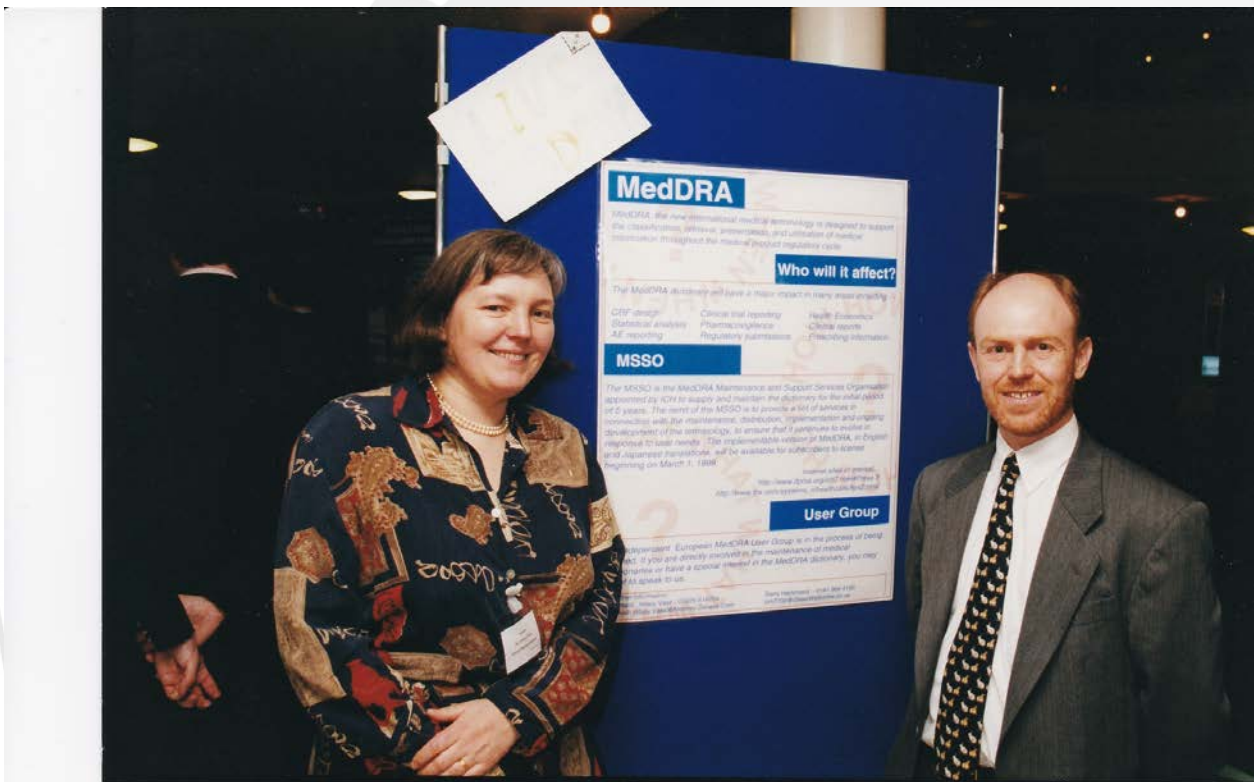
I would like to continue cooperating to extend MedDRA usage in such situations. ■■■

Industry Perspective of MedDRA's Impact on Drug Safety/ Pharmacovigilance

Dr. Christina Winter
GlaxoSmithKline/EFPIA

Prior to MedDRA, each company had their own postmarketing safety data and published literature for safety issues. No one knew how many reports a regulator may have on the same topic. Industry could request further information from the regulatory agency but the process was slow. When it was finally available, the data had to be manually assimilated.

MedDRA enabled electronic data exchange and, with databases using the same coding terminology, electronic safety signal detection is possible. With appropriate tools, industry can view the number of reports for the condition of interest in some regulators' databases and decide whether to proceed further. Further details can be obtained rapidly (e.g. case narratives may be obtained from the EU EudraVigilance database within 48 hours). This has revolutionised drug safety and enabled earlier identification of safety issues for the protection of patients.



Hilary Vass and Barry Hammond (former MedDRA Management Board members) at the Association for Clinical Data Management Annual Conference in the UK on 1 March 1999 when MedDRA was launched. The sign above the poster says "LIVE TODAY". (Photo provided by Hilary Vass).

MedDRA: From One Country via ICH to All Over the World

By: Dr. Daisuke Tanaka
MHLW/PMDA, Japan

MedDRA/J has been widely used in pharmaceutical regulatory activities in Japan due to the direction of the Ministry of Health, Labor and Welfare (MHLW). In Japan, MHLW recommends using MedDRA for the following:

- Data entry such as clinical trials, search, evaluation, and presentation for marketing authorisation application dossier
- Administrative reports such as adverse events reports, infectious diseases case reports, periodical benefit risk evaluation reports, etc.
- Transmission of adverse event information (package insert, etc.)

That was the situation when I first joined the MedDRA community as an MHLW alternative member on the ICH MedDRA Management Board (now Committee) several years ago. At that time, MedDRA had already expanded into the ICH member regions.

Due to human resources reshuffling in the Japanese Government, I stepped down and was away from MedDRA for a while, before joining the medicine safety team in the World Health Organization a few years later. I was happy that I had a second opportunity to work on the MedDRA Management Committee (MedDRA MC) as an observer from WHO. The MedDRA community gave me a heartfelt welcome back!

At that time, WHO decided to use MedDRA for the systems related to the WHO global Individual Case Safety Report (ICSR) database, VigiBase, which contains ICSRs submitted by the participating member states enrolled under the WHO Programme for International Drug Monitoring (WHO PIDM). Taking that opportunity, I had the pleasure to organise the first workshop to raise awareness of MedDRA for the member states of the WHO PIDM beyond ICH members, in collaboration with the MedDRA MC, MSSO and the WHO Collaborating Centre for International Drug Monitoring (Uppsala Monitoring Centre). On 6 November 2017, over 100 participants from over 30 countries arrived early in Kampala, Uganda to attend the preconference workshop on MedDRA, which was held back-to-back with the Annual Meeting of Representatives of the National Pharmacovigilance Centres participating in the WHO PIDM. (Ref. WHO Pharmaceuticals Newsletter No. 6, 2017 pages 21-22). I was really happy to be present at the scene of MedDRA becoming more global in its reach beyond ICH members.

From July 2019, I have fortunately come back again to the MedDRA community after working in a few divisions in MHLW. Seeing it from some different viewpoints, I am sure that MedDRA is vitally important for pharmaceutical regulation. In addition, I am of the opinion that JMO's contributions, especially to the high quality Japanese translation of MedDRA and support activities in Japan make it one of the pillars of pharmaceutical regulation in Japan. 🌐

20 Years of MedDRA: A Canadian Perspective

By: Heather Morrison
Health Canada, Canada

I remember hearing that MedDRA was to be a user-driven standardized terminology to assist with documentation and safety monitoring for medical products. At that point in time, I found that interesting but didn't anticipate the impact it would have on me and the organization I work for, Health Canada.

I started working with MedDRA in 1999 as one of the original members of the ICH M1 Points to Consider Working Group developing the MedDRA Term Selection: Points to Consider document. I remember thinking that it was progressive and very ambitious to create a document that would provide guidance on how to use the standardized terminology. It only made sense though, as otherwise the value of a standardized terminology was lost with people using inconsistently. In the early years, there were many modifications to the terminology to reflect changes recognized by the MSSO. Additionally, they incorporated submissions by users suggesting new terms to be added, identifying terms that could be better placed within the terminology, requesting expansion of the terminology to incorporate terms related to medication errors and product quality issues, and requesting the expansion of the languages in which the terminology is available. Keeping up with what users view the terminology should reflect and the quality of the terminology, in my view, have been two of the main reasons for the success of MedDRA. User needs continue to be responded to through the provision of the user training in many formats, the availability of multiple MedDRA browsers and tools, a presence on social media, and further expanding MedDRA's use by mapping to other terminologies.

One of the game changers for me and my function at Health Canada in pharmacovigilance was the development of the MedDRA Data Retrieval and Presentation: Points to Consider document, and the Standardised MedDRA Queries (SMQs). Gone were the days of figuring out what SOC/HLGT/HLT to use and remembering to include the uni-axial SOCs to develop search parameters for medical concepts and hoping they were in line with what other organizations were using for the same search. The introduction of SMQs was wonderful. It allows us to be certain the same search parameters were used to conduct searches when interacting with other organizations vs. hoping our query was similar to theirs. Again, standardization is the way to go - both for the input and extraction of information from a database. The use of MedDRA has also facilitated the electronic transmission of individual case safety reports to Health Canada by market authorization holders (manufacturers) directly into our database thus reducing the amount of manual data entry required for adverse reaction reports. The time-saving has been substantial and allows us to re-focus our resources on other activities, including surveillance.

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As a current member of the MedDRA Management Committee, I see firsthand how much work is done to ensure MedDRA continues to be an outstanding terminology that is responsive to user needs. The continued uptake of MedDRA demonstrates it is recognized as an invaluable tool by more and more organizations. I continue to use the terminology on a daily basis in the conduct of my work and I realize that what I had initially heard was indeed correct, MedDRA is a quality product and continues to be responsive to user needs - even 20 years later. 🎧



Heather Morrison presenting at the NMPA, China MedDRA Implementation Training in Beijing, China on 10 April 2018. (Photo provided by Anna Zhao-Wong)

20 Years of MedDRA: an EU Perspective

By: Dr. Sabine Brosch
EMA/EC, Europe

We are proud to see that MedDRA has become a success. It is a showcase for a strong international collaboration between medicines regulatory authorities, pharmaceutical industry and interested parties with a vision to create and maintain a robust medical terminology that can support drug regulatory activities from early development to approval as well as safety monitoring. Over the past two decades the terminology has continuously evolved based on an interactive user engagement with new areas being addressed e.g., medication errors or product issues. Guidance developed by medical experts of the ICH M1 Points to Consider Working Group has become core to a harmonised approach for data coding, retrieval and analysis as well as data quality. The medical and technical team of the MedDRA MSSO appointed by ICH has shown great dedication in maintaining MedDRA and its translations and provides the interface with the user community by delivering training, support and technology.

In the EU the development of an implementation strategy for MedDRA started in November 1999. The importance of data standardisation in the area of pharmacovigilance was identified at an early stage including the possibility of a phased approach to include other use cases such as communication of regulatory information. Challenges as regards the multilingual environment and delivering training to a large user community were addressed as part of the implementation strategy. At that time the importance of a clear message to the effect that the implementation of MedDRA in the EU would need to become mandatory within a defined timeframe was also agreed and reflected as part of the revision of the 2001 pharmaceutical legislation.

20 years later, MedDRA has proven to be a major accomplishment. The use of MedDRA is mandated in pharmaceutical legislation since 2004, MedDRA has been translated and is maintained in eight official EU languages, and thousands of users have completed MedDRA training. To date, almost 15 million Individual Case Safety Reports (ICSRs) have been submitted to EudraVigilance with medical information such as suspected adverse reactions, medical history, drug indications and test results coded in MedDRA. Data of more than 800,000 authorised medicinal products have been submitted to the European Medicines Agency with indications of use indexed in MedDRA and information on suspected adverse reactions presented by System Organ Class (SOC) and coded as MedDRA Preferred Terms (PT) in the Summary of Product Characteristics. Last year alone, more than 23 thousand data analysis reports on the safety of medicines coded in MedDRA were distributed to the EU network in support of evaluations and assessments carried out in pharmacovigilance procedures.

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Looking into the future, the evolution of MedDRA will continue. The MedDRA Management Committee has set numerous initiatives over the next five years to future-proof the terminology. This takes into account technology developments in the digital age, advances of the use of real-world data and evidence on the basis of physician and patient experience, and the need for interoperability with terminologies such as SNOMED CT and ICD. It also embraces the rollout of the terminology in China, Russia, the Republic of Korea, and other interested countries and efforts to manage translations, to delivery large scale user training and local support. We look forward to continue the successful international collaboration and engagement with an ever growing MedDRA user community with a view to meet business needs and to strengthen and protect public health. 🌐



A Score of Years for MedDRA and Me

By: Takahiro Goto
World Health Organization

When MedDRA was first released in March 1999, I was about to graduate from high school. I remember that I was thrilled that I would be studying pharmacy at a university in Japan and living in an apartment on my own, away from my family for the first time. Twenty years have passed, I am almost twice as old, and I have now been given a chance to join the MedDRA Management Committee (MedDRA MC) as an observer from WHO in 2018. I am honoured to have this position, to “observe” (and sometimes participate in) the animated discussions in the MedDRA MC biannual two-day meetings in multiple locations all over the world.

WHO's role in MedDRA is to support 194 WHO member states, especially low- and middle-income countries (LMICs), for the smooth transition from the WHO Adverse Reactions Terminology (WHO-ART) to MedDRA by organizing trainings and workshops in collaboration with the MSSO. I hope MedDRA will play a more important role in achieving patient safety in many more member states through harmonized coding of Individual Case Safety Reports (ICSRs). Also, last year, three milestones were marked in WHO: Three score and ten (70) years since the establishment of WHO; two score and ten (50) years of the WHO Programme for International Drug Monitoring (PIDM); and forty years of the WHO Collaborating Centre for International Drug Monitoring (the Uppsala Monitoring Centre, UMC). This year, I would like to congratulate MedDRA on its successful completion of twenty years. ●

Japanese Maintenance Organization (JMO) Overview

By: Hisaya Motojima
JMO

The JMO office is located in Shibuya which is one of the large lively downtown areas in Tokyo, and the globally famous crossing next to Shibuya St. is really accessible on foot. We launch all our highly quality products and provide various services for our MedDRA users in Japan under the ISO 9001 standard from this location.

What is new in our most recent ten years in business? We can focus on three main topics. First, we have provided some sophisticated original tools such as SMQ View for SMQ profiling and a MedDRA Tool for checking documents for correct citations of MedDRA terms. Secondly, an interactive discussion style training program has been introduced into our MedDRA Coding Course and we received high evaluations from JMO customers. Last is the Japanese translation of the Points to Consider Companion Document. Although medication errors might be out of scope for Japanese pharmacovigilance (PV) operations, we are sure that the document provides highly practical information to our globally oriented customers.

JMO has worked in collaboration with both ICH and the MSSO for the maintenance of MedDRA since the beginning of the ICH project. The Information Exchange Program between the MSSO and JMO is productive and enhances our mutual understanding of each organization's operations. We have participated in the MedDRA Management Committee, the ICH M1 Points to Consider Working Group, and the CIOMS SMQ Implementation Working Group in order to enhance the quality of MedDRA for not only Japan but for worldwide PV activities. We will continue to make a significant contribution to global MedDRA maintenance.



MedDRA User Group Meeting in Tokyo, Japan

Left to right: Ms. Ayumi Ochi, Ms. Haruka Higashi, Ms. Tomoko Narita, Mr. Kazuyuki Sekiguchi, and Dr. Mitsuru Takano of the JMO, Mr. Brian O'Hare of the MSSO, Dr. Miki Ota, PMDA, and Mr. Hisaya Motojima of the JMO (not pictured Dr. Yutaka Nagao, Director of the JMO)

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