MedDRA Evolution

MedDRA is an extensive and highly organised terminology that must be maintained with addition of terms as new medical knowledge grows. Under the governance of the ICH MedDRA Management Board, the MSSO has developed a strong maintenance process ensuring MedDRA integrity (logical structure and consistency) and that user needs are met. For more complex changes in scope or depth, the Board has supported the convening of advisory expert groups (called Blue Ribbon Panels).

The following are short descriptions of the main scope expansions and of a range of software tools developed by MSSO to support the use of MedDRA.

August 1999

Desktop Browser

The MedDRA Desktop Browser (MDB) was made available to MedDRA users in August 1999. This is a tool to browse and search MedDRA based on the files available on the user's computer. The MDB has been maintained and improved upon several times (e.g., all MedDRA versions and languages can be loaded).

March 2005

Medication Error Terms

In response to the regulatory need and with the active involvement of MedDRA subscribers and the MedDRA Management Board, the MSSO undertook the expansion of medication error hierarchy in Version 8.0 (March 2005). The medication error hierarchy was designed to facilitate the goal of accurately capturing various types of medication errors and ultimately preventing them to improve the quality of public healthcare.

March 2005

First SMQs in Use

The first two SMQs (Rhabdomyolysis/myopathy and Torsade de pointes/QT prolongation) were made available to MedDRA users with the release of MedDRA Version 8.0 (March 2005). With the release of MedDRA Version 8.0, the Change Request process for the maintenance of SMQs went into effect. Currently, there are approximately 100 SMQ topics available to users.

March 2006

Launched free face-to-face training for new users

To support new MedDRA users in gaining an understanding of MedDRA, the MSSO and the MedDRA Management Board (March 2006) decided to provide two basic face-to-face courses free of charge to new MedDRA users.

September 2006

Modified Terms

The MedDRA Management Board approved the Blue Ribbon Panel (BRP) recommendation in June 2004 on the addition of modifiers (e.g., acute, aggravated) to relevant MedDRA "base" terms. 266 modified terms were added (251 at the LLT level and 15 at the PT level) to MedDRA Version 9.1 (September 2006). The BRP members concluded that there is a need to accommodate terms with modifiers in MedDRA but not by a separate modifier data field. The impacts to coding practices, coding tools (e.g., autoencoders), existing MedDRA coded data, E2B and data analysis was considered to be too high compared to the benefit of implementing MedDRA modifiers. The MSSO also included new modifier concept descriptions to the MedDRA Introductory Guide.

March 2008

Device Patient Terms

With the release of MedDRA Version 11.0 (March 2008) the MSSO added a series of device patient adverse event terms. These terms were added to support the use of MedDRA for combination products (i.e., two or more separate products packaged together in a single package or as a unit and comprised of drug and device products, device and biological products, or biological and drug products). The terms added were unambiguous (i.e., most included the word "device" in their name) to ensure that new terms are clearly meant for combination products.

June 2008

Expanded the free face-to-face training to all users

In an effort to reach all MedDRA users, the MSSO and the MedDRA Management Board (June 2008) expanded the availability of free face-to-face courses from new users only to include all MedDRA users.

June 2008

WebCR tool 1.0

The Web-based Change Request Tool (WebCR) allows MedDRA users to submit change requests to MedDRA on-line. This initial version of this tool was launched in June 2008 and provided users the ability to request new terms and modify existing terms. Users can also search the history of all change requests submitted to the MSSO since MedDRA Version 5.1 (September 2002), resubmit a rejected request for reconsideration, and track the progress of submitted requests.

November 2008

Offered first free webinar

Continuing the practice of outreach to users, the MSSO (November 2008) offered the first free webinar, *Introduction to MedDRA Data Analysis and SMQs for Physicians*.

March 2009

Product Quality Terms

The US FDA proposed a set of product quality terms for inclusion into MedDRA so they can use a single coding system for both adverse events and product quality issues. The MedDRA Management Board approved the proposal to include the product quality terms for MedDRA Version 12.0 (March 2009). With the input from MedDRA Expert Panel, the MSSO medical team reviewed and processed the change requests of product quality terms. As a result, a number of product quality terms were added to MedDRA Version 12.0. A new HLGT Product quality issues was added to SOC *General disorders and administration site conditions*.

May 2009

CTCAE MedDRA Integration

The US National Cancer Institute (NCI) uses the Common Terminology Criteria for Adverse Events (CTCAE) as a terminology to describe adverse events for cancer clinical trials. Within the CTCAE a grading (severity) scale is provided for each term. With the release of CTCAE Version 4.0 (May 2009) MedDRA LLTs are used directly within the CTCAE terminology.

September 2009

Vaccine Terms

The MSSO, in collaboration with the CIOMS/WHO Working Group on Vaccine Pharmacovigilance, reviewed the published definitions of 22 adverse events following vaccination as developed by the Brighton Collaboration and proposed possible term additions to MedDRA to aid in vaccine pharmacovigilance. During the course of this review the MSSO identified new vaccine related terms that were implemented in MedDRA Version 12.1 (September 2009).

January 2010

Web-based Browser

The MedDRA web-based browser (WBB) was made available to MedDRA users in January 2010. This is a tool to browse and search MedDRA from a computer with an internet connection. The WBB is updated with each release of MedDRA and provides access to all MedDRA versions and languages.

March 2010

Device Hierarchy Changes

In MedDRA Version 13.0 (March 2010) the MSSO conducted a device related term review with the help of industry volunteers to enhance the hierarchical groupings of device related terms in MedDRA. New device related HLGTs and HLTs were added to SOC *General disorders and administration site conditions*.

March 2010

Microorganism Changes

The European Medicines Agency (EMA) proposed a set of microorganism terms to capture identification (by a test) of an organism when there is no documented infection. The MSSO worked with the EMA to harmonise the proposal within existing MedDRA rules and conventions and consulted with the MedDRA Expert Panel before implementing the new microorganism terms into SOC Investigations. As approved by the MedDRA Management Board, the MSSO added a total of 371 new PT and LLT terms and 194 existing terms were moved (e.g., demoted PTs, promoted LLTs, LLTs moving from one PT to another, etc.) in MedDRA Version 13.0 (March 2010).

September 2010

Toxic Chemical Terms

MedDRA was selected by the Alerting System for Chemical Health Threats (ASHT II) project, funded by the European Union Public Health Programme, for use in the Rapid Alert System for Chemical Incidence (RAS-CHEM). One of the ASHT II project goals is to incorporate a harmonised terminology of symptoms and syndromes to signal the possible release or exposure to toxic chemicals. MedDRA is used to improve information sharing, analysis and reporting of events between health professionals from poison centers and national public health officials.

The majority of concepts needed by the ASHT II project were already in MedDRA. In MedDRA Version 13.1 (September 2010) a few terms were added to MedDRA as well as a few term modifications to existing terms.

November 2010

Launched the first videocast

To further extend training formats, the MSSO offered the first videocast (i.e., recorded short topic). The first videocast was called *Primary System Organ Class (SOC) Allocation in MedDRA*.

July 2011

WebCR tool 2.0

The enhanced version was launched in July 2011 and adds support for Standardised MedDRA Queries (SMQs) and translation correction change requests. In addition, the user interface has been improved and several enhancements (e.g., improved change request history search, improved ability to view the results of submitted change requests) were made.

March 2012

Pharmacogenetic Terms

In MedDRA Version 14.1 (September 2011) the MSSO added an initial group of pharmacogenetic and pharmacogenomic terms (PTs and LLTs) to MedDRA. The criteria used to add these terms focused on those genetic concepts and factors that have a potential impact on drug therapy. In MedDRA Version 15.0 (March 2012), this initiative was completed with the addition of two new HLTs and the movement of some existing MedDRA terms under this new hierarchy.

September 2012

Versioning Tool

The MedDRA Version Analysis Tool (MVAT) was released in September 2012. The tool provides MedDRA users with the ability to view the differences between any two versions of MedDRA. Users can produce a full set of reports of all changes between selected MedDRA versions or a focused set of reports on terms identified by the user.

October 2012

Expanded videocasts in topics and languages

The MSSO produced additional videocasts including *MedDRA Structure and Scope, Introduction to the Points to Consider Documents, Getting started with MedDRA*, etc. In addition to English, the videocasts are also recorded in Chinese, French, German, and Spanish.

July 2013

Launch of New MedDRA Website

The MSSO is pleased to announce the launch of a new MedDRA website which introduces a refreshed and revitalised new visual identity for MedDRA, central to which is a new MedDRA logo. The new look and feel celebrates MedDRA as an ICH product and embodies aspects of ICH's own visual identity.

December 2014

New MedDRA Web-Based Browser (WBB)

The new MedDRA Web-Based Browser (WBB) was made available to MedDRA users in December 2014. This tool includes new features such as exporting search results, grouping of search results into categories for easier identification, the ability to view multiple supported languages simultaneously, and the ability to access the unique features of the MedDRA Japanese translation.

May 2015

Updated MedDRA Version Analysis Tool (MVAT)

The enhanced MVAT tool was launched in May 2015. The updated tool includes the option to change the user interface to any of the supported MedDRA languages, report output available in all supported MedDRA languages, an improved MedDRA term history output, the option to filter version report results by primary SOC, and improved report output related to SMQ changes.

October 2015

Updated MedDRA Desktop Browser (MDB)

The updated MDB was made available to MedDRA users in October 2015, with the following enhancements: user interface and functions more closely resembles the Web-Based Browser and can be displayed in all MedDRA languages, the primary SOC path is included in the export of search results and research bin content, and users have the ability to access the unique features of the MedDRA Japanese translation.

January 2016

MSSO European Help Desk

The MSSO has extended the hours of support from the MSSO Help Desk to respond to the growing number of users in the European time zones. As of this point in time, MedDRA is used by approximately 5,000 organizations in over 100 countries. The Help Desk responds to email or phone calls on all MedDRA related topics.

March 2016

Implementation of SOC *Product issues*

A new (27th) SOC *Product issues* was implemented in MedDRA Version 19.0. This SOC includes terms relevant for issues with product quality, devices, product manufacturing and quality systems, supply and distribution, and counterfeit products. One of the goals of incorporating product quality terms into MedDRA is to support the recording of product quality issues and any associated adverse

events using a single terminology. It is envisaged that the product quality terms, including those relating to manufacturing and distribution, may be used to report product defects to regulatory authorities and may also be used in organizations' internal databases to track and trend quality issues or deviations.

May 2016

Updated MedDRA Web-Based Browser (WBB)

The updated WBB was made available to MedDRA users in May 2016. This version includes the option to change the language interface to any of the currently supported MedDRA languages, multi-language term output in search results if selected, and hierarchy information is included in the export of search results and the research bin. These new features match the MedDRA Desktop Browser, which was deployed in October 2015.

November 2016

Unqualified Test Name Term List

The Unqualified Test Name Term List and an explanatory document were first made available on the MedDRA website in November 2016. The list is designed as an optional tool for MedDRA users to improve data quality by identifying the inappropriate use of unqualified test name terms in data fields other than the test name data element. It is a standardised, comprehensive list of all unqualified test name terms at the Preferred Term (PT) and Lowest Level Term (LLT) levels in SOC Investigations and is maintained and updated by the MSSO with each MedDRA release.

April 2017

Self-Service Application

The MSSO is pleased to announce that a new web-based tool called the MedDRA Self-Service Application, is now available to users. This application provides support to frequently asked Help Desk questions. The MSSO has developed a videocast that focuses on how to use this new application. The videocast is available for download or for direct viewing on the Training Materials page, under the Tools section.

March 2019

MedDRA in Russian

With the release of MedDRA Version 22.0, the Russian translation of MedDRA is available to all users. 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.

March 2019

20th Anniversary of MedDRA

With the release of MedDRA 22.0 in March 2019 the MSSO commemorated 20 years of MedDRA releases. The MSSO has produced a special edition of the MedDRA Messenger newsletter that included articles by members of the ICH MedDRA Management Committee offering their personal reflections on MedDRA in the past, present, and future.

April 2019

MedDRA Mobile Browser

The MedDRA Mobile Browser (MMB) was made available for use on iOS and Android mobile devices. The functions provided with this new tool are a subset of what is available in the existing MedDRA browsers (Desktop and Web-based) and was designed to have a similar look and feel to make uptake by users as easy as possible.

April 2019

New MSSO Local Support

The MedDRA Management Committee approved adding local support staff in Argentina, China, India, and Republic of Korea. The new staff was in place by April 2019. The local support staff significantly extended the MSSO's capabilities to provide support directly to users in more countries and in more languages. Local support staff provide training, respond to Help Desk inquiries, and support the use of MedDRA by regulatory authorities and other users.

September 2019

MedDRA in Korean

The MSSO provided the initial release of the Korean translation of MedDRA on 15 September 2019. The Korean translation includes all MedDRA terms and user documentation. The initial translation of MedDRA was developed by MFS, Republic of Korea and was reviewed and updated to MedDRA version 22.1 by the MSSO. MedDRA is now available in 13 languages.

October 2019

WebCR Update

The MSSO produced an update to the MedDRA Web-based Change Request tool (WebCR version) that allows MedDRA users to submit translation change requests using only their MedDRA ID and Password without requiring their Change Request ID (CRID). The change was made to allow more users to submit translation changes.

March 2020

MedDRA in Brazilian Portuguese

The MSSO provided the initial release of the Brazilian Portuguese translation of MedDRA on 15 March 2020. This Brazilian Portuguese translation includes all MedDRA terms and user documentation. The effort to produce the translation was a collaborative effort between ANVISA, Brazil and was reviewed and updated to MedDRA version 23.0 by the MSSO. MedDRA is now available in 14 languages.

April 2020

MedDRA Support for COVID-19

At the direction of the MedDRA Management Committee, the MSSO produced an updated version of MedDRA 23.0 in April 2020. This update included all of the changes from the original MedDRA 23.0 release in March 2020 and added or changed over 80 COVID-19 related terms. The MSSO provided additional support to MedDRA users (e.g., webinars, additional user documentation) to support the update.

April 2021

SNOMED CT – MedDRA Maps Available

This includes two independent maps (MedDRA to SNOMED CT and SNOMED CT to MedDRA) which were derived from frequently used and key pharmacovigilance MedDRA terms identified from the European Medicines Agency and the UK's Medicines & Healthcare products Regulatory Agency. The maps are intended to facilitate the exchange of data between regulatory databases (which use MedDRA) and healthcare databases/electronic health records (which use SNOMED CT).

April 2021

MapCR

Licensed users of either MedDRA or SNOMED CT may submit requests for new mappings or changes to existing mappings by using a mapping change request submission tool (MapCR). Updated maps are released each April based on the x.1 version from the previous year and the January release of SNOMED CT International Edition of the current year. Licensed MedDRA users can access the maps on the Downloads page of the MedDRA website.

September 2022

MedDRA in Swedish and Latvian

The MSSO provided the initial release of the Latvian and Swedish translations of MedDRA on 15 May 2022. The effort to produce these translations was a collaborative effort with State Agency of Medicines of the Republic of Latvia (SAMLV), Latvia and the MSSO and Swedish Medical Product Agency (MPA), Sweden and the MSSO. MedDRA is now available in 16 languages.

November 2022

MedDRA in Greek and Polish

The MSSO provided the initial release of the Greek and Polish translations of MedDRA on 15 November 2022. The effort to produce these translations was a collaborative effort with EOF, Greece and the MSSO and Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Poland and the MSSO. MedDRA is now available in 18 languages.