



MESSENGER

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What's new for Version 9.1

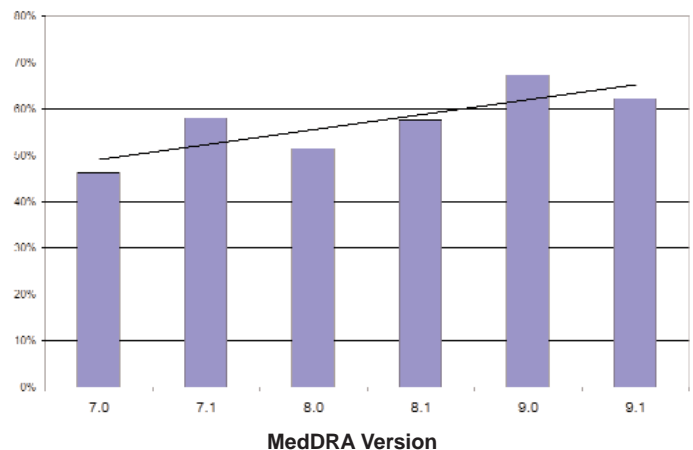
By Dr. M. Meinders and J. Sawyer

MedDRA Version 9.1 has its own unique character compared to prior releases. The number of change requests processed per version has been on a downward trend since Version 4.0 which was the largest release with 7,727 changes processed. The smallest release thus far was Version 8.1 with 1,615 change requests processed. But this trend may be changing.

Version 9.0, with 2,454 change requests processed, was the largest complex release (complex change versions are normally larger than the simple change versions) since Version 6.0. Similarly, Version 9.1 is the largest simple change release since Version 6.1. The MSSO will have to monitor several subsequent releases to determine if this is truly an increasing trend and if so, what factors are causing this increase.

The main factor that contributed to the increase in change requests in Version 9.1 was the addition of modified terms. The addition of modified terms was a recommendation of a Blue Ribbon Panel in 2004. The Panel's recommendation was to conduct a one time review of all previously rejected modified terms as well as query the user community for additional modified terms that were needed. This review resulted in 420 modified terms being processed, of which 266 were accepted. Of the accepted terms, 251 were placed at the LLT level and the remaining 15 terms at the PT level.

Percentage of Subscriber Change Requests Approved for MedDRA Versions 7.0-9.1



The MSSO has analyzed the rate of acceptance to rejection for subscriber requests from Version 7.0 through 9.1 and found that the overall percentage of acceptance has risen from 46% in Version 7.0 to 62% in Version 9.1. The MSSO will need to continue to monitor this emerging trend in order to determine the cause for this increase and further assess any possible impact it may have. However, it is possible that this increase is due to the growing subscriber community becoming increasingly familiar with MedDRA.

Number of terms for MedDRA Version 9.1

System Organ Classes (SOC)	26
High Level Group Terms (HLGT)	332
High Level Terms (HLT)	1,682
Preferred Terms (PT)	17,505
Lowest Level Terms (LLT) *	47,115

* LLT total includes unique LLTs only. For specific details on MedDRA Version 9.1, refer to the What's New document found in the MedDRA Version 9.1 release documentation (either on CD-ROM or via Internet File Download at www.meddramsso.com/translations/translationdownloads.htm).



MedDRA Concept Descriptions

New to Version 9.1 is a MedDRA concept descriptions appendix to the MedDRA Introductory Guide.

A concept description is a description of how a medical concept is interpreted, used, and classified within the MedDRA terminology. It is not intended as a medical definition. The concept descriptions are intended to aid the consistent and accurate use of MedDRA in coding, retrieval, and analysis.

The MSSO expects this appendix to grow as subscribers request additional concepts to be included.

For MedDRA Version 9.1, the MedDRA concept description appendix contains:

- Medication error concept descriptions developed by the MSSO in conjunction with the FDA to aid in the understanding and use of medication error terms.

- “Modifier” concept descriptions defined during the review of modified terms in Version 9.1 to assist the consistency of term evaluation and placement.

In the next release (MedDRA Version 10.0), concept descriptions in other parts of the MedDRA Introductory Guide will also be moved to this appendix, such as the use of “dilation” vs. “dilatation” and “drainage” vs. “discharge.”

Special Search Categories (SSC) Retirement Reminder

The MSSO would like to remind MedDRA subscribers of the retirement of Special Search Categories (SSC) in Version 10.0. This notice is intended to provide subscribers a sufficient time frame to make necessary changes to their MedDRA ASCII file loading software tools and related processes.

SSCs have been a complementary component of MedDRA since the initial release of Version 2.1, in March 1999. With the recent development and implementation of Standardised MedDRA Queries (SMQs) in MedDRA, however, the purpose of SSCs becomes subsumed.

In MedDRA Version 9.1, the SSCs received minimal maintenance (e.g., new PTs added in these versions considered towards inclusion in existing SSCs). However, please note that no more new SSCs will be developed.

The MSSO will discontinue the maintenance and distribution of SSCs as of MedDRA Version 10.0.

The MSSO expects the potential impact to subscribers to be on their

MedDRA ASCII file loading software tools. The MSSO intends to archive the existing SSC files and thus make the files still available on the subscriber section of the MSSO Web site.

Beginning with MedDRA Version 10.0, the SSC ASCII files (spec.asc and spec_pt.asc) will not be included in the set of MedDRA distribution files (Internet file download or CD-ROM).

MedDRA Version Update Reports

The MedDRA Version Update Reports are a series of reports presented in Microsoft® Excel® that are designed to identify the changes from one version of MedDRA to the next.

It should be noted that these reports do not replace the ASCII files as the official source of MedDRA terms and relationships that provide all of the details related to the latest version of MedDRA.

The most current MedDRA Version Reports summarizing changes made between MedDRA Version 9.1 and the previous MedDRA Version 9.0 may be accessed at: www.meddramssso.com/MSSOWeb/mssosubs/coresubs/version_reports.htm.

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ACKNOWLEDGEMENTS

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Making the Most of MedDRA Translations

By Dr. T. Moraleda

MedDRA is currently available in six European languages besides English; it is also available in Japanese.

The French and German translations of MedDRA have recently been completed to include the Lowest Level Term (LLT). Previously, they had only been translated down through the Preferred Term (PT) level.

This article describes the value of MedDRA translations to subscribers and suggests different ways that they may be used in practice.

How are different MedDRA translations currently used by regulatory authorities and by industry?

Some European regulatory authorities use the version of MedDRA in their official national language, and in many European countries, unlike the US, this is the main source of post-regulatory approval safety information (rather than coming from the industry).

Pharmacovigilance (PV) services in European Union (EU) countries are often organized in a regional structure, and it is in the PV departments of these regions where the coding of information takes place (e.g., an individual case safety report occurring in the Canary Islands will initially be coded by the regional PV department using a Spanish MedDRA translation before it is classified in Madrid and made ready for further distribution).

Industry utilizes MedDRA translations in various ways.

Some companies have a centralized coding system in which English is the reference language and the only task

for affiliates is to translate reported information from their local language to English.

A "conventional" dictionary can be used for this purpose, but so can MedDRA. One could enter the local language verbatim term into the translated MedDRA Browser application or an auto-encoding tool, retrieve the eight-digit MedDRA code for that term, and then enter this digit in a search tool for the English translation of MedDRA. This should provide the user with a reasonable translation of the original concept.

If this is not the case, a change request can be submitted to the MSSO for purposes of improving the translation. This method can also be used in conjunction with a "conventional" dictionary to provide a definition of the medical term.

There is also utility in using a MedDRA translation in instances in which coding is de-centralized, that is, where

affiliates perform coding.

During coding, the "best" or most appropriate MedDRA term can be directly selected using the local language. The term will be automatically translated into English through the common eight-digit MedDRA code. If a subscriber disagrees with the English translation of the local language term, a change request can also be submitted to the MSSO.

In summary, there are several uses of MedDRA translations. Subscribers are encouraged to explore on their own additional practical ways that MedDRA translations could be used and are encouraged to share those ideas with fellow MedDRA subscribers.

The MedDRA Forum (www.med-dramssso.com/MSSOWeb/mssosubs/BulletinBoard/default.asp) is a place where subscribers can freely share ideas on any number of topics.

Read Anything About MedDRA Lately?

By Dr. P. Mozzicato

The MSSO would like your help in collecting published literature articles that mention MedDRA.

The MSSO posts on its web site (www.meddramssso.com) a list of literature articles about MedDRA. We update the list monthly, if new articles are identified by us. However, if you have found a recently published article about MedDRA that isn't on our posted list, we'd appreciate it if you would share it with us. We'd be interested in any article that mentions MedDRA in the "Methodology" section or any other section of an article.

Please send information about literature you have found to the Help Desk at mssohelp@ngc.com.

The MSSO encourages MedDRA users to consider publishing articles on your experiences using MedDRA. Please keep in mind the proper way to cite MedDRA in publications (see "FAQs" on the MSSO Web site, or contact the Help Desk for more information, mssohelp@ngc.com).

WE WANT YOUR FEEDBACK!

PLEASE CONTACT US

TOLL FREE INTERNATIONAL 877-258-8280 (AT&T)

DIRECT: 703-345-7799 FAX: 703-345-7791

E-MAIL: MSSOHELP@NGC.COM

IF YOU WANT TO BE ADDED TO THE MAILING LIST, PLEASE VISIT THE WEBSITE WWW.MEDDRAMSSO.COM OR E-MAIL US.



A Change in the Development and Production of SMQs

By Dr. P. Mozzicato

“Phase II” refers to the time when pre-production Standardised MedDRA Queries (SMQs) were made available to MedDRA subscribers for initial database testing.

Based on these phase II testing results, SMQs were then re-evaluated (and sometimes changed) by the CIOMS Working Group for SMQs.

Following that step, SMQs were then authorized by the Management Board for production use. Once in production, the maintenance of SMQs is through the MISO’s change request process.

Recently, the MedDRA Management Board opted to merge the phase II subscriber testing period with the production release of SMQs. Elimination of phase II now puts SMQs into the hands of MedDRA users for production use after the CIOMS Working Group has completed its own testing phase (so called “phase I” testing).

Comments and feedback from the

user community on production SMQs will be reviewed by CIOMS SMQ development teams 18-24 months after the release of each SMQ. The 18-24 month review is an in depth review of all change requests related to the particular SMQ and will allow necessary modifications to be made based on

users’ input.

Note that SMQs will be put into production as part of scheduled MedDRA releases (i.e., 1 March and 1 September); SMQs will not be released into production between MedDRA releases.

In the first half of 2006, some SMQs had been posted for phase II testing.

The MISO welcomes your feedback on SMQs.

Please contact us at msohelp@ngc.com.

SMQ Phase II Posting Date	SMQs involved	Projected Production Date
March 2006	<i>Dementia (SMQ)</i>	March 2007 (MedDRA Version 10.0)
April 2006	<i>Adverse pregnancy outcome/reproductive toxicity (SMQ), Convulsions (SMQ), Embolic and thrombotic events (SMQ), Pseudomembranous colitis (SMQ).</i>	March 2007 (MedDRA Version 10.0)



Friends of MedDRA

The MISO has initiated an award to recognize “Friends of MedDRA” (FOM).

The award is presented to MedDRA users that have demonstrated a sustained level of support to MedDRA through active participation in MedDRA issues, helping the MISO resolve difficult issues, and being a resource for MedDRA experience to fellow subscribers.

The MISO was pleased to award the first two FOM medals to Dr. Philippe Thouvy (Hoffmann-La Roche) and JoAnn Medbery (Johnson & Johnson) at the two most recent User Group meetings in Paris and Philadelphia.

The MISO looks forward to acknowledging future MedDRA users.



MedDRA OPEN TRAINING

SEPTEMBER – DECEMBER 2006

The training schedule is periodically updated. Please access www.meddramsso.com for updates.

EUROPE

	FULL SCOPE	CODING WITH MedDRA	ADVANCED CODING	MedDRA: SAFETY DATA ANALYSIS & SMQs
SEPTEMBER	London, UK 26-27 September		London, UK 27 September	London, UK 28 September
OCTOBER		Madrid, Spain 4 October		Madrid, Spain 5 October
NOVEMBER	Frankfurt, Germany 1-2 November		Frankfurt, Germany 2 November	
DECEMBER		Utrecht, the Netherlands 5 December		Utrecht, the Netherlands 6 December

NORTH AMERICA

SEPTEMBER		Toronto, Canada 13 September	Toronto, Canada 14 September	Toronto, Canada 14-15 September
OCTOBER		San Diego, CA USA 3 October		San Diego, CA USA 4 October
NOVEMBER		Waltham, MA USA 1 November		Waltham, MA USA 2 November
DECEMBER	Orlando, FL USA 13-14 December		Orlando, FL USA 14 December	Orlando, FL USA 15 December

WEBINARS

<p>What's New in MedDRA 9.1 – 29 August Session One: 8:30AM - 10:00AM Session Two: 1:30PM - 3:00PM</p> <p>MedDRA for the IT Professional Date TBD</p>
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NEW SUBSCRIBER TRAINING SESSIONS

FALL 2006

London, UK – 25 September

Frankfurt, Germany – 31 October

Orlando, FL USA – 12 December

REGULATOR TRAINING SESSIONS

FALL 2006

London, UK – 22 September

Reston, VA USA – 27 September

Registration for all open sessions can be accomplished through the MSSO Web site
www.meddramsso.com AT&T toll free number: (877) 258-8280



MedDRA Course Descriptions

ADVANCED CODING: CODING CONVENTIONS AND THE MedDRA “POINTS TO CONSIDER” DOCUMENT (1/2-DAY SESSION)

This half-day course provides experienced MedDRA users with a basis for understanding the importance and utility of coding conventions as they pertain to the conversion of legacy data to MedDRA and for new data received post-conversion. Participants will be given a thorough overview of the MedDRA Term Selection: Points to Consider document and will see examples of challenging verbatim terms to code by applying the principles described in the document. Finally, participants will take a final ‘test’ to assess their knowledge and understanding of what had been presented in the course.

CODING WITH MedDRA (1-DAY SESSION)

In addition to lecture instruction providing a basic understanding of the scope, structure, and rules of MedDRA, trainees receive ‘hands-on’ experience coding challenging verbatim terms to demonstrate their knowledge of MedDRA’s structure and rules.

MedDRA: SAFETY DATA ANALYSIS AND SMQs (1-DAY SESSION)

Combines the materials of two former MedDRA courses, “MedDRA: Interpreting Data and Query Development” and “Standardised MedDRA Queries (SMQs) Primer,” into a full-day class designed to provide an overview of the features of MedDRA that relate to the analysis and retrieval of MedDRA encoded data.

THE FULL SCOPE OF MedDRA (1 1/2-DAY SESSION)

Provides a basic understanding of the scope, structure, and rules of MedDRA, reviews the System Organ Classes that are unique to MedDRA, and explains how MedDRA was developed. With electronic regulatory submissions now in place, it is imperative for your organization to understand the rules, usage, and practices of the only international, clinically validated, maintained medical terminology for biopharmaceutical regulatory purposes. The course illustrates coding examples as they pertain to the scope of MedDRA, the differences between older coding terminologies and MedDRA, tools that support coding, and a hands-on approach to coding verbatims and narratives with MedDRA.

Webinar Training Topics

MedDRA FOR THE IT PROFESSIONAL (WEBINAR PRESENTATION IN TWO 2-HOUR SESSIONS)

MedDRA will soon become a regulatory requirement. Most organizations are taking advantage of the time now to develop a MedDRA implementation strategy. The IT systems provide the

infrastructure for this process. MedDRA for the IT Professional covers MedDRA implementation issues from the IT perspective and identifies the key points to consider for existing or new systems, data issues, MSSO interaction, and electronic submissions.

WHAT’S NEW IN MedDRA (WEBINAR PRESENTATION IN ONE 1 1/2-HOUR SESSION)

The MSSO periodically schedules webinars to provide information on changes incorporated into new version releases.

On-Site MedDRA Training

All of the above listed topics are available for on-site presentation.

Training Module Available for Download

DATA QUALITY, CODING AND MEDDRA TRAINING MODULE (FREE OF CHARGE — SUBSCRIBER LOG-IN REQUIRED)

This course provides a general discussion of the importance of collecting quality data and the role of MedDRA. The target audiences are investigators, study coordinators, and pharmaceutical company and CRO personnel includ-

ing physicians, CRAs, safety officers, statisticians, programmers, and data managers. The presentation has a ‘place holder’ slide for subscribers to customize the course with their own company-specific data collection and reporting conventions. This feature can be a very useful adjunct for investigator training.

New Subscriber Sessions

The MedDRA MSSO offers free training for New, Basic, Core 0 and Core 1 subscribers. Eligible organizations receive two training credits which can be used to attend specific new subscriber training sessions.

Regulator Sessions

The MedDRA MSSO offers free training to regulators. Regulators receive two training credits per year.

Course descriptions may be found at www.meddramsso.com