



MESSENGER

Published quarterly by MedDRA® MSSO for our subscribers

What's new for MedDRA Version 7.0

By **Marvin Meinders**
Terminology Maintenance Manager

We'd like to provide our users with a short overview on upcoming events in the Version 7.0 release, scheduled for distribution on March 1, 2004.

The initiatives within Version 7.0 can be divided into two categories:

BUSINESS AS USUAL

It's a continuation of work performed during the Version 6.1 release. In addition to normal subscriber change requests, the MSSO will continue to process changes directed by the MedDRA Management Board. These include:

1. Continuation of the British and American English term representation reviews. This ensures that for every British or American English spelled term, there is an appropriate representation of the alternative spelling. This review is estimated to result in approximately 150 change requests to the database.

2. Continuation of the Modified Term review in order to determine whether the presence of the modifier separates medical concepts from the

base term. Approximately 291 terms will be reviewed, most of which are not expected to generate change requests in MedDRA. The modified terms to be reviewed during Version 7.0 include: Secondary, Recurrent, Traumatic, Accidental, Related, Increased (non Investi-

gation), and Decreased (non Investigation).

NEW RELEASE ITEMS

1. Recommendations by a panel that met in May are under review for adoption by the MedDRA Management Board. Although many issues were discussed, the focus of the panel was on the level of detail for terms in the Investigation SOC. Once a decision is made by the Management Board, approximately 129 Investigation SOC terms, currently suspended, will be resolved via the normal change request process.

2. Recommended complex changes for Version 7.0 will be finalized and implemented. The initial proposed complex changes were posted on the MSSO website in April for a 60-day period for subscriber comments. The information was then updated and posted for an additional 60-day comment period. Subsequently, these changes will be analyzed for impact, implemented, and will begin to be included in the supplemental change postings on the MSSO website in October or November.

As always, the MSSO's overall goal is to minimize the impact of changes to MedDRA while continuing to respond to subscriber needs.

MedDRA International User Group Meeting Osaka, Japan

OSAKA INTERNATIONAL
CONVENTION CENTER
12 NOVEMBER 2003
0900 -1200

In conjunction with ICH-6

check

www.meddramssso.com
for information regarding
the User Group meetings.



Sequential files: a helpful versioning tool

By Pat Revelle
Director
Products and Services

One of the frequent topics for discussions at the MedDRA User Group meetings and in MedDRA meetings in general is that of addressing MedDRA versions.

The issue is typically how to identify and if needed, to update existing data with the latest version of MedDRA. This article will address the first step in the process which is to identify the changes in the latest version of MedDRA.

To help with this process, the MSSO produces what are called sequential files. These files provide the detail of the changes (e.g., added terms, modified terms) for a specific version based on the previous version in a computer readable format.

For instance, when the MSSO released MedDRA 6.1 on September 2, 2003, we included a directory on the CD-ROM entitled SeqAscii. This directory includes 12 ASCII text files with a ".seq" suffix. These files correspond in name to the standard complete MedDRA version files found in the MedAscii directory and identify the change between MedDRA 6.0 and the new version — MedDRA 6.1. For example, the "llt.seq" files address the changes to the LLT level between version 6.0 and 6.1.

All MedDRA data files, including the sequential files, are ASCII text files. "ASCII" stands for American Standard Code for Information Interchange; this is the most common format for text files in computers and on the Internet. In an ASCII file, each alphabetic, numeric, or special character is represented with a 7-bit binary number (a string of seven 0s or 1s) that can be viewed with simple desktop tools like Notepad.

The sequential files only contain the changes in the current version from the previous version. By using the sequential files, an organization can produce a report that will list all of the terms that were added (e.g., new LLTs, new PTs) in a specific version, identify any changes to existing terms (e.g., LLTs that become non-current, changes in primary SOC for a particular PT) and identify promotions (e.g., LLT to PT) and demotions (e.g., PT to LLT) of terms.

The set of sequential files always consists of 12 files regardless of the number or type of changes from the previous to the current version.

For example, the SOC.seq file is included in the listing but is usually an empty file (0 bytes in length) because sequential changes to SOCs are very rare. Each sequential file is structured very similarly to the complete version file format with two additional data fields. The two additional fields consist of a date field (the MedDRA release

date, day/month/year) and an action code that identifies the type of change (A = Add, M = Modify, D = Delete).

Please note that the "delete" type of change is relative to the file in which the term was included in the previous version. For example, if a PT in MedDRA 6.0 is demoted in MedDRA 6.1 to an LLT, the PT will be listed in the PT.seq file (for this version of the sequential files) but with the action code of "D" for "delete." As with the complete version of MedDRA, the data fields in the sequential files are separated with a "\$."

The MSSO strongly recommends that organizations utilize the sequential files to clearly identify the changes from version to version and their potential impacts to MedDRA coded data.

Since the number of changes is still relatively large, the MSSO also encourages organizations to download the supplemental changes from the MSSO core website on a regular basis to break the task of identifying the changes into smaller, more easily reviewed sets of data.

The sequential files represent the collection of supplemental changes released between MedDRA versions. For more detailed information on the format of the sequential files, refer to the MedDRA Consecutive File Documentation (Conseq.pdf) on the MedDRA distribution CD-ROM.

SMQs scheduled for release

By Patricia Mozzicato, M.D., U.S. Medical Officer, MSSO

The first set of four Standardised MedDRA Queries (SMQs), jointly developed by CIOMS and the MSSO, had been initially scheduled for release with version 6.1 of MedDRA.

The MedDRA Management Board, at its July 2003 meeting in Brussels, decided that the distribution of the first four SMQs for user testing will be authorized following the Board's review of the development procedures, validation methodology and initial testing results in the three ICH regions.

As of this date, this review has not been completed. Thus, the SMQs will not be released with version 6.1; a new release date for the initial set of SMQs has not been scheduled. Please continue to monitor our website (www.meddrassso.com) for developments and updates on SMQs.

MedDRA® MSSO
VAR1/11B/MSSO
12011 Sunset Hills Road
Reston, VA 20190-3285
USA

TOLL FREE INTERNATIONAL
877.258.8280 (AT&T)

DIRECT
703.345.7799 (USA)

FAX
703.345.7791 (USA)

MSSO-DI-7110-6.0.0



Register for all open sessions on the MSSO web site:
www.meddramsso.com

MSSO Training Advantages

The MSSO provides expert MedDRA training to members of the pharmaceutical industry. MSSO instructors have an extensive industry and MedDRA background.

In addition to this expertise, the MSSO offers continuing education credits to recipients of MedDRA training.

Check out the MSSO website for specific information about CEUs for each course:

www.meddramsso.com.

Up-to-date MedDRA Training

MedDRA training materials are periodically updated to remain current with the latest version of MedDRA. Course materials will reflect the latest MedDRA updates.

On-Site Training

In addition to the open enrollment training chart above, the MSSO provides enterprise-wide and individual training courses at your company's location.

Percentage discounts apply. Please contact the MSSO for more information.

OCTOBER – DECEMBER 2003 SCHEDULE

Listed below are the currently scheduled MSSO classes. The training schedule is periodically updated. Please access www.meddramsso.com for updated information. For your convenience and quick reference, course descriptions are provided.

EUROPE

<u>CLASS</u>	<u>LOCATION</u>	<u>DATES</u>
Full Scope of MedDRA	Milan, Italy	21-22 October 2003
Advanced Coding	Paris, France	12 November 2003
MedDRA: Interpreting Data and Query Development	Paris, France	12 November 2003
MedDRA Fundamentals & Coding Principles	Lisbon, Portugal	2 December 2003
Advanced Coding	Lisbon, Portugal	3 December 2003
MedDRA: Interpreting Data and Query Development	Lisbon, Portugal	3 December 2003

UNITED STATES

MedDRA for CRAs and Study Coordinators	Washington Metro Area	28 October 2003
MedDRA Fundamentals & Coding Principles	Washington Metro Area	29 October 2003
Advanced Coding	Washington Metro Area	30 October 2003
Full Scope of MedDRA	Orlando, FL	5-6 November 2003
MedDRA for CRAs and Study Coordinators	Washington Metro Area	18 November 2003
MedDRA Fundamentals & Coding Principles	Washington Metro Area	19 November 2003
Advanced Coding	Washington Metro Area	20 November 2003
Full Scope of MedDRA	Phoenix, AZ	3-4 December 2003
MedDRA for CRAs and Study Coordinators	Washington Metro Area	9 December 2003
MedDRA Fundamentals & Coding Principles	Washington Metro Area	10 December 2003
Introduction to MedDRA	Washington Metro Area	10 December 2003
Advanced Coding	Washington Metro Area	11 December 2003
MedDRA: Interpreting Data and Query Development	Washington Metro Area	11 December 2003
MedDRA for the IT Professional	Washington Metro Area	12 December 2003

Course descriptions are on the website
www.meddramsso.com



MedDRA Forums debut for subscribers

Eric Lindamood
Manager of Products and Services

In response to subscriber requests, the MSSO debuted MedDRA Forums in July on the MedDRA MSSO website.

These message boards provide another means of exchanging information and ideas, and discussing solutions with the MedDRA community.

Any subscriber can post a reply or initiate a discussion on the Forums. Users must register to reply or post, but

can view the discussion without registering.

The MedDRA Forums can be found on the MedDRA MSSO website at www.meddramsso.com/newwebaug2001/meddramsso/coresubs/BulletinBoard/. Any core subscriber can view the topics and messages.

A registration is required to participate in the discussion. To register, enter a valid e-mail address, user name and password. Other information, such as geographical location, organization, and job title can be optionally included

in your profile.

Once you are logged in, there are several options available. You can edit your profile, or look at the profiles of other members. You can search the messages by keywords, forum, dates, and member. New posts are highlighted, as are posts that have generated more than 20 replies.

Current topics on the MedDRA Forums include “**ICD-10CM and MedDRA**,” “**Updating clinical trial data with new MedDRA versions**,” “**Social Circumstances and AEs**,” and “**Coding Secondary SOC**,” among others. More than 40 users are currently viewing and discussing topics on the Forums. MSSO staff will also participate in and monitor the discussions.

A recent discussion on “**Updating clinical trial data new MedDRA versions**” included posts from medical coders, other industry experts, and MSSO staff on the updating of clinical trial data with new versions of MedDRA. Participants in the discussion topic exchanged views on a variety of different approaches to the versioning problem. The message thread included comments on updating synonym tables, the structure of coded data in the database, and the use of autoencoding tools.

This topic and many others are being actively discussed on the MedDRA Forums. The MSSO encourages all subscribers to logon and participate in the Forums.

New subscription rates for 2004

There will be a 3% price increase from 2003 pricing. The pricing is effective for MedDRA subscription renewals due January 1, 2004, through December 31, 2004. The pricing for each category of MedDRA is as follows:

MedDRA annual subscription rates

Basic Service	\$3,278 USD
System Developer	\$5,465 USD
Core Service	
Core Service 0 (Annual Revenue <\$1 Million)	\$3,713 USD
Core Service 1 (Annual Revenue \$1-\$10 Million)	\$7,649 USD
Core Service 2 (Annual Revenue \$10-\$500 Million)	\$13,113 USD
Core Service 3 (Annual Revenue \$500-\$1 Billion)	\$25,133 USD
Core Service 4 (Annual Revenue \$1-\$5 Billion)	\$67,750 USD
Core Service 5 (Annual Revenue >\$5 Billion)	\$89,604 USD

WE WANT YOUR FEEDBACK!

PLEASE CONTACT US

TOLL FREE INTERNATIONAL

877-258-8280 (AT&T)

DIRECT: 703-345-7799

FAX: 703-345-7791

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

ACKNOWLEDGEMENTS

MedDRA® is a registered trademark of the International Federation of Pharmaceutical Manufacturers Associations.