



# MESSENGER

Published by MedDRA MSSO for our Subscribers

## What's New for Version 11.0

By Jim Mundell  
Manager, Terminology Maintenance

**M**edDRA Version 11.0 was made available to subscribers on 1 March from the MSSO Web site [www.meddramsso.com](http://www.meddramsso.com). This version is classified as a complex release which means that MedDRA hierarchy change requests, in addition to the regular LLT and PT level change requests, were processed. A total of three new SMQs were released into production in MedDRA Version 11.0. There are now 58 SMQs in production as of this version.

Most of the complex changes implemented in this version are the result of recommendations coming out of the fifth Blue Ribbon Panel (BRP) held in November 2006. The BRP recommendation was to assist data analysis by eliminating multi-axiality at the HLT level in the primary SOC view. This was done by adding five new HLTs and relinking all impacted PTs appropriately. In this process, seven HLTs were deleted and replaced by the new HLTs.

Injury and damage concepts were discussed by a MedDRA Expert Panel which resulted in new guidelines for MedDRA. Based on this, injury and damage terms in MedDRA will now be considered generally as synonymous. Injury or damage to a major organ that has a low probability for a traumatic causality will be placed primary to the site of manifestation, unless causality "due to accident" is the more obvious or the most probable. In this case, the term will be linked primarily to SOC *Injury, poisoning and procedural complications*. Following this guidance some liver injury terms were realigned. PT *Cholestatic liver injury*, PT *Mixed liver injury*, and PT *Liver injury* are considered non-traumatic and are primarily linked to SOC *Hepatobiliary disorders* while PT *Traumatic liver injury* is primarily linked to SOC *Injury, poisoning and procedural complications*.

A review of pregnancy and injury terms in Version 11.0, based on Points to Consider Working Group change requests, resulted in terms involving fetal exposure to drugs and other substances (e.g., tobacco) in MedDRA to be linked primarily to SOC *Injury, poisoning and procedural complications*, with a secondary link to SOC *Pregnancy, puerperium and perinatal conditions*. Terms directly attributable to birth trauma events however are primarily linked to SOC *Pregnancy, puerperium and perinatal conditions*.

### Number of terms: MedDRA Version 11.0

System Organ Classes (SOC)	26
High Level Group Terms (HLGT)	332
High Level Terms (HLT)	1,688
Preferred Terms (PT)	18,075
Lowest Level Terms (LLT)	66,135

For specific details on MedDRA Version 11.0, refer to the What's New document found in the MedDRA Version 11.0 release documentation (Internet File Download at [www.meddramsso.com/translations/translationdownloads.htm](http://www.meddramsso.com/translations/translationdownloads.htm)).

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# The MedDRA MSSO Announces WebCR

By Jim Mundell

**W**ebCR is a web based tool for creating, reviewing, and submitting MedDRA change requests (CRs). This tool, in addition to providing the means of entering your CR information, provides additional functionality that the MSSO feels will be of interest:

- A requester can set up multiple profiles

A subscriber may need to work on more than one set of CRs at a time. Multiple profiles will provide the means for a subscriber to allocate the work of CR preparation. The profiles can be provided as needed to reviewers in your organization to allow them online access and to review the proposed CR prior to submission to the MSSO.

- There is a direct tie-in to the most current supplemental version of MedDRA

WebCR data tables will be refreshed with each new supplemental update to MedDRA. This enables the tool to inform the user, while they are creating a CR to add a new term, if that term has already been added. When they request to move an LLT, the current PT for the LLT will automatically be displayed. This is not only a time saver, but it can also be informative when someone else has already requested the LLT moved since the last MedDRA version.

- Users can view unsubmitted batches of CRs

CRs in unsubmitted batches can be modified at any time until they are submitted. WebCR allows users to input multiple CRs over any time period prior to submission to the MSSO.

- Users can query the status of submitted batches: This tool improves the transparency between the MSSO's change request process and MedDRA batches.

- While entering a MedDRA term, WebCR will query MedDRA terminology based on the level being entered (LLT, PT, etc.) along with key words the user types in, to provide a pick list of terms to simplify data entry when possible.

- A MedDRA term search is also provided to find MedDRA terms to complete CR data entry.

- Access to change request history

This feature allows a user to search the MSSO Change Request repository going back to MedDRA Version 5.1 for CRs. This can be helpful to see if the term you want to add to MedDRA has already be requested before and if it was rejected. A user can also find CRs that move a term multiple times over multiple MedDRA versions.

- WebCR provides warnings and error messages during the CR creation process to point out problems or potential problems.

The MSSO enlisted volunteers to review and provide feedback on the WebCR prototype. The MSSO is now implementing the subscriber recommendations and plans to make WebCR available by mid-2008.

**WE WANT YOUR FEEDBACK!**

**PLEASE CONTACT US**

**TOLL FREE INTERNATIONAL 877-258-8280 (AT&T)  
DIRECT: 703 272-5505 (USA) FAX: 703-272-5635 (USA)**

**EMAIL: [MSSOHELP@NGC.COM](mailto:MSSOHELP@NGC.COM)**

**WEB SITE: [WWW.MEDDRAMSSO.COM](http://WWW.MEDDRAMSSO.COM)**



# MedDRA MSSO 2008 Subscription Rates

By Kathy Leonardo

**A**s previously announced, the MedDRA Management Board approved the MSSO's proposed subscription rates for 2008, and with a rapidly growing subscriber base, the cost of maintaining MedDRA continues to be shared across a larger number of subscribers. Consequently, for the third consecutive year there will be a significant reduction for lower revenue subscribers and no increases to other subscription levels.

For 2008, the reductions are for Core 1 subscribers (\$1-10 million in annual revenue) reduced 28% to \$850 and Core 2 subscribers (\$10-500 million in annual revenue) reduced 5% to \$5,850. The table above provides the complete MedDRA subscription rates for 2008.

The new subscription rates became effective as of 1 January 2008.

The subscription rate reductions will have no impact to the MSSO services. All MSSO services (e.g., change request processing, User Groups, Blue Ribbon Panels, Help Desk, twice yearly releases) will continue as before. The MSSO believes these services are vital to the continued growth and support of MedDRA.

Subscription Levels	2007	2008
Basic	\$0	\$0
Core 0 (Annual Revenue/Turnover \$0M - < \$1 Million)	\$200	\$200
Core 1 (Annual Revenue/Turnover \$1M - < \$10 Million)	\$1,177	\$850
Core 2 (Annual Revenue/Turnover \$10M - < \$500 Million)	\$6,159	\$5,850
Core 3 (Annual Revenue/Turnover \$500M - < \$1 Billion)	\$12,270	\$12,270
Core 4 (Annual Revenue/Turnover \$1 Billion - < \$5 Billion)	\$50,243	\$50,243
Core 5 (Annual Revenue/Turnover < \$5 Billion)	\$66,451	\$66,451
Developer	\$3,152	\$3,152

Please feel free to contact the MSSO Help Desk ([mssohelp@ngc.com](mailto:mssohelp@ngc.com)) if you have any questions.

## What's New for Version 11.0

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There was an increase in vaccine specific terms requested during this release. Many of those requested terms involved post-vaccine concepts with numerous infection related post-vaccine concepts. This led to the addition of a broad PT *Vaccine breakthrough infection* under HLT *Infections NEC*.

**Statistics:** The total number of change requests processed during MedDRA 11.0 development was 1770. Of this number, 1145 CRs were approved, 590 were rejected, and 35 were suspended for further consideration and resolution beyond this version. Of these suspended terms, 12 are for family risk factor terms.

During this release, in support of medical device regulatory reporting, some device-related patient adverse event terms were also reviewed and implemented in MedDRA. These terms were taken from a list of patient problem terms that were provided by the Center for Devices and Radiological Health (CDRH) at FDA. This effort will be ongoing and will continue over several MedDRA releases.

### Clinical Trials Survey

#### Your Feedback is Needed!

Have you filled out the MedDRA Clinical Trials Survey?

Please submit your survey responses no later than 4 April 2008.

Visit the [MedDRA MSSO Web site](#) for details and incentives.



# CTCAE - MedDRA Mapping Update

By Dr. Judy Harrison  
MedDRA MSSO  
Dr. Anna Zhao-Wong  
Manager, Terminology Development  
and Services



The CTCAEv3.0 to MedDRA mapping is updated once a year during the "X.0" release. The updated mapping is posted on the MSSO Web site (<http://www.meddramsso.com/translations/downloads.htm>) by 15 March each year.

The current mapping is an update from the previous MedDRA Version 10.0 mapping to MedDRA Version 11.0. Upon review of CTCAE terms and descriptions, and the available MedDRA LLTs, six changes of mapped MedDRA terms were identified, representing better matches for the CTCAE concept (see table below). The changed records (see below) are indicated in the spreadsheet that is posted on the MSSO Web site.

Category	AE supra-ordinate term	Select AE	MedDRA LLT (v10.0)	MedDRA LLT (v11.0)
NEUROLOGY	Speech impairment (e.g., dysphasia or aphasia)		Speech disorder	Dysphasia
GROWTH AND DEVELOPMENT	Growth velocity (reduction in growth velocity)		Developmental delay	Growth retardation
LYMPHATICS	Phlebolymphatic cording		Lymphangitic streak	Lymphangiopathy
GASTROINTESTINAL	Dental: dentures or prosthesis		Dental prosthesis user	Medical device discomfort
OCULAR/VISUAL	Ophthalmoplegia/diplopia (double vision)		Diplopia	Ophthalmoplegia
PULMONARY/UPPER RESPIRATORY	Nasal cavity/paranasal sinus reactions		Nasal congestion	Sinus disorder

**MedDRA MSSO**  
3975 Virginia Mallory  
Drive  
Chantilly, VA 20151  
USA  
Toll Free International  
877.258.8280 (AT&T)  
Direct  
703.272.5505 (USA)  
FAX  
703.272.5635 (USA)

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## Acknowledgements

MedDRA<sup>®</sup> is a registered trademark of the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA).

# MedDRA Activities at the EuroDIA Meeting

By Scott Vitiello  
MSSO Customer Operations

**M**edDRA was highly visible at the recent EuroDIA Meeting held in Barcelona, Spain. As at previous meetings, the MSSO hosted a booth in the exhibit hall and held a MedDRA User Group Meeting following conclusion of the EuroDIA meeting.

The MSSO's booth provided the opportunity for many of our subscribers and potential users of MedDRA to meet with MSSO staff. The MSSO addressed questions about MedDRA terms and structure, changes in recent versions, translation status, subscription information, and MedDRA services (e.g., training). The MSSO MedDRA Browser was available for browsing the English and translated versions of MedDRA .

Two of the MSSO's physicians gave presentations at EuroDIA sessions. Dr. Eva Rump discussed "MedDRA and Medication Error Reporting: The Operational Implications to Mitigate and Prevent the Risk of Medication Errors." Dr. Tomás Moraleda spoke about "Approaching 'Data Retrieval and Presentation: Points to Consider'."

On 6 March 2008, the MSSO conducted the MedDRA International User Group Meeting. The meeting was well attended by MedDRA subscribers (over

60 attendees). Dr. Astrid Herpers from Roche provided a presentation on the implementation of SMQs at her company, Dr. Patricia Mozzicato led a discussion of MedDRA versioning; she was joined via teleconference by Dr. Sabine Brosch of EMEA. Dr. Moraleda gave a presentation entitled "MedDRA and the European Regulatory Environment." Dr. Brosch was the latest recipient of the Friend of MedDRA medal. The meeting concluded with an open question and answer session with subscribers that included discussions about MedDRA definitions and the frequency of MedDRA releases.



## Friend of MedDRA



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

In March 2008, the MSSO awarded the FOM medal to Sabine Brosch of the European Medicines Agency at the MedDRA International User Group meeting in Barcelona, Spain.

The MSSO looks forward to acknowledging future MedDRA users.

The MSSO thanks all of those in the MedDRA community who stopped by our booth, attended a MedDRA-related session, attended the User Group Meeting, or otherwise contributed to the discussion of MedDRA during the EuroDIA meeting. We look forward to meeting even more of our subscribers at the upcoming DIA annual meeting in Boston, Massachusetts, USA (22-26 June 2008) and at the EuroDIA meeting in Berlin, Germany (23-25 March 2009).



# MedDRA TRAINING SCHEDULE MARCH – JULY 2008

Listed below are the currently scheduled MSSO classes. This training schedule is subject to change. Please refer to the MSSO Web site for confirmed course offerings

[www.meddramsso.com/MSSOWeb/training/training.htm](http://www.meddramsso.com/MSSOWeb/training/training.htm).

## EUROPE

	<b>CODING WITH MedDRA</b>	<b>ADVANCED CODING</b>	<b>MedDRA: SAFETY DATA ANALYSIS &amp; SMQs</b>
<b>APRIL</b>	Frankfurt, Germany 8 April	Frankfurt, Germany 9 April	Frankfurt, Germany 9-10 April
<b>MAY</b>	London, England 21 May	London, England 22 May	
<b>JUNE</b>	Frankfurt, Germany 26 June		Frankfurt, Germany 27 June
<b>JULY</b>	London, England 8 July	London, England 9 July	London, England 9-10 July

## NORTH AMERICA

<b>MARCH</b>	Princeton, NJ USA 25 March	Princeton, NJ USA 26 March	Princeton, NJ USA 26-27 March
<b>APRIL</b>	Phoenix, AZ USA 22 April	Phoenix, AZ USA 23 April	Phoenix, AZ USA 23-24 April
<b>MAY</b>	Boston, MA USA 6 May		Boston, MA USA 7 May
<b>JULY</b>	Chantilly, VA USA 23 July	Chantilly, VA USA 24 July	Chantilly, VA USA 24-25 July

## WEBINARS

<b>Introduction to MedDRA TBD</b>	<b>Introduction to MedDRA Data Analysis and SMQs for Physicians 12 March</b>
<b>MedDRA Coding Basics 15 May</b>	<b>MedDRA for Statisticians &amp; Programmers 16 April</b>
<b>MedDRA for the IT Professional 16 July</b>	<b>What's New in MedDRA 11.1 August (Date TBD)</b>

## NEW SUBSCRIBER TRAINING SESSIONS

<b>Spring/ Summer 2008</b>	Frankfurt, Germany 7 April	London, England 20 May	Frankfurt, Germany 25 June	Chantilly, VA USA 22 July
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## REGULATOR TRAINING SESSIONS

<b>Spring/ Summer 2008</b>	London, England 8 July
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Registration for all sessions can be accomplished through the MSSO Web site Training page:  
<http://meddramsso.com/MSSOWeb/training/training.htm>. AT&T toll free number: (877) 258-8280



# MedDRA Course Descriptions

## **Advanced Coding: Coding Conventions and the MedDRA “Points to Consider” Document**

This half-day course provides 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**

This one-day course provides a basic understanding of how and why MedDRA was developed, provides an introduction to the basic scope, structure, and rules of MedDRA terminology, and reviews the System Organ Classes that are unique to MedDRA. Additionally, it is designed for individuals involved with coding, those affected by coding guidelines and associated standard operating procedures, and those involved with synonym lists.

The course illustrates coding ex-

amples 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.

## **MedDRA: Safety Data Analysis and SMQs**

In this one day session, combined materials from two former MedDRA courses, “MedDRA: Interpreting Data and Query Development” and “Standardised MedDRA Queries (SMQs) Primer,” provide an overview of the features of MedDRA that relate to the analysis and retrieval of MedDRA encoded data.

## **Webinar Topics:**

### **Introduction to MedDRA Data Analysis & SMQs for Physicians** (1.5 hour webinar session)

The material in this course provides a brief overview of MedDRA and an introduction to the applications of MedDRA for data presentation, retrieval, and analysis (including use of SMQs) from a medical perspective.

### **MedDRA Coding Basics** (1 hour webinar session)

Coding Basics provides a brief overview of MedDRA; introduces the “MedDRA Term Selection: Points to Consider” document; uses coding examples to illustrate general principles of coding; and provides trainees with a set of coding “pearls” based on the broad coding experience of MSSO’s medical personnel.

### **MedDRA for Statisticians and Programmers** (2 hour webinar session)

The Statisticians and Programmers webinar provides a brief overview of MedDRA and focuses on the practical use and application of MedDRA for data presentation, retrieval, and analysis (including use of SMQs) from a statistical programming perspective.

### **MedDRA for the IT Professional** (2 hour webinar session)

The IT systems provide the infrastructure for this process. MedDRA for the IT Professional covers MedDRA implementation and deployment issues from a systems perspective.

## **On-site MedDRA Training: 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 including 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.

**All MedDRA courses and Webinars are available for on-site presentation.**



## Free MedDRA Training for New Subscribers

Since January 2006, the MSSO has been offering free training to new subscribers at the Basic, Core 0, and Core 1 subscription levels. Two slots are available per qualified organization, and the training must be accomplished within the first year of the new subscription.

To date, many new subscribers have taken advantage of these specially scheduled classes. If your organization has not taken full advantage of this opportunity, the MSSO encourages your organization's participation.

The New Subscriber sessions cover the same material as is covered in the *Coding with MedDRA* open training course. The New Subscriber training schedule is listed under the Training tab on the MSSO Web site. Please click on the link below to view this schedule:

[www.meddramsso.com/MSSOWeb/training/newsuscr\\_trng.htm](http://www.meddramsso.com/MSSOWeb/training/newsuscr_trng.htm)



### Please visit us at the Drug Information Association Annual Meeting

**US DIA 44th Annual Meeting**  
Boston, Massachusetts USA  
22-26 June 2008

and the

### US MedDRA User Group Meeting

**MedDRA User Group Meeting**  
Boston Convention and Exhibition  
Center  
415 Summer Street  
Boston, Massachusetts USA  
26 June 2008  
1230—1700

## Webinar Topics

*Continued from page 7*

The webinar covers key points for new/existing systems, data issues, and electronic submissions.

**What's New in MedDRA** (1.5 hour webinar session)

The What's New in MedDRA webinar is designed to provide information on changes incorporated into each new version. Sessions are scheduled to coincide with the corresponding version.

### 20th Annual Euro DIA Meeting and MedDRA International User Group Meeting a Success!

It was great to see so much interest in MedDRA and so many subscribers stopping to visit members of the MSSO at the booth.

The success of the User Group meeting was in part due to the record number of subscribers who attended. Valuable discussions on various topics of interest took place. To view the briefings, visit the [User Group Meeting](#) page on the MedDRA MSSO Web site.