



# MESSENGER

Published quarterly by MedDRA MSSO for our subscribers

## Feasibility Study of MedDRA Hierarchy Modifications

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In response to subscribers' requests, the MSSO conducted a feasibility study on MedDRA hierarchy structure modifications.

Within ICH regions, MedDRA is the standardized medical terminology for pharmaceutical industry and regulators at all phases of drug development for coding, data presentation, retrieval, and analysis. Many MedDRA users have moved from the initial implementation and focus on coding to data retrieval and analysis.

The MSSO is actively involved in several activities to ensure the proper maintenance and development of MedDRA to meet the needs of the users.

Based on subscribers' inputs, the MSSO explored the possibility of modifications to MedDRA's grouping terms (i.e. HLTs and HLGTS) to improve their utility in supporting statistical analysis and reporting. The existing MedDRA rules and conventions, such as primary SOC allocation, were reviewed in this context. Analysis was based on MedDRA Version 8.0. The following are the areas involved:

1. Review "NEC" HLTs (including "NEC" HLGTS)
2. Group congenital PTs and their acquired counterparts under the same HLT where applicable
3. Multi-axiality of SOC *Investigations*
4. Multi-axiality of SOC *Social circumstances*

Spreadsheet Topic	xls	Notes on Interpretation
Review "NEC" HLTs (including "NEC" HLGTS)	#1	Further changes are planned to be performed on subscriber requests
Group congenital PTs and their acquired counterparts under the same HLT where applicable	#2	Further changes are planned to be performed on subscriber requests
Multi-axiality of SOC <i>Investigations</i>	#3	Further second allocations are planned to be performed on subscriber requests
Multi-axiality of SOC <i>Social circumstances</i>	#4	Further changes are planned to be performed on subscriber requests
Multi-axial HLTs in Cumulative Data Output	#5	Further changes are planned to be performed on subscriber requests
Primary SOC for Post Procedural Terms	#6	Further changes are planned to be performed on subscriber requests

5. Multi-axial HLTs in Cumulative Data Output

6. Primary SOC for Post Procedural Terms

7. Consider whether hyper- and hypo- metabolic disorders should be under the same HLT in SOC *Metabolism and nutrition disorders*.

The MSSO derived spreadsheet with recommended outcomes of the review. The posted spreadsheets contain proposed MedDRA changes based on the topics listed above and are open for subscriber comment on the MedDRA web site. The correlation between the topics and the spreadsheets is in the box above.

**Note to Readers:**

- The term "disorder SOCs" used in

this document refers to MedDRA SOCs that classify diseases, such as SOC *Metabolism and nutrition disorders*. The term is used to differentiate from MedDRA supporting SOCs: *SOC Investigations*, *SOC Social circumstances* and *SOC Surgical and medical procedures*.

➤ The term "anatomical SOCs" used in this document refers to a subgroup of MedDRA disorder SOCs. Each anatomical SOC classifies diseases of a specific anatomical body system, such as *SOC Cardiac disorders*, *SOC Gastrointestinal disorders*, *SOC Hepatobiliary disorders*, etc. The term is used to differentiate from those disorder SOCs that are based on etiology, such as *SOC Congenital, familial and genetic*

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# Standardised MedDRA Queries (SMQ) Update and Phase II Testing Explained

By Dr. Patricia Mozzicato  
International Medical Officer  
MedDRA MSSO

**M**edDRA users are *strongly encouraged* to perform phase II testing for the SMQs to help assure that SMQs perform as intended by the CIOMS Working Group. To prepare for phase II testing, users should initially read the SMQ Introductory Guide to understand the principles of testing SMQs on safety databases as well as

## Hierarchy

*Continued from front page disorders, SOC Neoplasms benign, malignant and unspecified (incl cysts and polyps), and SOC Infections and infestations.*

The posted spreadsheets can be found on the MedDRA website [www.meddrassso.com/NewWeb2003/mssosubs/subscriber\\_announce.htm](http://www.meddrassso.com/NewWeb2003/mssosubs/subscriber_announce.htm) contained in a zip file under the link called **Feasibility Study of MedDRA Hierarchy Modifications**.

The MSSO encourages subscribers to submit their feedback to [MSSORequest@ngc.com](mailto:MSSORequest@ngc.com).

the specific inclusion/exclusion criteria for terms in an SMQ. Then, users can perform the same type of testing as the CIOMS Working Group did, that is, applying a phase II SMQ to a "test" product in a database and assessing the quality of the cases retrieved. Please note that the SMQ Introductory Guide has been recently streamlined into bulleted summaries of all phase I development and testing information.

Testing results are considerably more helpful in evaluating the ability of an SMQ to retrieve cases than a simple critique of the included terms. Although the Working Group does take such comments into consideration, they are not as helpful as test results in evaluating the potential for an SMQ to work. Again, before sending in your feedback on an SMQ, please be sure to read the SMQ Introductory Guide where the scope and purpose of the SMQ, the definition of the condition, and the inclusion/exclusion parameters for each query are listed.

The SMQ Introductory Guide also contains results of phase I testing by the CIOMS Working Group; it helps to compare your testing results against those of the Working Group. Results of your phase II testing should be reported directly back to the MSSO (you need not identify the specific product tested); alternatively, you can provide testing

results via the **SMQ Feedback** link on the MSSO website [www.meddrassso.com/NewWeb2003/survey/SMQ\\_Feedback.asp](http://www.meddrassso.com/NewWeb2003/survey/SMQ_Feedback.asp).

Once all phase II testing has been collected from the users, the information will be evaluated at the next CIOMS Working Group meeting. The cumulative results of phase II testing will be used to refine (if needed) the SMQ before it goes into production release.

At its recent meeting in Berlin, Germany, the CIOMS Working Group agreed on ten additional SMQs to be posted for phase II testing by mid-2005. These ten phase II SMQs are: Drug abuse, dependence and withdrawal; Haemorrhages; Hyperglycaemia/new onset diabetes mellitus; Interstitial lung disease; Ischaemic heart disease; Neuroleptic malignant syndrome; Suicide/depression; Systemic lupus erythematosus; Taste and smell disorders; and Vasculitis.

CIOMS and the MSSO recognize the user community's need for SMQs and the critical role you play in making this much needed tool work best. We look forward to your continued interest and participation in the development of SMQs.

As always, feel free to contact the MSSO ([mssohelp@ngc.com](mailto:mssohelp@ngc.com)) at any time with your questions about SMQs.

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## WE WANT YOUR FEEDBACK!

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IF YOU WANT TO BE ADDED TO THE MAILING LIST, PLEASE VISIT THE WEBSITE [WWW.MEDDRAMSSO.COM](http://WWW.MEDDRAMSSO.COM) OR E-MAIL US.

## ACKNOWLEDGEMENTS

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



## MedDRA OPEN TRAINING

## SEPTEMBER – DECEMBER 2005

Listed below are the currently scheduled MSSO classes. The training schedule is periodically updated. Please access [www.meddramsso.com](http://www.meddramsso.com) for updated information.

### NORTH AMERICA

	FULL SCOPE	CODING WITH MedDRA	ADVANCED CODING	MEDDRA FOR DRUG SAFETY PROFESSIONALS: DATA RETRIEVAL, ANALYSIS & SMQs	IT
SEPTEMBER	Mississauga, Ontario, Canada 20-21 September			Mississauga, Ontario, Canada 21-22 September	
OCTOBER		Raleigh-Durham, NC 18 October	Raleigh-Durham, NC 19 October		Raleigh-Durham, NC 19 October
NOVEMBER	Las Vegas, NV 15-16 November		Las Vegas, NV 16 November	Las Vegas, NV 17 November	
DECEMBER		Iselin, NJ 14 December	Iselin, NJ 15 December		Iselin, NJ 15 December

### EUROPE

SEPTEMBER		Amsterdam, The Netherlands 27 September	Amsterdam, The Netherlands 28 September		
OCTOBER		Barcelona, Spain 18 October		Barcelona, Spain 19 October	
NOVEMBER	London, England 15-16 November		London, England 16 November		London, England 16 November
DECEMBER		Frankfurt, Germany 13 December	Frankfurt, Germany 14 December	Frankfurt, Germany 14-15 December	

**Course descriptions may be found at [www.meddramsso.com](http://www.meddramsso.com)**

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



# Getting to the Point!

By **Kate Studeman**  
**Customer Operations**

**D**id you know?  
*In order to protect the privacy of our subscribers, the MSSO does not give out subscription specific information to anyone but the main Subscription Point of Contact who is responsible for disseminating that information to those people within their organization who require access to it!*

## **MAIN SUBSCRIPTION POINT OF CONTACT (POC)**

- Receives subscriber sensitive information (such as User ID, Passwords, Change Request ID, and Unzip Passwords)
- Responsible for distributing that information to members of their organization, including those in alternate locations
- Determines who within the organization receives subscription information
- Responsible for notifying the MSSO (via web form — [www.meddra.mssso.com](http://www.meddra.mssso.com)) of any changes in the POCs listed on the original subscriber agreement
- Subscription sensitive information **WILL NOT** be given to any members of your organization through the MedDRA MSSO helpdesk; those inquiries will be directed to the main POC
- Responsible for renewal invoices

as well as accounts receivable and accounts payable matters if a billing POC is not designated.

It is recommended that the main POC be familiar with the subscription agreement terms, other designated points of contact, and MedDRA MSSO web activity. Additionally, they will receive a copy of our *MedDRA Messenger* quarterly newsletter.

## **ALTERNATE SUBSCRIPTION POINT OF CONTACT (POC)**

Designee is copied in on all correspondence from the MSSO for informational purposes, and serves as the main POC in the event that the main POC is unavailable.

## **BILLING POINT OF CONTACT (POC)**

Designee who is the point person regarding all renewal invoices or accounts receivable/collections issues (Note: If the billing center is not in the same location as the main POC, it is recommended that a billing POC be designated).

## **TERMINOLOGY POINT OF CONTACT (POC)**

Designee who is the point person regarding questions or issues arising from change requests or other dictionary management items. They should have access to the Change Request ID, User ID, and Passwords.

## **SHIP TO**

If a product needs to be shipped to a subscriber who has an alternate receiving department, a "Ship To" con-

tact should be designated and should handle the material only to the point of delivery to the main POC.

## **MAILING LIST RECIPIENT**

A person designated as a mailing list recipient will be kept abreast of new MedDRA developments and announcements via broadcast emails. Additionally, they will receive a copy of our *MedDRA Messenger* quarterly newsletter.

## **41st Annual DIA Meeting and MedDRA International User Group Meeting a Success!**

**I**t 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 [www.meddrasso.com/NewWeb2003/activities/usrmtg.htm](http://www.meddrasso.com/NewWeb2003/activities/usrmtg.htm) and reference the June 2005, Washington DC location.

## **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.meddrasso.com](http://www.meddrasso.com).

## **MSSO Training Materials**

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

Fall 2005 will reflect MedDRA 8.1 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.



# MedDRA and the European New Member States

By Dr. Eva Rump  
International Medical Officer  
MedDRA MSSO

On 01 May 2004, the following ten nations joined the European Union (EU): Cyprus, Czech Republic, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovakia, and Slovenia.

Within the framework of this enlargement of the EU, the successful implementation of the MedDRA is an important and critical component of drug regulatory reporting.

To facilitate MedDRA's use, the European Agency for the Evaluation of Medicinal Products (EMA) has sent a letter to all 'Heads of Agencies' of the new Member States to announce that the MSSO is offering to conduct — free of charge — MedDRA orientation sessions for regulators and industry representatives in the new Member States.

The MSSO has asked the regulators to facilitate these orientation sessions by providing a local meeting room, and invitations to all interested organizations within the respective country such as pharmaceutical companies, service providers such as contract research organizations, and government regulatory personnel.

The first two sessions were held in Poland (Warsaw, 08 December 2004) and in Lithuania (Vilnius, 07 June 2005) with more than 60 participants at each meeting. The feedback from the audiences was excellent and reflected the need for a broad overview of MedDRA, critical for implementation and use of this reporting standard in the EU.

To enhance the understanding of MedDRA, the orientation sessions provide an overview that includes the following topics:

- ▶ MedDRA's historic background
- ▶ Overview of MedDRA and its hierarchy



- ▶ System Organ Class (SOC) design and comparison with older terminologies
- ▶ Coding with MedDRA
- ▶ MedDRA in multiple languages
- ▶ Maintenance rules and conventions
- ▶ Issues for consideration regarding implementation and management of version updates

- ▶ Regulatory status of mandatory use of MedDRA.

These three- to four-hour orientation sessions, provide time for an interactive question and answer period. Sessions are generally conducted by International Medical Officers (IMOs) of the MSSO who are European citizens.

The MSSO looks forward to orientation sessions already scheduled in the Czech Republic (14 September 2005, Prague) and Malta (30 September 2005). We hope to meet many more enthusiastic participants and to help further MedDRA's use in the EU.

Agencies of new Member States with interest in conducting MedDRA orientation sessions should contact Mr. Patrick Reville, Director, MedDRA MSSO, at Patrick.Reville@ngc.com or by telephone at (703) 345-7722 (USA).

## Your Feedback is Needed for the NEW "Points to Consider" Draft Document

Please visit the MSSO website: [www.meddramsso.com/NewWeb2003/document\\_library/index.htm#DataPoints](http://www.meddramsso.com/NewWeb2003/document_library/index.htm#DataPoints) to read and provide feedback on a NEW "Points to Consider" draft document that specifically addresses data retrieval and presentation. Your feedback is requested as soon as possible, but no later than **22 October 2005**. Please send your feedback via email to [mssohelp@ngc.com](mailto:mssohelp@ngc.com).

This new draft document on data retrieval and presentation was developed by the same ICH Working Group that wrote the original "MedDRA® Term Selection: Points to Consider." Your feedback will be reviewed and considered by the Working Group. The Working Group would also like your ideas on graphical displays and tables of MedDRA-coded data to be used as examples in a future Appendix to the document.

Feedback is encouraged by all MedDRA subscribers, but particularly from those involved in the presentation of MedDRA-coded data and in the development of queries for MedDRA-coded databases.

On behalf of the ICH Points to Consider Working Group, we thank you for your continued interest in MedDRA.



## New MedDRA Version Reports

By Patrick Revelle, Director, MedDRA MSSO

The MSSO has continued to receive requests for "reports" on MedDRA version updates. Originally, we believed that the sequential files (.SEQ files) would suffice for this purpose. These files provide the differences between the one version and the next but they require some level of IT knowledge or support to be able to accurately use them.

To address this issue we have developed a

spreadsheet with a series of reports in separate tabs. The idea of a spreadsheet allows for easier access and manipulation by non-IT MedDRA users. We tried to capture the types of changes we thought were most useful to users and included the appropriate data for each type of change.

The first set of reports will be available for download from the MSSO website relating the changes between MedDRA 8.0 and 8.1. Please provide the MSSO with your comments on these reports.

## MSSO Debuts New Course

### *MedDRA for Drug Safety Professionals: Data Retrieval, Analysis and SMQs*

By Liz Thomas, Training Coordinator

**M**edDRA for Drug Safety Professionals: Data Retrieval, Analysis and SMQs is a full day course designed to provide an overview of the features of MedDRA that relate to the analysis and retrieval of MedDRA-encoded data.

The first part of the course focuses on the use of MedDRA to retrieve and present aggregated data, based on the principles outlined in the *MedDRA Data Retrieval and Presentation: Points to Consider* document. A few real-life examples and hands-on exercises are

included.

The second part of the course is a thorough overview of Standardised MedDRA Queries (SMQs) and their application in the investigation of drug safety issues and in case identification. Participants learn about the development, testing, and maintenance of SMQs and see detailed examples of individual SMQs.

This course is beneficial to anyone who works with and interprets MedDRA-encoded data, especially from the point of view of case review and retrieval. Recommended participants include Drug Safety/Pharmacovigilance Professionals, Clinical Monitors, Medical Writ-

ers, Data Coordinators, Clinical Programmers, and Statisticians.

#### **FALL 2005 SCHEDULE FOR THIS COURSE**

- ▶ 22 September 2005, Mississauga, Ontario, Canada
- ▶ 19 October 2005, Barcelona, Spain
- ▶ 17 November 2005, Las Vegas, NV, USA
- ▶ 15 December 2005, Frankfurt, Germany

Registration is available via the MSSO web site: [www.meddramssso.com/NewWeb2003/training/training.htm](http://www.meddramssso.com/NewWeb2003/training/training.htm).



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