



# MESSENGER

Published quarterly by MedDRA® MSSO for our subscribers

## Maintenance and Support Services Organization (MSSO) earns ISO 9001:2000 certification

**T**he MSSO, a member of the NGMS GITD Healthcare Group, achieved ISO 9001:2000 certification from BSI, Inc., a quality management systems registrar, on November 4, 2003.

The ISO 9000:2000 standards, released in December 2000, is an internationally recognized quality management system standard developed by the International Organization for Standardization (ISO).

To be certified to the standard, enterprises must implement a Quality Management System (QMS) encompassing the activities of the enterprise from controlled product planning, ensuring staff training on their roles and responsibilities in the QMS, the controlled development of products, controlled purchasing of materials and services, and the controlled delivery of the products and services.

This is done using principles of



ISO 9001-2000  
FS 77114

process management, demonstrating steps taken to provide customers the services pledged in the enterprise contract or charter. Certification to ISO 9001:2000 reinforces to customers through an independent third-party, that the MSSO operates a QMS in accordance with the standard.

"The MSSO has, since inception, been committed to providing MedDRA subscribers the highest levels of service

excellence," said Pat Revelle, the MSSO's Program Manager.

"We are proud to be certified to ISO 9001:2000 standards. It demonstrates our commitment to our MedDRA subscribers that the MSSO is heavily engaged in process improvement, world-class performance, and continuous monitoring of our terminology maintenance operations to ensure that we deliver on the commitments we make to our subscribers, staff, and vendors."

What does this mean to our customers? Simply stated, the MSSO has demonstrated to an independent third party that it has implemented and operates a high quality terminology maintenance process designed to efficiently and accurately maintain, from a process perspective, the MedDRA terminology on behalf of subscribers.

## MSSO changes due to renewed contract with IFPMA

**W**e want to bring to our subscribers' attention a few key changes at the MSSO as a result of our renewed contract with the IFPMA.

Most of our services have remained unchanged with the exception of a few that are highlighted below:

1. The MSSO will continue to distribute MedDRA twice a year, but we will not produce a copy of MedDRA in paper for sale as had been previously avail-

able.

2. User Group meetings will continue to be held in Europe and the United States; however, the MSSO will not conduct a User Group meeting in Japan. The Japanese Maintenance Organization will conduct User Group meetings in Japan for MedDRA/J subscribers.

3. Standard change requests will be acknowledged within 24 hours of receipt. Time of receipt is defined as the first business day when the change

request is initially reviewed or the next business day if the change request is received after business hours. The change is the definition of the first business day and the impact of receiving change requests after MSSO business hours.

4. Users submitting standard change requests (if accepted) will be notified in writing of the supplemental term and its placement within the terminology,

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# What's new with MedDRA Version 7.0

By **Marvin Meinders**  
**Terminology Maintenance Manager**

In the November 2003 issue of the Messenger, we discussed the upcoming events that were scheduled during the development of Version 7.0 in order to give you insight of potential impact to MedDRA.

At the writing of this article, the finishing touches are being placed on Version 7.0, and there are a few items that might be of interest to you that we would like to highlight.

This was a complex change version where changes are made to the hierarchy level. Most of the changes were accomplished in order to better name or group the concept under the respective HLT.

However, there were four HLTs demoted to the PT/LLT level for coding purposes and replaced by new MedDRA grouping terms. These HLTs were Dementia vascular, Increased intracranial pressure, Muscle weakness, and Pelvic prolapse.

Note that these HLT terms were in singular form and should be at the PT/LLT level since hierarchy terms are grouping terms and will normally be plural.

The subscriber PT/LLT change requests remained essentially at the same level as the last two releases with a little more than one thousand

requests submitted per each release, although you will notice a precipitous drop in the number of changes to Version 7.0. This drop is due in most part to a decrease in maintenance changes.

The large reviews, such as demoting the NOS terms to the LLT level and British/American English reviews to ensure both spellings are represented at the LLT levels, are coming to closure.

Most of the maintenance changes made during this release were a result of suspended SOC Investigation terms

that were resolved based upon the recommendations of the Blue Ribbon Panel that met in May 2003, and endorsed by the MedDRA Management Board. Therefore we predict that number of changes to MedDRA should remain low for the next few releases.

For specific details on MedDRA 7.0, you can refer to the What's New document that can be found on the Version 7.0 release CD or in the Core Subscriber area on the MSSO Homepage.

## ***New training offering***

The Standardised MedDRA Queries (SMQs) Primer is a new MedDRA training offering from the MSSO. SMQs have been jointly developed by CIOMS and the MSSO to provide a better way to analyze your MedDRA-coded data. SMQs will be released along with future versions of the MedDRA terminology.

Now is the time to get familiar with this new analytical tool. The SMQ Primer covers the medical and structural/IT perspectives of the SMQs — how they have been developed, how they will be maintained, their purpose, use and structure.

See the MedDRA MSSO website ([www.meddramsso.com](http://www.meddramsso.com)) for more information and to register for upcoming classes. A list of classes through July is on pages 3 and 4 of this newsletter.

## **MSSO changes**

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or advised to use an existing term within seven (7) calendar days to fourteen (14) calendar days. The supplemental terms will also be available on-line via the MSSO website within seven (7) calendar days in the same period. This change extends the outer limit of the MSSO response time.

5. The MSSO will provide confirmation of current subscriber status to any MedDRA subscriber. For instance, if a pharmaceutical wants to ensure that a

potential CRO is a current MedDRA subscriber, the pharmaceutical company can contact the MSSO for this information.

6. Unrelated to the extension of the MSSO contract, Jim Mundell has transitioned to a new project within Northrop Grumman and Patrick Revelle has assumed the responsibilities of Director of the MSSO.

If you have any questions, please feel free to contact the MSSO at [MSSO-help@ngc.com](mailto:MSSO-help@ngc.com). We look forward to serving your MedDRA needs in 2004.

**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)**

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# Let's go browsing...

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

When my colleagues and I are out providing MedDRA training to subscribers, we often use as a training adjunct the “free” MedDRA browser. And just as often, we get quizzical looks from some of the trainees who were not aware that they (or their companies, that is) actually have that browser as part of their MedDRA subscription.

That usually is welcome news to our trainees because the MedDRA browser is a very user-friendly tool that can help virtually anyone learn more about MedDRA. The MSSO has also made the browser (without loaded MedDRA files) available on our website (www.med-dramsso.com) for you to download.

The MedDRA browser is included with the delivery of MedDRA to a new subscriber. Since MedDRA version 2.1, the first implementable version, first-time subscribers have received the initial beta version of the MedDRA browser, along with their MedDRA ASCII files. This very simple tool is a desktop-based application that is easily loaded from the CD or from the website. Once the browser is loaded onto your desktop, the separate MedDRA ASCII files can be easily imported into it.

In the course of about five minutes, we can generally get our trainees cruising through MedDRA using the browser. It occurred to us that many subscribers may have access to the browser but do not know how to utilize all of the browser's functions. This article is intended to fill you in on the basics of how to use the browser and to give you some hints on functionality you may not have known exists.

## SOC View

When the browser loaded with MedDRA files first opens, the window you are shown is the “SOC View” displaying all 26 SOC's in the lower pane. If you double click on any SOC, its HLGTS are displayed. If you then click on the “+”



“Download MedDRA Browser” (circled) on the MedDRA website.

sign to the left of any HLGTS, its HLT's are displayed, and so on down to the LLT level; you can perform the same action also by double clicking on the term.

In the upper pane, any term from the lower pane that you click on is shown in its hierarchical relationship in that SOC. To “roll up” any term displayed in the lower pane, you can either click on the “-” sign on the term level above it (e.g., click on the “-” of an expanded HLT to “roll up” its PT's); or, right click on the term and select “Collapse Tree” from the drop down list or select “Collapse Tree” from “View” in the tool bar.

## Special Search Categories (SSCs) View

If you would like to view the contents of any of the SSC's, click on “View” on the tool bar and select “Show Special Search Categories.” To see the PT's for any SSC, double click on the SSC of your choice. To return to the “SOC View,” select “Show System Organ Classes” from the “View” drop down list.

## What do the color boxes mean?

You may wonder why the PT's in the “SOC View” have varied colored boxes around them and why some LLT's are designated with red boxes.

The key to this color code can be found by choosing “Legend” from “Tools” in the tool bar. The colors designate whether a PT is single-axial (red box), and if multi-axial, whether the position you are viewing represents its primary (blue box) or secondary (green box) location. A red box around a LLT means it is non-current. To find out what a blue box around a SOC means, read on.

## Search Function

Searching for MedDRA terms is quite simple. On the tool bar, click on “Tools,” then “Search,” then “MedDRA Term.” A new window pops up which is the “Search by MedDRA Term” window. The search “Level” in the upper part of the window defaults to “ALL” which means that all levels of the hierarchy

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## SPRING 2004 TRAINING SCHEDULE

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. For your convenience and quick reference, course descriptions are provided.

### UNITED STATES

<u>CLASS</u>	<u>LOCATION</u>	<u>DATES</u>
MedDRA Fundamentals & Coding Principles	RTP, NC	May 18 2004, 9 a.m.-5 p.m.
Advanced Coding: Coding Conventions and the MedDRA "Points to Consider" Document	RTP, NC	May 19 2004 8:30 a.m-12:30 p.m.
MedDRA: Interpreting Data and Query Development	RTP, NC	May 19 2004, 1-5 p.m.
MedDRA for CRAs and Study Coordinators	Metro Washington, DC	8 June 2004 8:30 a.m-12:30 p.m.
MedDRA for the IT Professional	Metro Washington, DC	8 June 2004, 1-5 p.m.
Coding with MedDRA	Metro Washington, DC	9 June 2004, 9 a.m.-4 p.m.
MedDRA Fundamentals & Coding Principles	Metro Washington, DC	10 June 2004, 9 a.m.-5 p.m.
Advanced Coding: Coding Conventions and the MedDRA "Points to Consider" Document	Metro Washington, DC	11 June 2004 8:30 a.m-12:30 p.m.
MedDRA: Interpreting Data and Query Development	Metro Washington, DC	11 June 2004, 1-5 p.m.
Full Scope of MedDRA	Chicago, IL	14-15 July, 9 a.m.-4 p.m.

Registration for all open sessions can be accomplished through the MSSO web site: [www.meddramsso.com](http://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](http://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 for Spring 2004 will reflect MedDRA 6.1 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.

Course descriptions are on the website  
[www.meddramsso.com](http://www.meddramsso.com)

## MedDRA course descriptions

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.

**MEDDRA: INTERPRETING DATA AND QUERY (1/2 DAY COURSE)** is designed to provide an overview of the features of MedDRA that relate to the analysis and retrieval of MedDRA-encoded data. The objective is for the participant to understand why MedDRA-encoded data may look different vs. data coded using older terminologies. In addition, the participant will learn strategies to approach finding cases of interest from a database using MedDRA-encoded terms.

**MEDDRA FOR THE IT PROFESSIONAL (1/2 DAY COURSE)** covers MedDRA implementation issues from the IT perspective and identifies the key points to consider for existing or new systems data issues, and electronic submissions.

**MEDDRA FOR CRAs AND STUDY COORDINATORS (1/2 DAY COURSE)** describes how MedDRA is organized and how it is used; impact of MedDRA on adverse event and clinical trial data reporting; how case report form data translates into MedDRA.



## MedDRA course descriptions

**INTRODUCTION TO MEDDRA (1/2 DAY COURSE)** provides an overview of the “how and why” development history of MedDRA along with an introduction to the basic structure, scope, and rules of the terminology.

**MEDDRA ESSENTIALS (1 DAY COURSE)** Scope, structure and rules of MedDRA; examination of the idiosyncrasies of each System Organ Class and how it was developed; provides insight into the rules, usage and practices of the medical terminology.

**CODING WITH MEDDRA (1 DAY COURSE)** illustrates coding examples as they pertain to the scope of MedDRA; differences between current terminologies and MedDRA; tools that support coding, and a hands-on approach to coding verbatims and narratives with MedDRA.

**THE FULL SCOPE OF MEDDRA (2 DAY COURSE)** MedDRA Essentials and Coding with MedDRA. Offered as a package (more hands on than when offered separately).

**MEDDRA FUNDAMENTALS AND CODING PRINCIPLES (1 DAY COURSE)** provides an overview of the history, rationale for creation, structure, and scope of MedDRA, as well as the opportunity to apply what you learn through a “hands-on” approach to coding with MedDRA. The course includes an introduction to MedDRA browsing and complete coding exercises designed to reinforce what you have learned about MedDRA.

**ADVANCED CODING: CODING CONVENTIONS AND THE MEDDRA “POINTS TO CONSIDER” DOCUMENT (1/2 DAY COURSE)** provides experienced MedDRA users with a basis for understanding the importance and utility of coding conventions as they pertain to the conversion

## SPRING 2004 TRAINING SCHEDULE

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. For your convenience and quick reference, course descriptions are provided.

CLASS	EUROPE	
	LOCATION	DATES
Advanced Coding: Coding Conventions and the MedDRA “Points to Consider” Document	Prague, Czech Republic	8 March 2004, 9 a.m.-1 p.m.
MedDRA: Interpreting Data and Query Development	Prague, Czech Republic	8 March 2004, 2-6 p.m.
MedDRA for CRAs and Study Coordinators	Prague, Czech Republic	9 March 2004, 9 a.m.-1 p.m.
Coding with MedDRA	Milan, Italy	17 March 2004, 2-6 p.m.
MedDRA: Interpreting Data and Query Development	Warsaw, Poland	21 April 2004, 9 a.m.-1 p.m.
MedDRA for the IT Professional	Warsaw, Poland	21 April 2004, 2-6 p.m.
MedDRA Fundamentals & Coding Principles	Madrid, Spain	25 May 2004, 9 a.m.-6 p.m.
Advanced Coding: Coding Conventions and the MedDRA “Points to Consider” Document	Madrid, Spain	26 May 2004, 9 a.m.-1 p.m.
MedDRA: Interpreting Data and Query Development	Madrid, Spain	26 May 2004, 2-6 p.m.
Full Scope of MedDRA	Copenhagen, Denmark	23-24 June 2004, 9 a.m.-4 p.m.
UNITED STATES		
MedDRA for CRAs and Study Coordinators	Metro Washington, DC	23 March 2004, 1-5 p.m.
MedDRA Fundamentals & Coding Principles	Metro Washington, DC	24 March 2004, 9 a.m.-5 p.m.
Advanced Coding: Coding Conventions and the MedDRA “Points to Consider” Document	Metro Washington, DC	25 March 2004 8:30 a.m.-12:30 p.m.
MedDRA: Interpreting Data and Query Development	Metro Washington, DC	25 March 2004, 1-5 p.m.
Full Scope of MedDRA	Princeton, NJ	14-15 April 2004, 9 a.m. - 4 p.m.
MedDRA Fundamentals & Coding Principles	Seattle, WA	28 April 2004, 9 a.m.-5 p.m.
MedDRA for the IT Professional	Seattle, WA	29 April 2004, 9 a.m.-1 p.m.

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## Let's go browsing...continued

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will be searched. If you want to limit your search to an LLT, or a PT, etc., just select the level you want from the drop-down list.

The "Logical" (Boolean) drop-down lists at the upper right part of the Search window are set to default to "AND" (even though you will not see "AND" pop up until you populate "Value" or "Search Condition"). This means that if you choose two words or partial words, the browser will retrieve terms that contain both of those words or partial words. You may instead select "OR" which means the browser will retrieve terms that contain either of those words or parts of words. It is recommended that you leave the default set to "AND" for most searches.

At the left end of the upper part are the "Search Conditions" that require you to select a value of "contains," "begins with" or "ends with" for each corresponding search parameter you enter. Generally, you will find "contains" and "begins with" to be the most helpful.

Now you can enter your search words/partial words in the "Value" space(s). The browser automatically "wildcards" your searches; you do not need to add any extraneous characters to the words/partial words you choose.

Once you have filled in these spaces, click on the "Search" button near the top middle of the window. This

will begin to execute the search; if you would like to cancel the search and start over, you can click the "Cancel Search" button to the right. If you want to clear everything back to the default settings, click on "Clear All."

### Advanced features

The key to getting the most out of the MedDRA browser is to right click liberally.

In the "SOC View" window, if you right click on any term, you see a menu of additional options. For example, if you select "Show Occurrences," a window displays the hierarchy for that term in all its axial locations. For multi-axial terms, a blue box around a SOC indicates that this is the primary SOC for that term.

Also in the right click menu is an option called "Open Details." For PTs, HLTs, HLGs and SOCs, selecting "Open Details" displays a window that gives you some useful information about this particular term, such as its MedDRA code and whether or not it was "inherited" from one of the earlier terminologies such as WHO-ART<sup>®</sup> or COSTART<sup>®</sup>.

The primary SOC for your selected PT is again designated by a blue box. For LLTs, clicking on "Open Details" provides much of the same information as for the other levels of the terminology and also lets you know if that LLT is current ("Y") or non-current ("N").

Right click options for terms dis-

played in the "Search by MedDRA Term" window are similar to those for the "SOC View" window. There is an additional option of "Go to Browser." For a single-axial term, selecting "Go to Browser" opens up the hierarchy in the "SOC View" window and highlights the term you selected in your "Search" window. For multi-axial terms, there is an intervening window that shows all the axial linkages for the term you selected; double clicking on any term in this window quickly brings you to that term in the "SOC View" window.

### Coming soon...

Very soon, there will be a new downloadable version of the MedDRA browser (beta v1.2) on the MSSO website.

This new version has been improved to overcome some of the installation problems that some users, particularly those with Windows XP and Windows 2000 operating systems, have experienced.

In order to properly install beta v1.2, you will first need to uninstall beta v1.1. Also, in the near future, a redesigned version of the browser with improved features, some recommended by subscribers, will become available.

Space does not permit a full description of all of the MedDRA browser's current features, but hopefully, this brief "tutorial" will interest you to load the browser onto your desktop and explore MedDRA like you never have before. (Remember to right click!).

## 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.

## ACKNOWLEDGEMENTS

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