



MESSENGER

Published quarterly by MedDRA® MSSO for our subscribers

The purpose of the Primary SOC

By **Nandini Mehrotra, MD**
Medical Officer, MSSO

A common question I receive from my training attendees at the MSSO course offerings is on the Primary SOC assignments.

Most question the purpose of a Primary SOC and then there are some who would also like to know why the MSSO and not the subscribers get to assign a Primary SOC to a term in MedDRA. The sentiment voiced is that the subscriber would be a better authority to decide on the outcome of clinical data at their end.

Each PT in MedDRA is assigned a primary SOC. This is required because PTs can be represented in more than one SOC (multi-axiality). The main purpose of assigning a Primary SOC is to avoid "double counting" while retrieving information from all SOCs and to ascertain consistency in reporting.

It prevents an individual PT from being displayed more than once in cumulative SOC-by-SOC data outputs, which would result in over-counting of terms. Primary SOC assignment determines the SOC where the term is displayed in these outputs. This facility however, does not preclude the user from viewing the term in any of the secondary SOCs in which it is represented for data retrieval purposes.

Consistency in reporting is a major

concern in submission to the regulatory authorities. If people from different medical backgrounds were to assign a term and the primary association, then the potential exists for the same term to map to different SOCs.

In order to promote consistency in reporting, the primary linkages are pre-assigned in MedDRA, so that each PT

links to the same primary SOC uniformly.

The following rules are used for the allocation of the primary SOC:

- PTs that are only represented in one SOC (i.e. that are not multi-axial) are automatically assigned to that SOC as the primary.

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**COME SEE US AT DIA
 41ST ANNUAL MEETING
 WASHINGTON CONVENTION CENTER
 801 MOUNT VERNON PLACE, NW
 WASHINGTON, DC 20001 UNITED STATES**

JUNE 26-30, 2005

**STOP BY OUR BOOTHS AT 1806 AND 1808
 TO VISIT WITH THE MSSO STAFF**

**MedDRA INTERNATIONAL
 USER GROUP MEETING**

**WASHINGTON CONVENTION CENTER
 WASHINGTON, DC**

30 JUNE 2005, 1300 -1630



Why join the MedDRA User Group?

By Elizabeth d'Alelio

The MedDRA User Group offers benefits to everyone – for people who are new to MedDRA, people who are veterans in the industry, and for everyone in between.

Many meetings will feature speakers from three sources: staff from the MSSO, members of the User Group who are MedDRA Users or from the regulatory bodies of the FDA, the EMEA or the MHLW. The meetings are held twice a year, usually in conjunction with the Euro DIA meeting and the US Annual DIA meeting.

You are therefore invited to join our growing community. Free of charge, the MedDRA User Group is designed to encourage and support communities of MedDRA users. The meeting provides the opportunity to learn more about MedDRA and network with other MedDRA users.

This is your chance to share your knowledge and information about MedDRA while hearing from other users on how they have successfully used and implemented MedDRA. You can get your questions answered, meet contacts in the industry and have an opportunity to voice your opinion about MedDRA and what you'd like to see in the upcoming MedDRA releases.

The purpose of the Primary SOC

Continued from front page

• PTs relating to diseases or signs and symptoms are assigned to the prime manifestation site SOC with the following exceptions:

1. Terms that reflect congenital and hereditary anomalies are assigned to SOC *Congenital, familial and genetic disorders* as the primary SOC.

2. Neoplasm PTs are assigned to SOC *Neoplasms benign, malignant and unspecified (including cysts and polyps)* as primary SOC. This does not apply to cyst and polyp terms. These

terms are represented in the SOC for which the manifestation site is the primary SOC.

3. Infections are assigned to SOC *Infections and infestations* as the primary SOC.

If a PT links to more than one of the above three SOCs, the priority used to determine the primary SOC is as follows:

1. SOC *Congenital, familial and*

genetic disorders.

2. SOC *Neoplasms benign, malignant and unspecified (including cysts and polyps).*

3. SOC *Infections and infestations.*

The decision on the three SOCs was made during the development of MedDRA to facilitate signal identification, since all PTs relating to such categories are grouped together on cumulative data outputs.

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PLEASE CONTACT US

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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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MedDRA OPEN TRAINING

JUNE – JULY 2005

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

	FULL SCOPE	CODING WITH MedDRA	ADVANCED CODING	DATA/ QUERY	SMQ	IT
JUNE	Frankfurt, Germany 15-16 June		Frankfurt, Germany 16 June			
<u>NORTH AMERICA</u>						
JUNE		Las Vegas Nevada 15 June		Las Vegas Nevada 16 June		Las Vegas Nevada 16 June
JULY				Washington, D.C. 1 July	Washington, D.C. 1 July	
JULY		Boston, Massachusetts 20 July		Boston, Massachusetts 21 July	Boston, Massachusetts 21 July	

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.

MSSO Training Materials

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

Spring 2005 will reflect MedDRA 8.0 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.

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)

Coding professionals will be directly impacted by the conversion to the MedDRA terminology. This new terminology will directly affect coding guidelines, standard operating procedures, synonym lists and queries. Therefore, it is critical that the pharmaceutical, biotechnology and medical information industries prepare their coding staff for the implementation of MedDRA.

The MedDRA Maintenance and Support Services Organization (MSSO) is uniquely qualified to train coding and data management professionals to meet the challenges posed by MedDRA. The MSSO team, many of whose members worked closely with international regulatory agencies during the development of MedDRA, has established a large staff of highly qualified trainers and practicing coders. They are committed to the success of MedDRA, and to the success of those organizations that must adopt it.

THE FULL SCOPE OF MedDRA (2-DAY SESSION)

Provides a basic understanding of the scope, structure, and rules of Med-

DRA, 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.

INTRODUCTION TO MedDRA (1/2-DAY SESSION)

Introduction to MedDRA is designed to provide 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 FOR THE IT PROFESSIONAL (1/2-DAY SESSION)

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 Information Technology training covers the 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.

MedDRA : INTERPRETING DATA AND QUERY DEVELOPMENT (1/2-DAY SESSION)

This class are 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.

STANDARDISED MedDRA QUERIES (SMQ) PRIMER (1/2-DAY SESSION)

This class covers the Standardised MedDRA Queries from both a medical perspective (e.g., purpose, use, how they have been developed to date) and a structural/IT perspective (e.g., how SMQs are delivered by the MSSO, how they are maintained).

Need Subscription Confirmation?

**By Tiffany Bram
Customer Operations Representative**

Have you been asked to provide confirmation of your MedDRA subscription?

If so, have no fear. Simply send the MSSO Helpdesk (mssohelp@ngc.com) an e-mail providing the contact information for the receiving company and we'll take care of it.

If you are inquiring about a sponsor or vendor, just send the MSSO a list of names of those companies. The MSSO will send you an e-mail confirming subscription status and the effective period for subscribers in good standing or a non-subscription confirmation for those companies without subscriptions or expired subscriptions.



Change requests (CRs) and their rejection outcome

By **Maya Nair, MD**
Medical Officer, MSSO

At the MSSO, the setting is an early morning transatlantic teleconference call.

As international medical officers (IMOs), we are debating on a term "Stertor" to be added at the preferred term level (PT) in MedDRA. The term was submitted in the form of a change request (CR) by a MedDRA subscriber for consideration to be placed in the dictionary. The term proves difficult to be interpreted uniformly by the international medical group due to language limitations. A consensus is reached to reject the request rather than add an ambiguous concept to MedDRA.

REASONS PROVIDED

This international consensus decision will be communicated to the subscriber as a final notification letter, detailing the outcome of the change request they had submitted. Reasons for rejecting the term are also provided:

"The proposal to add new PT Stertor is not approved. While a medically valid concept, it is not an internationally recognized term. Since MedDRA is an international terminology, this concept could not be accommodated. Please consider PT Stridor for your needs. If the suggested term does not meet your needs, please resubmit providing additional explanation."

The underlying premise is that, while the requested concept is medically valid in certain languages, it could not be approved in an international medical setting.

In context, MedDRA is a medically validated thesaurus of concepts that resonate uniformly across the international medical community.

Change requests (CR) submitted by subscribers have a vital role in the up-to-date maintenance of the terminology. There are instances when a concept relevant to a current clinical trial is not yet represented in MedDRA. A request can be thus for new term consideration or for existing concepts in MedDRA.

THOROUGH SCRUTINY

The CR submission process and related information are elaborated in detail at the MSSO website. Providing clear and specific information supporting the requested concept significantly aids in the decision making process by the IMOs during their consensus discussions.

Each concept submitted in a change request is subjected to a thorough scrutiny by the MSSO medical team for their appropriate representation in MedDRA. Some get approval to be placed in MedDRA as requested, and others get approval but to be placed not as requested; invariably there are some that are rejected or not approved for ambiguity in concepts, etc.

In case of a rejection outcome, MSSO provides the reasons for the rejection status and also, if applicable, their recommendations. One of the common recommendations made to subscribers is to resubmit the concept providing medical reasoning and literature citations for reconsideration.

CHECK WEBSITE

Before submitting change requests, it is pertinent that subscribers look up two key areas in the MSSO website under Subscriber area (requires log in). One is the monthly Rejections postings and the other, the weekly Supplemental postings. Propounding transparency on rejection decisions, the MSSO posts all CR rejections with reasons for rejection on the website. This can be accessed at

www.meddramssso.com/NewWeb2003/mssosubs/coresubs/rejections.asp

COMPLETE REPORTS

Cumulative rejection reports comprehensively outline all requests that were rejected in the various MedDRA versions. That enables an overall historic view of concepts rejected through the versions.

Version specific reports list just the rejections to that particular version. In both reports, the rejected terms are listed alphabetically (alpha order) to facilitate subscriber search utility. The change request numbers included can also be used as a quick reference. Some change requests and rejection decisions are shown here as examples.

- The proposal to add a new term, LLT *Merkel cell carcinoma* is not approved. The term was recently requested by another subscriber and subsequently approved for inclusion in Version 8.0. You will find this term in MedDRA Version 8.0, which was released in March 2005.

- The proposal to add new LLT *Palpatory resistance* is not approved. The term as requested is ambiguous. In lieu, kindly find new PT *Palpatory finding abnormal* applicable to your coding needs. Also kindly review existing PTs *Abdominal rigidity*, *Abdominal rebound tenderness* and LLT *Abdominal guarding*.

- The proposal to add a new PT *Family history of other medical condition* is not approved. The requested term is unclear in its scope of concept. In lieu, a new PT *Familial risk factor* is added in an associate request of CR2004304050.



New browser to be released

By **Eric Lindamood**
Products and Services Manager

The MSSO is currently developing a new MedDRA browser to replace the Version 1.1 Browser.

The new MedDRA Browser will feature enhancements to the current MedDRA browsing capability and will add SMQ browsing and search capabilities. The new MedDRA Browser will be available for download on www.meddramsso.com later this spring.

ENHANCED MedDRA BROWSING

The new MedDRA Browser will feature some cosmetic changes as well as significant enhancements to the current MedDRA browsing functions. Some of the more notable enhancements are:

- Print capability for tree views and

search windows — users will now be able to print a tree view from the SOC view window. Users will also be able to print search results, including search conditions and the MedDRA tree shown in the results window.

- Toggle show/hide non-current LLTs option — users will now have the option of whether to display non-current LLTs.

SMQ BROWSING AND SEARCHING

The most significant new features of the MedDRA Browser pertain to SMQs. You will now be able to load the SMQ ASCII files into the browser, view the SMQs in a tree view, and search SMQs.

The new browser will allow you to import the SMQ ASCII files along with the MedDRA ASCII files.

Similar to the current SSC view, there will be an SMQ view option for

the browser. The SMQ view will display the SMQs in a tree hierarchy with the PTs and LLTs associated with them. Icons will identify narrow and broad terms, PTs by category, and inactive terms. Right clicking an SMQ or included term will provide a show details option to display SMQ-related data.

The new browser will allow users to search SMQs by SMQ term or included PTs and LLTs.

As with the new MedDRA browsing capability, there will be print functions for the SMQ tree views and search results.

The MSSO believes the new MedDRA Browser will be a valuable tool for our subscribers in learning about and implementing SMQs.



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