



MESSENGER

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MedDRA MSSO 2007 Subscription Rates

The MSSO is pleased to announce the 2007 MedDRA MSSO subscription rates. You will notice that the rates have been reduced for all levels of subscriptions, and in some cases, the reductions are significant.

The MSSO developed the 2007 subscription rates in consultation with the MedDRA Management Board. The Board and the MSSO wanted to lessen the cost impact for all subscription levels

SUBSCRIPTION LEVELS	2006	2007
Basic	\$507	\$0
Developer	\$3,940	\$3,152
Core 0 (Annual Revenue/Turnover \$0M - < \$1 Million)	\$765	\$200
Core 1 (Annual Revenue/Turnover \$1M - < \$10 Million)	\$1,576	\$1,177
Core 2 (Annual Revenue/Turnover \$10M - < \$500 Million)	\$8,104	\$6,159
Core 3 (Annual Revenue/Turnover \$500M - < \$1 Billion)	\$15,532	\$12,270
Core 4 (Annual Revenue/Turnover \$1 Billion - < \$5 Billion)	\$55,826	\$50,243
Core 5 (Annual Revenue/Turnover greater than \$5 Billion)	\$73,834	\$66,451



Happy Holidays

During this holiday season, our thoughts turn gratefully to MedDRA subscribers who have supported the MSSO throughout 2006.

We look forward to another year of continued success and partnership.

We would also like to extend best wishes for a happy and peaceful holiday season.

CHEERS!

with particular emphasis on the lower revenue subscription levels.

It should be noted that the Basic subscription level is available to eligible subscribers at no cost. The Basic subscription is reserved for non-profit organizations and activities that include the following:

- Medical libraries
- Educational institutions involved in non-commercial activities
- Direct patient care providers such as hospitals and individual health care providers involved in non-commercial activities (i.e., limited industry sponsor funding)
- Government agencies.

MedDRA has matured and has become a standard for the biopharmaceutical industry and regulators. With over 1,400 subscribing organizations around the world, the costs of maintenance

are shared over a much larger group, thereby reducing the costs for any single subscriber.

The new subscription rates are effective 1 January 2007. Any outstanding subscription renewals from 2006 should be paid based on the invoiced amount. All new subscription requests will be quoted with the 2007 rates.

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 vitality of MedDRA.

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



Blue Ribbon Panel on Proposed HLGT/HLT Changes to Improve MedDRA Data Analysis

By Dr. Anna Zhao-Wong

The fifth Blue Ribbon Panel (BRP) meeting was held on 16 November 2006 at Ingelheim, Germany. The focus of the BRP was the proposed HLGT/HLT changes to improve MedDRA data retrieval and analysis.

In 2005, the MSSO conducted a feasibility study on possible MedDRA hierarchy changes and their impact on data coding, retrieval, and analysis. Seven categories of potential changes were proposed:

1: Review “NEC” HLTs and HLGTs (Note: “NEC” stands for “not elsewhere classified;” only HLTs and HLGTs in MedDRA may contain “NEC” as part of the term text.)

- Explore alternative naming of terms for clearer indication of their content
- Review large sized HLT groupings for possible reduction of the number of subordinate PTs by building sub-groupings

2: Group PTs representing congenital disorders and their acquired counterparts to the same HLT where applicable

3: Allow multi-axiality of SOC

Investigations

4: Allow multi-axiality of SOC *Social circumstances*

5: Eliminate multi-axial HLTs (meaning an HLT shows in more than one SOC) in cumulative data outputs when only the primary paths are displayed

6: Change primary SOC for post procedural terms. Should it be SOC *Injury, poisoning and procedural complications* or should it be the site of manifestation SOC?

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

The MSSO implemented proposals 2 and 7 in Version 9.0. Proposal 6 was not implemented based on subscriber comments. Proposals 1, 3, 4, and 5 were the topics for the HLGT/HLT BRP.

There were 20 observers from the user community and 5 panel members in attendance. For many attendees, this was their first BRP experience; they found that it was informative and helpful. The BRP panel included the following:

- Dr. Gottfried Kreutz (CIOMS)
- Dr. Jürgen Kübler (EU Industry)
- Mr. Reiji Tezuka (Japan)

- Mr. George Rochester (US regulator)
- Dr. Greg Gribko (US Industry)

Meeting facilitators were Dr. Eva Rump and Dr. Anna Zhao-Wong from the MSSO.

For each topic, the MSSO facilitator presented background information, MSSO analysis, a proposed solution, user feedback, and questions to the panel members. All BRP participants, including the observers, were encouraged to voice their opinions. The final recommendations were based on the consensus among the panel members:

“NEC” HLTs

“NEC” naming should not be revised unless there is a more medically meaningful name within the hierarchy

Large-sized “NEC” groupings should be analyzed for possible new groupings with the following priority:

- Oversized HLTs (50 PTs)
- Medium or large HLTs with higher frequencies in a regulator’s database
- Utilize regulatory risk assessment areas for prioritization

HLT re-grouping should be based on medicine, such as pathology or physiology:

- Avoid force fitting of PTs for the purpose of reducing HLT size

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Free MedDRA Training

By Eric Lindamood

The MSSO offers free MedDRA training to eligible new subscribers.

Eligible subscribers are new Basic, Core 0, or Core 1 level subscribers. Each eligible organization receives credits to send two individuals to new subscriber training sessions during the first year of their subscription.

The sessions are held at locations in the United States and Europe.

Nearly 200 companies are eligible for "New Subscriber" training. The credits expire after the first year of an organization's MedDRA subscription, so be sure to check the training schedule and register in advance. Training credits are not transferable to other MSSO offered classes.

The complete eligibility details, schedules, and registration information can be found on the MSSO Web site at www.meddrassso.com/MSSOWeb/training/new_subscr_trng.htm.

Blue Ribbon Panel on Proposed HLGT/HLT Changes

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- Avoid over-granularity at the HLT level
- Consider the use of age and gender criteria

Consider a schedule that completes the implementation in a short timeframe:

- Consider the potential of consecutive complex releases

SOC INVESTIGATIONS

Recommend a pilot study on concept attribute approach:

- MSSO to develop a sample set of investigation terms with concept attributes
- To be tested by regulators and industry volunteers

SOC SOCIAL CIRCUMSTANCES

Request PTC Working Group to provide additional guidance on SOC *Social circumstances*, specifically, addict/dependence/abuse terms

No change to current System Organ Class structure

Review "abuse" related LLTs:

- Clarify the PT/LLT wordings to differentiate terms in SOC *Social circumstances* from those in SOC *Psychiatric disorders*:
 - Move "abuse" terms to SOC *Psychiatric disorders* and keep them as independent PTs from "dependence" counterparts
 - Keep terms that refer to people, such as PT *Drug abuser*, in SOC *Social circumstances*

MULTI-AXIAL HLTs IN CUMULATIVE DATA OUTPUT

Create separate HLTs for cyst and polyps terms:

- Consult expert pathologists and oncologists

Review all multi-axial HLTs to ensure primary SOC are appropriate

For detailed Blue Ribbon Panel meeting minutes and presentation slides, please visit the MSSO Web site at meddrassso.com/MSSOWeb/activities/blueribbonpanels.htm.

WE WANT YOUR FEEDBACK!

PLEASE CONTACT US

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



MedDRA OPEN TRAINING

JANUARY – JUNE 2007

The training schedule is periodically updated. Please access www.meddramsso.com for updates.

EUROPE

	FULL SCOPE	CODING WITH MedDRA	ADVANCED CODING	MedDRA: SAFETY DATA ANALYSIS & SMQs
FEBRUARY		Frankfurt, Germany 7-8 February	Frankfurt, Germany 8 February	
APRIL	London, UK 25-26 April			London, UK 27 April
MAY	Frankfurt, Germany 9-10 May			Frankfurt, Germany 10-11 May

NORTH AMERICA

JANUARY		Reston, VA USA 24 January	Reston, VA USA 25 January	Reston, VA USA 26 January
MARCH	Chicago, IL USA 6 March			Chicago, IL USA 7 March
APRIL		Seattle, WA USA 19 April		Seattle, WA USA 20 April
MAY	Reston, VA USA 2-3 May		Reston, VA USA 3 May	Reston, VA USA 4 May
JUNE	San Francisco, CA USA 6-7 June		San Francisco, CA USA 7 June	

WEBINARS

What's New in MedDRA 10.0: 27 February

MedDRA Coding Basics: 19 January

MedDRA for the IT Professional: 25 May

Use of Medication Concepts in MedDRA:

21 March 11 April 15 May

MedDRA for Statisticians & Programmers

28 March 20 April 30 May

NEW SUBSCRIBER TRAINING SESSIONS

SPRING 2007

Reston, VA USA 23 January 1 May	Frankfurt, Germany 6 February 8 May	Seattle, WA USA 18 April	San Francisco, CA USA 5 June
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REGULATOR TRAINING SESSIONS

SPRING 2007

London, UK — 24 April	Ottawa, Canada — TBD
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Registration for all 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)

In addition to lecture instruction providing a basic understanding of the scope, structure, and rules of MedDRA, trainees receive ‘hands-on’ experience coding challenging verbatim terms to demonstrate their knowledge of MedDRA’s structure and rules.

MedDRA: SAFETY DATA ANALYSIS AND SMQs (1-DAY SESSION)

Combines the materials of two former MedDRA courses, “MedDRA: Interpreting Data and Query Development” and “Standardised MedDRA Queries (SMQs) Primer,” into a full-day class designed to provide an overview of the features of MedDRA that relate to the analysis and retrieval of MedDRA encoded data.

THE FULL SCOPE OF MedDRA (1 1/2-DAY SESSION)

Provides a basic understanding of the scope, structure, and rules of MedDRA, 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.

Webinar Training Topics

Course descriptions may be found at www.meddramsso.com

MEDDRA CODING BASICS (ONE 1 1/2 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 (ONE 2-HOUR WEBINAR SESSION)

The Stats 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 (WEBINAR PRESENTATION IN TWO 2-HOUR SESSIONS)

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 for the IT Professional covers 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.

USE OF MEDICATION ERROR CONCEPTS IN MEDDRA (ONE 1 1/2 HOUR WEBINAR SESSION)

The Med Errors webinar provides a

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Training Modules 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.

NEW SUBSCRIBER SESSIONS: The MSSO offers free training for new subscribers at the Basic, Core 0 and Core 1 subscription levels. Eligible organizations receive two training credits which can be used to attend specific new subscriber training sessions.

REGULATOR SESSIONS: The MSSO offers free training to regulators. Regulators receive two training credits per year.

All of the above topics are available for onsite presentation



MedDRA Maintenance and Support Services Organization (MSSO) Retains ISO 9001:2000 Certification

By Mike Burke

The MSSO announced that, effective October 17, 2006, it has successfully defended and retained its ISO 9001:2000 certification from BSi Inc., a quality management systems registrar.

The ISO 9001:2000 standard, 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, training on

roles and responsibilities in the QMS, controlled development of products, controlled purchasing of materials and services, and controlled delivery of the products and services. This is done using principles of process management and 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.

Pat Revelle, MSSO Director, said: "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 continuously monitoring our terminology maintenance operations to ensure that we deliver on the commitments we make to our subscribers, staff, and vendors."

The MSSO achieved its first certification on November 14, 2003.

Maintaining certification involves subsequent surveillance inspections. The last inspection was a full scope assessment to determine a registrant's continuing ability to demonstrate compliance with all applicable clauses of the standard. The MSSO successfully demonstrated full scope compliance. BSi will continue to periodically conduct routine surveillance audits of the MSSO's business operations.

Quality Checks in MedDRA

By Dr. Maya Nair

A rigorous set of quality control measures is adhered to for every change request processed by the MSSO.

In addition, a series of reviews and quality control checks is undertaken each version to ensure that the rules and conventions established in the current version of the MedDRA Introductory Guide are followed.

Term placement reviews are conducted routinely by the medical officers during a version based on issues identified through change requests and feedback. These are followed by additional standard queries run at the end of each version to enhance the quality process.

The MSSO has developed a set of queries based on the MedDRA Rules and Conventions that are documented in the Introductory Guide.

Whenever new MedDRA term placement rules are formulated, they are introduced to the subscribers in the What's New document, followed by mention in the Introductory Guide for a

subsequent version.

New queries may be designed for the new rules and parameters to determine if any violation or exceptions may exist in the term placements in MedDRA.

The query results are documented and MedDRA term placements are analyzed by the medical officer. Negative findings are analyzed to determine if they are "exceptions" to the rule, or if they need to be further addressed and corrected before the version is released.

Some broad examples of MedDRA query validation include:

1. Any orphan (unlinked) HLGT, HLT or SOC
2. Any missing LLTs (terms are made non-current, not deleted)
3. LLT currency (current or non-current) change criteria
4. Single-axial SOC violations in SOC *Investigation*, SOC *Social*, and SOC *Surgical*
5. Primary SOC violations in SOC *Congenital*
6. Any terms with missing spaces (e.g. Chestpain)
7. Any discrepancy in lexical variants at the PT/LLT levels (terms that are

grouped under different concepts)

These standard quality control queries run at the end of each release are another step taken by the MSSO to ensure that each MedDRA release is a quality product.

Webinar Training Topics

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brief overview of MedDRA and focuses on the medication error concept descriptions drafted by the FDA and the MSSO. Practical examples of coding medication errors are included.

WHAT'S NEW IN MedDRA (WEBINAR PRESENTATION IN ONE 1 1/2-HOUR SESSION)

The MSSO periodically schedules webinars to provide information on changes incorporated into new version releases.