What's New for MedDRA Version 13.1

By Brian J. O'Hare
Manager, Terminology Maintenance

MedDRA Version 13.1 was made available to subscribers on 1 September 2010 from the MSSO Web site. MedDRA v13.1 is a simple change version which means changes are made only at the PT and LLT level. There were a total of 1,051 change requests processed for this version; 734 change requests were approved and implemented, and 241 change requests were rejected. There are, in addition, 76 change requests suspended for further consideration and resolution beyond this version. Please see the “What’s New MedDRA Version 13.1” document for specific details.

<table>
<thead>
<tr>
<th>Number of Terms: MedDRA Version 13.1</th>
</tr>
</thead>
<tbody>
<tr>
<td>System Organ Classes (SOC)</td>
</tr>
<tr>
<td>High Level Group Terms (HLGT)</td>
</tr>
<tr>
<td>High Level Terms (HLT)</td>
</tr>
<tr>
<td>Preferred Terms (PT)</td>
</tr>
<tr>
<td>Lowest Level Terms (LLT)</td>
</tr>
<tr>
<td>Standardised MedDRA Queries (SMQ)</td>
</tr>
</tbody>
</table>

Of note, MedDRA was selected by the Alerting System for Chemical Health Threats (ASHT II) project, funded by the European Union Public Health Programme, for use in the Rapid Alert System for Chemical Incidence (RAS-CHEM). One of the ASHT II project goals is to incorporate a harmonized terminology of symptoms and syndromes to signal the possible release or exposure to toxic chemicals. MedDRA will be used to improve information sharing, analysis and reporting of events between health professionals from poison centers and national public health officials.

The majority of concepts needed by the ASHT II project were already in MedDRA. The ASHT II project members requested the addition of a set of terms that were not in MedDRA. After a review by the MSSO, a total of 95 changes were made for MedDRA v13.1 which includes 20 new PTs, 69 new LLTs, 5 moved terms and an additional link for an existing PT. Please see the subscriber section of the MSSO Web site under announcements for a detailed list of these changes.
By Judy E. Harrison, MD
MedDRA MSSO

In March 2010, the MSSO and other MedDRA experts were invited to participate in a three-day MedDRA workshop in Kuala Lumpur, Malaysia. This workshop was designed to provide regulatory authorities and industry personnel in ASEAN (Association of Southeast Asian Nations) with an overview of MedDRA and its applications from both industry and regulatory authority perspectives. The National Pharmaceutical Control Bureau (NPCB) of the Ministry of Health, Malaysia was given the responsibility to organize the workshop under the ASEAN cooperation scheme of the ICH Global Cooperation Group.

The invited speakers were: Dr. Judy Harrison, MedDRA MSSO; Dr. Christina Winter, GlaxoSmithKline; and Dr. Sonja Brajovic, Office of Surveillance and Epidemiology, Center for Drug Evaluation and Research, FDA.

There were 22 participants from regulatory authorities present at the workshop representing Malaysia, Singapore, Indonesia, Philippines, Cambodia, Vietnam, Laos, and Brunei. In addition, there were 26 participants from industry, ethics committees, and CROs, and from the Malaysian Biotechnology Corporation - a government agency which facilitates biotechnology investment in the country.

The meeting agenda was as follows:

Day One. 17 March 2010

- MedDRA: An ICH Success Story. Presenter: Dr. Christina Winter
- Coding with MedDRA course. Presenter: Dr. Judy Harrison

Day Two. 18 March 2010

- MedDRA: Safety Data Analysis and SMQs course. Presenter: Dr. Judy Harrison

Day Three. 19 March 2010

- MedDRA from an industry perspective. Presenter: Dr. Christina Winter.
- MedDRA from a regulatory authority perspective. Presenter: Dr. Sonja Brajovic
- Q&A and panel discussion

To access the presentations on the ICH Web site, go to http://www.ich.org/trainings/ich-trainings.html.

For most of the participants, this was their first formal exposure to MedDRA and they were presented with a thorough overview of its applications in both coding and data analysis, including practical hands-on exercises using the MedDRA Desktop Browser.

Continued on page 8
Results of SMQ Survey 2010

By Patricia Mozzicato, MD
MSSO Chief Medical Officer

The MSSO reported the results of the SMQ Survey 2010 to the MedDRA Management Board at its meeting in Tallinn, Estonia in June 2010.

The purpose of the SMQ Survey 2010 was similar to that of the original (2006 – 2007) SMQ Survey, namely:

1. To assess the extent and ways in which SMQs are currently utilized and identify impediments to SMQ use
2. To solicit suggestions to improve the utility of SMQs

Additional questions were added to the 2010 survey to gather information about whether certain SMQs, or types of SMQs, are more challenging for users to implement than others.

There were 263 responders to the survey which included both MSSO and JMO subscribers. The survey responders represented a reasonable cross-section of subscribers although not proportionally distributed among all subscribers; slightly over half of the responders were those with low company revenues; these represent the largest number of subscribers overall). Approximately one-fifth were from high revenue organizations (i.e., large biopharmaceutical companies and CROs). Regulatory authorities represented 16% of responders. Of the non-regulatory responders, the majority identified themselves as a pharmaceutical company, a biotechnology or device company, or a CRO.

The overall conclusions were:

- SMQs continue to be used (and plan to be used in the future) to support general safety surveillance/pharmacovigilance functions more than clinical trial functions
- Relatively few responders indicate that they modify SMQs
- There continues to be a need and desire for SMQ training
- Relatively few responders use algorithmic SMQs, and technical challenges for their implementation were cited

- A larger proportion of responders use their own internal queries than had been reported in the 2006 – 2007 survey
- Some responders suggest to make SMQs available in SAS format

The significant findings of the original 2006 – 2007 survey were that more technical tools and training for SMQs was needed by users. Since then, the MSSO has been in contact with various software vendors to alert them to users’ needs. Also, the MSSO began to offer free training to subscribers on the analysis of MedDRA-coded data, including use of SMQs.

Based on the survey results, the MSSO plans to continue the free SMQ training offered to regulatory authorities and industry users, investigate how SMQs could be provided to MedDRA users in SAS format, and address specific improvement to individual SMQs identified in the survey results.

The MSSO thanks all those MedDRA users who took the time to answer the 2010 survey. We look forward to working with users to support their SMQ needs.
The MSSO User Group (UG) meetings provide an opportunity for MedDRA users to meet face-to-face and to discuss MedDRA related topics, to ask questions directly to the MSSO, and to share experiences with other users. In 2010, the MSSO conducted User Group meetings in Monaco (March), in Beijing (May), and in Washington, DC (June).

At the Monaco User Group meeting, Dr. Sabine Brosch of the EMA provided an informative update on the use of MedDRA in the ICH E2B ICSR. An update on the use of MedDRA at FDA was presented by Dr. Sonja Brajovic at the Washington, DC meeting. Dr. Alan Hochberg (Roche) also gave a presentation on the Evaluation of MedDRA Search Strategies for Potential Osteonecrosis of the Jaw.

At both the Monaco and Washington, DC meetings, the MSSO engaged attendees in a discussion of proactive maintenance vs. reactive maintenance of MedDRA. In the past ten years, the changes to MedDRA have been mainly user-driven in the form of subscriber change requests. The MSSO is developing a proposal for a more proactive level of maintenance.

On 17 May 2010, the MSSO conducted its first User Group meeting in Beijing. Most users in China are new to MedDRA (note: the Chinese translation of MedDRA was initially released in September 2009). This meeting was provided in conjunction with a two-day MedDRA free training program. The guest speakers were Catherine Xie from Pfizer, Xiulan Wang from DMS-Pharma, and Carol Su from Protech Pharmaservices Corporation. They shared their experiences about MedDRA in coding and data analysis. Meeting attendees were offered “lessons learned” tips, information on helpful software tools, etc.

For detailed information of 2010 MSSO User Group meetings, please visit the MSSO Web site.
The MSSO is pleased to recognize three individuals who are recipients of this year’s Friend of MedDRA (FOM) award.

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

At the MedDRA User Group meeting in March 2010, in Monaco, the FOM was presented to Dr. Barry Arnold of AstraZeneca.

In June 2010, at the MedDRA User Group meeting in Washington, DC, USA, FOM medals were awarded to Eric Tate of Allergan, and to Ann Setser of the National Cancer Institute (USA).

The MSSO congratulates the 2010 FOM awardees and looks forward to recognizing future deserving supporters.
The MedDRA MSSO is announcing effective 17 August 2010 that it has successfully maintained its ISO 9001:2008 certification from BSi™, a quality management systems registrar.

The ISO 9001:2008 standard, released in November 2008, 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 for 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. Certification to ISO 9001:2008 reinforces to customers, through an independent third-party, that the MSSO operates a QMS for the maintenance of MedDRA in accordance with the standard.

Pat Revelle, MSSO Director, notes: "We are proud to maintain a certification to the ISO 9001:2008 standard. It demonstrates our commitment to our MedDRA subscribers that the MSSO is heavily engaged in process improvement, world-class performance, and is continuously monitoring our terminology maintenance operations to ensure that we deliver on the commitments and performance requirements we make to our subscribers, staff, and vendors."

The MSSO achieved its first certification to the ISO 9001:2000 standard on 14 November 2003, and then its certification to the ISO 9001:2008 on 18 August 2009. Certification is maintained through inspections for compliance to the parts of the ISO standard that apply to MSSO processes. In this recent inspection, the MSSO demonstrated full compliance.
The MSSO on the Web

By Judy E. Harrison, MD
MedDRA MSSO

The MSSO is keen to explore new ways of communicating with subscribers and has recently begun using two well-known social media tools: Twitter and YouTube.

Twitter is a free social networking service with over 100 million users worldwide including private individuals, news outlets, and businesses. Users can send and receive short text-based “tweets” which are limited to 140 characters. The MedDRA MSSO is using Twitter to post summaries of its usual broadcast emails and other important announcements of interest to subscribers. Please consider following the MSSO on Twitter; there is a “Follow us on Twitter” button on the Home page of the MSSO Web site or you can go directly to http://twitter.com/MedDRAMSSO. Your feedback on this communication method is welcomed.

Fostering the use of MedDRA through educational offerings is one of the most important goals of the MSSO. In addition to our traditional face-to-face training classes and webinars, we are now starting to produce free training “videocasts” for viewing on the popular video-sharing site, YouTube. These short videos represent an easy way for subscribers to learn about MedDRA at their own convenience. To date, we have produced two videocasts: “Primary System Organ Class (SOC) Allocation in MedDRA” and “MedDRA Desktop Browser: History File.” The links to these videocasts on YouTube as well as direct download links are provided on the MSSO Web site. A new videocast on how to review MedDRA-coded data is in production and we would very much appreciate your ideas for future videocast topics.

Watch out for us on the Web!

WE WANT YOUR FEEDBACK!

PLEASE CONTACT US
TOLL FREE INTERNATIONAL  +1 877.258.8280

MSSO HELP DESK
WEB SITE:  WWW.MedDRA.ORG
TWITTER:  HTTP://TWITTER.COM/MedDRAMSSO

7
What’s New for Version 13.1

Continued from page 1

SMQs

A total of 2 new level 1 SMQs were released into production in MedDRA v13.1 – SMQ Ocular infections and SMQ Ocular motility disorders. There are now 84 level 1 SMQs in production as of this version. Please see the Introductory Guide for Standardised MedDRA Queries (SMQs) v13.1 for details on these new SMQs.

In addition to new SMQs, there has been one major change made to SMQs this version. In consultation with the CIOMS SMQ Working Group, the MSSO reassigned the scope of 18 PTs in the SMQ Dementia from broad to narrow. Additionally, 2 PTs were flagged inactive in the SMQ Dementia: PT Cerebral atrophy congenital and PT Delusional disorder, jealous type. Please see the MedDRA v13.1 Version Report for details on these changes.

CORRECTING TRANSLATED MedDRA TERMS

Besides English, MedDRA is currently available in nine other languages (Chinese, Czech, Dutch, French, German, Italian, Japanese, Portuguese, and Spanish). The MSSO frequently receives requests from MedDRA users to correct misspellings or replace translated terms with an improved translation. The number of available languages is expected to increase and as a result, the MSSO anticipates receiving more of these requests. To better manage these changes, a formal translation correction change process has been instituted.

There are two methods available to request translation corrections: WebCR (capability currently under development) and the Translation Correction Change Request form located on the change request section of the MSSO Web site. Using either method, the following information is required when submitting a translation correction.

- English Term Text
- MedDRA Code
- Language
- Current translated term
- Replacement translated term
- Justification of request

Once submitted, the MSSO will review the request and communicate the disposition of the request as soon as possible. All other changes to the terminology (e.g., adding new terms, moving existing terms, SMQ related requests, etc.) must be requested using the established change request methods. Please see the change request section of the MSSO Web site for more information.

For questions about the Japanese translation, please contact the Japanese Maintenance Organization.

ASEAN Workshop on MedDRA

Continued from page 2

A demonstration of the MedDRA Web Based Browser was also provided.

The focus of Day Three was on the regulatory and industry frameworks for the use of MedDRA in the clinical development process and the final Panel Discussion session included an overview of the pharmacovigilance systems in the ASEAN countries. In general, the number of adverse reaction reports to regulatory authorities is small and, as yet, there is no single standardized medical terminology being employed throughout the region.

This workshop represented a valuable opportunity to introduce MedDRA to regulatory authorities and industry in the ASEAN region and to establish personal contacts.
MedDRA Training Schedule
SEPTEMBER — DECEMBER 2010

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

OPEN ENROLLMENT SESSIONS

<table>
<thead>
<tr>
<th>Coding with MedDRA</th>
<th>MedDRA: Safety Data Analysis and SMQs</th>
<th>Webinars</th>
</tr>
</thead>
<tbody>
<tr>
<td>San Diego, CA USA</td>
<td>San Diego, CA USA</td>
<td>What’s New in MedDRA 13.1 Recorded session</td>
</tr>
<tr>
<td>29 September 2010</td>
<td>30 September 2010</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Boston, MA USA</td>
<td>Medication Errors and Product Quality Issue Concepts in MedDRA 22 September 2010</td>
</tr>
<tr>
<td>6 October 2010</td>
<td>7 October 2010</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Düsseldorf, Germany</td>
<td>MedDRA Versioning 13 October 2010</td>
</tr>
<tr>
<td>19 October 2010</td>
<td>20 October 2010</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Orlando, FL USA</td>
<td>Introduction to MedDRA 10 November 2010</td>
</tr>
<tr>
<td>15 December 2010</td>
<td>16 December 2010</td>
<td></td>
</tr>
</tbody>
</table>

FREE SUBSCRIBER TRAINING SESSIONS

<table>
<thead>
<tr>
<th>Coding with MedDRA</th>
<th>MedDRA: Safety Data Analysis and SMQs</th>
<th>Free Webinars</th>
</tr>
</thead>
<tbody>
<tr>
<td>London, UK</td>
<td>London, UK</td>
<td>MedDRA Coding Basics 9 September 2010</td>
</tr>
<tr>
<td>20 September 2010</td>
<td>21 September 2010</td>
<td></td>
</tr>
<tr>
<td>(waiting list only)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>14 October 2010</td>
<td>15 October 2010</td>
<td></td>
</tr>
<tr>
<td>(waiting list only)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>23 November 2010</td>
<td>24 November 2010</td>
<td></td>
</tr>
<tr>
<td>(waiting list only)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Chicago, IL USA</td>
<td>Princeton, NJ USA</td>
<td>Introduction to MedDRA Data Analysis and SMQs for Physicians 8 December 2010</td>
</tr>
<tr>
<td>17 November 2010</td>
<td>18 November 2010</td>
<td></td>
</tr>
</tbody>
</table>

Registration for all sessions can be accomplished through the MedDRA MSSO Web site Training Page
MedDRA Course Descriptions

Coding with MedDRA
This one-day course is designed to provide an understanding of the scope, structure, and characteristics of MedDRA and the application of the terminology in coding clinical data. It is designed for individuals involved with coding, those affected by coding guidelines and associated standard operating procedures, and those involved with synonym lists. Participants will be given an overview of the "MedDRA Term Selection: Points to Consider" document and will perform hands-on coding exercises to demonstrate the principles described in the document.

Introduction to MedDRA
This two-hour course is designed to provide a basic understanding of the scope, structure, characteristics, and maintenance of MedDRA, and the relevant regulations concerning its use. In addition, it provides an overview of coding with MedDRA and applications of MedDRA in data retrieval and analysis, including use of Standardised MedDRA Queries (SMQs) in safety signal detection and case identification.

MedDRA: Safety Data Analysis and SMQs
This one-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 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 query development exercises are included. The course also includes a thorough overview of Standardised MedDRA Queries (SMQs) and their application in the investigation of drug safety issues. Participants learn about the development, testing and maintenance of SMQs and see detailed examples of individual SMQs. Examples of practical applications of SMQs for case identification and safety signal detection are presented.

Webinar Topics

Introduction to MedDRA (2 hours)
This webinar is designed to provide a basic understanding of the scope, structure, characteristics, and maintenance of MedDRA, and the relevant regulations concerning its use. In addition, it provides an overview of coding with MedDRA and applications of MedDRA in data retrieval and analysis, including use of Standardised MedDRA Queries (SMQs) in safety signal detection and case identification.

Introduction to MedDRA Data Analysis & SMQs for Physicians (1.5 hours)
This webinar presentation 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 (1.5 hours)
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.

Medication Errors and Product Quality Issue Concepts in MedDRA (1.5 hours)
This webinar provides a brief background introduction to the inclusion of medication error and product quality issue concepts in MedDRA and focuses on their definitions and concept descriptions. Practical examples and approaches to coding and analyzing both medication errors and product quality issues are included.

MedDRA Version Updates (1.5 hours)
This webinar provides an overview of the background and rationale for versioning and describes the resources available to assist with updates. The timing of updates for both clinical trials and single case reports will be discussed together with the various recoding options defining the extent of an update. The impact of updates on coding and analysis within organizations will be described using practical examples.

What’s New with MedDRA (1.5 hours)
What’s New with MedDRA webinars provide information on changes incorporated into each new version release. Sessions are scheduled to coincide with the corresponding version release.

On-site MedDRA training: All of the above listed courses and topics are available for on-site presentation. Course material can also be customized to our organization’s specification.
MedDRA FREE TRAINING

Videocasts
Need a quick refresher on Primary System Organ Class allocation? Check out the Downloads page on the MSSO Web site.

For Subscribers and Regulators:
The MSSO offers free training to subscribers and regulators. Please check the MSSO Web site for details and conditions.

Data Quality, Coding and MedDRA Training presentation (FREE with subscriber log-in)
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.

… On 17 May 2010, the MSSO conducted its first User Group meeting in Beijing...This meeting was provided in conjunction with a two-day MedDRA free training program...