



MESSENGER

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What's New for Version 10.1

By Jim Mundell
Manager, Terminology Maintenance

As of 1 September 2007 the MedDRA release Version 10.1 has been available on the MISO Web site www.meddramsso.com. This release is classified as a simple release which means only change requests at LLT and PT levels were processed.

We are pleased to announce that with this release the Czech translation of MedDRA is available. In addition, 17 new Standardised MedDRA Queries (SMQs) have been added. This release also implements part of the recommendation from the 5th Blue Ribbon Panel regarding “abuse” terms. And lastly, this is the first MedDRA release that will be distributed totally through the MISO Web site.

Distribution: MedDRA release material will no longer be available on CDs. All material can be downloaded from the MedDRA MISO Web site. The release download will be a zip file containing only release related materials. The subscription related documents such as Subscriber Portfolio, Change Request Instruction, and phone card will not be included. These documents will still be available through the MISO Web site for downloading (www.meddramsso.com/translations/downloads.htm), just not as part of the release package. With regard to the release package, please note that the ASCII Files document and the Consecutive Files document have been com-

bined into a single document, now called MedDRA ASCII and Consecutive Files Documentation.

The Blue Ribbon Panel (BRP): The 5th BRP that was convened in November 2006 made recommendations regarding “abuse” terms. These recommendations were approved in May 2007 by the MedDRA Management Board for implementation starting with MedDRA Release 10.1. In Version 10.1 the LLT/PT level changes have been implemented. “Abuse” terms that relate to dependency conditions were moved out of SOC *Social circumstances* and placed in SOC *Psychiatric disorders*. Those terms relating to the person, (e.g., PT *Drug abuser*), will remain in SOC *Social circumstances*. LLT *Addict* and LLT *Drug addict* were moved to SOC *Psychiatric disorders*, but these two terms will be moved back during MedDRA Version 11.0 development.

Medication Errors: Four new medication error concept descriptions have been added in the MedDRA Introductory Guide under Appendix B:

- PT *Documented hypersensitivity to administered drug*
- PT *Labelled drug-disease interaction medication error*
- PT *Labelled drug-drug interaction medication error*
- PT *Labelled drug-food interaction medication error*

Number of terms: MedDRA Version 10.1

System Organ Classes (SOC)	26
High Level Group Terms (HLGT)	332
High Level Terms (HLT)	1,682
Preferred Terms (PT)	17,867
Lowest Level Terms (LLT) *	47,738

Statistics: The total number of change requests processed during MedDRA Version 10.1 development was 1752. Of this number, 1093 change requests were approved, 615 were rejected, and 44 were suspended.

Thirty-four of the suspended change requests are related to an ongoing question about how to define “injury.” This topic was the subject of the MISO’s first MedDRA Expert Panel (EP) conference. The recommendations from the EP are currently being prepared for proposed implementation review.

LLT total includes unique LLTs only. For specific details on MedDRA Version 10.1, refer to the What’s New document found in the MedDRA Version 10.1 release documentation (Internet File Download at www.meddramsso.com/translations/translationdownloads.htm).

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MedDRA Version Update Reports

By Pat Revelle
Director of MSSO

At our most recent MedDRA User Group meeting on 21 June 2007 in Atlanta, the MSSO asked the attendees what versioning means to them. Most organizations have developed tools and processes to update to the latest version of MedDRA. The same organizations have identified and tasked resources to complete this process. The MSSO’s question was focused on better defining the timing and scope of the update.

In 2002, the MSSO developed a series of MedDRA versioning papers. These documents were endorsed by the MedDRA Management Board as “Best Practice” which means they are helpful in harmonizing the use of MedDRA

MedDRA subscribers at the User Group meeting encouraged the MSSO to communicate the transition date to regulatory authorities with a goal of harmonizing the version change requirement. This regulatory harmonization will encourage a similar harmonization among industry users required to submit regulatory reports.

The other point discussed with the User Group attendees was the definition of the scope of a MedDRA update. In other words, what does it mean to update to the latest version of MedDRA? Some organizations load the latest version of MedDRA and make no changes to existing coded data based on:

Sun	Mon	Tue	Wed	Thu	Fri	Sat
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11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

1 March 2007 - MedDRA Version 10.0 Released

Sun	Mon	Tue	Wed	Thu	Fri	Sat
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29	30					

7 May 2007 – First Monday in May

Sun	Mon	Tue	Wed	Thu	Fri	Sat
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6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

but they do not represent regulatory requirements. In one of those documents,)The MedDRA MSSO’s Recommendations for Single Case Reporting using Semi-annual Version Control, www.meddramsso.com/MSSOWeb/Docs/VCGuidesemiannual.pdf, the MSSO proposed that all organizations transition to the new version of MedDRA on the same date and time (i.e., “A new release version of MedDRA should become the reporting version on the first Monday of the second month after it is released. To synchronize this event over the three ICH regions, the MSSO recommends midnight GMT, Sunday to Monday, for the switchover.”).

Most organizations update their version of MedDRA sometime within the 60-day window between the release of MedDRA and the first Monday of the second month following the release. This 60 day “window” of version change allows for the potential of organization “A” updating to the latest version of MedDRA before organization “B.” Organization “B” may not recognize a MedDRA term being sent from Organization “A.” This theoretical possibility became reality when an EU regulator rejected an E2B report sent in Version 10.0 of MedDRA prior to the official transition date for MedDRA Version 10.0 (i.e., before 7 May 2007).

1. MedDRA currency changes (i.e., LLTs becoming non-current; they should no longer be used)
2. Direct matches between reported terms and newly added MedDRA LLTs and PTs
3. Medically “better” terms available in the new release.

The User Group attendees encouraged the MSSO to develop a version update grading scale. The grading scale would define the levels of upgrade briefly described above and each organization would voluntarily assign a grade to their version update process. This version upgrade scale would be beneficial to organizations when they are transferring data or combining data to understand how the data was maintained.

The MSSO appreciates the feedback and interest in the discussion at the User Group meeting and plans to discuss these concepts with the MedDRA Management Board at the Board meeting in October 2007.



SMQ Survey Results

By Pat Revelle
Director of MSSO and
Patricia Mozzicato
Chief Medical Officer, MSSO

In spring of 2007, the MSSO and JMO completed collection of an SMQ survey from MedDRA subscribers. The purpose of the survey was to assess the extent and ways in which SMQs are currently utilized, to identify challenges to SMQ use, and to solicit suggestions to improve the utility of SMQs.

There was an excellent response to the survey, with MSSO and JMO collecting a combined 166 responses (51 JMO responses and 115 MSSO responses) that were a representative cross-section of subscribers across geographical regions and subscription types.

The overall conclusions of the survey were:

- Survey responders appear to be on the upward part of a learning curve regarding SMQs
- Most responders are using, or plan to use, SMQs for general safety/ pharmacovigilance purposes
- There is general interest in exploring the utility of SMQs in clinical trials
- Challenges to the use of SMQs are:
 - Lack of IT tools
 - Lack of understanding of the utility and purpose of SMQs
- The CIOMS Working Group for SMQs, MSSO, and JMO should continue to improve the general distribution aspects of SMQs by:
 - Encouraging software development
 - Providing robust documentation and training options

Here are some additional details about the collected survey responses.

Extent and ways SMQs are currently utilized

Of the 115 MSSO responses, 38 answered that they are currently using SMQs. As expected, the early adopters tend to be the

larger organizations (Core 4 and Core 5 subscribers) with greater resources. Conversely, a larger percentage of Core 0 – 3 level responders have not yet implemented SMQs. No survey responses were submitted by MedDRA software developers.

Algorithmic SMQs tend to be used less than SMQs with narrow/broad or hierarchy (sub-search) features. Only a handful of SMQs were of the algorithmic type as of the distribution of this survey, which may be part of the explanation. MSSO and JMO may need to monitor the development of tools to ensure that algorithm SMQs can be utilized.

Based on “free text” comments in the survey, most responders are pleased with or neutral toward the SMQ documentation, although some improvements could be made, especially in regard to technical details.

Challenges to SMQ Utilization

The most frequent reason for non-use/ infrequent use of SMQs – especially smaller organizations (Basic, Core 0-3 level subscribers) – is the lack of available IT tools. To address this, MSSO has been in contact with software vendors to monitor progress on the development of tools; MSSO has also been encouraging subscribers to relate their concerns to vendors. As of the completion of the survey, an informal poll of the major vendors of safety database software all indicate that SMQ tools are available or will be available to their clients soon.

Another cited reason for non-use/ infrequent use of is lack of understanding of the purpose or applicability of SMQs. Both the MSSO and the CIOMS Working Group for SMQs have stepped up their efforts to “spread the word” by presentation at major venues (DIA meeting, user group meetings, etc.). More scientific publications should also be encouraged by all involved parties. The MSSO currently offers commercial training courses for both the technical and medical aspects of SMQ usage.

A fair number of responders indicated that non-use/infrequent use of SMQs is because they create their own queries. This may be because SMQs do not cover all possible safety issues, and it is likely that many users will continue to have to create queries specific to their needs. Responders also cited their reason for non-use/infrequent use of SMQs is because they are not mandated by regulatory authorities; with the advent of the Volume 9A Pharmacovigilance Guideline in the EU (which recommends the use of SMQs for signal detection), an increased interest in SMQs may result.

Of those responders currently not using SMQs, it is encouraging to observe that a minority have no plans to use SMQs in the future while a significant percentage of responders do.

Most responders did not identify an alternate distribution method for SMQs. However, in narrative comments, several responders provided specific examples of additional distribution methods they would like to see. Of note, many items on this “wish-list” have, to date, already been addressed by MSSO, including provision of SMQ terms in Excel® spreadsheets for ease of “copy-and-paste” function.

Next steps

The SMQ survey was a success and yielded important information about the challenges and possibilities for the implementation and use of MedDRA. Based on the feedback from the survey, the MSSO will implement improvements to the SMQ documentation as well as taking advantage of all possible training and speaking opportunities to increase the awareness and knowledge of SMQs. As always, the MSSO is interested in hearing from our subscribers. Please see the following URL (www.meddramsso.com/MSSOWeb/SMQ/index.htm) to submit a new SMQ or change an existing SMQ. We are grateful to all of you who took the time to respond to our survey, and we look forward to addressing the “take-home” messages that the survey brought to light.



Ten Years of MedDRA at FDA— Dr. Lumpkin Shares His Thoughts

In November 1997, the US Food and Drug Administration (FDA) became the first organization in the world to begin to use MedDRA on real-time data. To commemorate this important milestone in MedDRA's history, the MSSO invited the FDA's Dr. Murray Lumpkin – Deputy Commissioner, International and Special Programs – to share his memories and thoughts on MedDRA at the FDA.

How did you first get involved with MedDRA?

In the mid-1990's, US FDA's CDER and CBER were looking for a more cost- and time-efficient way of processing suspected adverse reaction reports. We knew that most companies had them stored electronically in their corporate databases, and we stored them in our database electronically. But between the two systems, it all reverted to paper. Companies submitted individual reports of suspected adverse reactions to us on paper, and we then manually coded the event and entered all the information on the report into our system. With the numerous new drugs that were being authorized here and abroad at that time due to the added research spending in the 1980's, and the ever-increasing numbers of suspected adverse reaction reports we were receiving annually, we knew we had to convert to a system that was all elec-

tronic and that allowed as- seamless-as- possible, direct submission of individual reports from a company's database to ours. At that time, one of the major problem areas that prohibited such was the fact that most companies and we used multiple event coding systems, and, even worse, individual "versions" of more formal coding systems in use at that time, such as WHOART and COSTART. What was clearly needed was a "common" coding system that both industry and regulators used that was well maintained, of the right granularity to be helpful both in "coding into" and in researching "out of" databases, and that "automatically" put vernacular terms into consistent "preferred" terms.

We began working at that time with and trying to learn from our British drug regulatory colleagues about their new system of coding ("ADROIT") that had been developed under the leadership of the late Dr. Susan Wood and Dr. Louise Wood at the then-named Medicines Control Agency (UK MCA). It seemed rather obvious to all concerned that, if the British and we were thinking about using the same coding system, then this idea should be discussed as a possible ICH topic as a way of perhaps, using "ADROIT" as a base, to develop a well-maintained coding system that would be acceptable to regulators and industry in all the ICH regions. For industry, the "holy grail" was being able to code the event once and submit simultaneously to all the regulatory agencies worldwide that wishes to receive such reports. For US FDA, the "holy grail" was being able to receive consistently coded reports from all companies electronically without having to re-code and re-enter into our database.

At that time, I was the Deputy Center Director for Review Management at CDER.

One of the offices that reported to me at CDER was the office responsible for post-authorization safety assessments and that maintained our suspected adverse reaction report database. In addition, I had been the US FDA representative to the WHO's CIOMS post-authorization safety working group since the early 1990's and, through this forum, knew most of the leaders in international regulatory and industry in this field. I had a very keen personal interest in this area of the life of our pharmaceutical products, and, therefore, I became the lead for the US FDA team in the working group at ICH that took on this assignment.

How was the decision made at FDA to integrate MedDRA into AERS?

As mentioned in the previous answer, CDER and CBER were very much searching for a more cost- and time-efficient way of entering the ever-increasing number of suspected adverse reaction reports into our database. A well-designed, well-maintained, and well-recognized coding terminology that provided consistently and appropriately coded events was an integral, if not the pivotal primary part of our initiative to establish electronic reporting. Once the MedDRA terminology was agreed under the ICH process, US FDA made the decision to implement it as the coding basis for all of the reports in our system at that time and for all new reports that came into the system subsequently.

Who was the implementation team for integrating MedDRA into AERS?

I am sure I will leave some name out, so I'd prefer not to try to mention any specific names. Suffice it to say, it took a special effort by many, many people in

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MedDRA Activities at the US Drug Information Association (DIA Annual Meeting)

By Eric Lindamood
Manager, Products and Services

MedDRA was highly visible at the recent DIA Annual Meeting held in Atlanta, Georgia. As at previous annual meetings, the MSSO hosted a booth in the exhibit hall. MedDRA was also a topic in several sessions, and at the official MedDRA User Group Meeting.

The MSSO's booth provided the opportunity for many of our subscribers as well as potential future users of MedDRA to meet with MSSO staff. Information on subscribing to MedDRA, MedDRA training classes, and the 10th anniversary of the FDA's use of MedDRA was available to those who visited the booth. The MSSO MedDRA Browser was available on two workstations for browsing the English and translated versions of MedDRA.

Several presentations related to MedDRA were presented throughout the week. The MSSO's Dr. Patricia Mozzicato chaired a session on SMQs and the Data Retrieval and Presentation: Points to Consider Document. In addition, the DIA meeting featured a tutorial on MedDRA and MedDRA-related sessions on adverse event and medication error coding using MedDRA, and the FDA Adverse Event Reporting System (AERS).

After the close of the official DIA meeting, the MSSO conducted the MedDRA International User Group Meeting. The meeting was well attended by MedDRA subscribers. After a buffet lunch, the meeting proceeded with a presentation by the MSSO director, an SMQ panel discussion, presentation of the latest recipient of the Friend of MedDRA medal, and an open discussion session on MedDRA versioning.

The MSSO thanks all of those in the MedDRA community who stopped by our booth, attended a MedDRA-related session, attended the international User Group Meeting, or otherwise contributed to the discussion of MedDRA during the DIA Annual Meeting. We look forward to meeting even more of our subscribers at the upcoming DIA annual meetings in Barcelona (3-5 March 2008) and Boston (22-26 June 2008).

What's New for Version 10.1

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Seven SMQ suspended change requests involve questions and issues that are being presented to the SMQ Working Group as part of the 18 to 24 month SMQ review process. Other suspended change requests depend on complex changes to be resolved during MedDRA Version 11.0 development.

Highlights of the change impacts are the following. SOC *Psychiatric disorders* had the most changes (218). This was partially due to the implementation of the BRP "abuse" terms recommendation. SOC *Ear and labyrinth disorders* had the fewest changes (3).

There were 485 new LLTs added, including 218 new PTs. No new PTs or LLTs were added to SOC *Blood and lymphatic system disorders*.

There were 25 LLTs promoted and 95 PTs demoted. Of the 95 demoted PTs, 42 were demoted because newly added PTs were deemed better to represent the concept. There were 37 PTs that changed primary SOC, and 207 LLTs were impacted by the combination of primary PT changes and moved LLTs. Lastly, 13 LLT changed their currency status.

The MSSO has implemented 17 new SMQs in this release of MedDRA. One sub-search SMQ was promoted to level 1, *Torsade de pointes/QT prolongation (SMQ)*. It had formerly been a sub-search SMQ in *Cardiac arrhythmias (SMQ)*.

Friend of MedDRA

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

In 2007, the MSSO awarded the FOM medal to Christina Winter of GlaxoSmithKline at the March 2007 MedDRA International User Group meeting in Vienna, and to John ("Jake") Kelsey of FDA at the June 2007 MedDRA User Group meeting in Atlanta.

The MSSO looks forward to acknowledging future MedDRA users.





MedDRA TRAINING SCHEDULE SEPTEMBER – DECEMBER 2007

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

www.meddramssso.com/MSSOWeb/training/training.htm.

EUROPE

	CODING WITH MedDRA	ADVANCED CODING	MedDRA: SAFETY DATA ANALYSIS & SMQs
OCTOBER	Frankfurt, Germany 16 October	Frankfurt, Germany 17 October	
NOVEMBER	London, UK 21 November	London, UK 22 November	London, UK 22-23 November
DECEMBER	Frankfurt, Germany 4 December		Frankfurt, Germany 5 December

NORTH AMERICA

SEPTEMBER	San Diego, CA USA 25 September	San Diego, CA USA 26 September	San Diego, CA USA 26-27 September
OCTOBER	Chicago, IL USA 16 October		Chicago, IL USA 17 October
NOVEMBER	McLean, VA USA 7 November	McLean, VA USA 8 November	McLean, VA USA 8-9 November
DECEMBER	Orlando, FL USA 5 December	Orlando, FL USA 6 December	

WEBINARS

What's New in MedDRA 11.0 TBD	Use of Medication Error Concepts in MedDRA 10 October
MedDRA Coding Basics TBD	MedDRA for Statisticians & Programmers 14 November
MedDRA for the IT Professional 19 September	Introduction to MedDRA Data Analysis and SMQs for Physicians 12 December

NEW SUBSCRIBER TRAINING SESSIONS

Summer/ Fall 2007	Frankfurt, Germany 15 October	McLean, VA USA 6 November	Frankfurt, Germany 3 December
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REGULATOR TRAINING SESSIONS

Summer/ Fall 2007	London, UK 20 November
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Registration for all sessions can be accomplished through the MSSO Web site:

www.meddramssso.com.

AT&T toll free number: (877) 258-8280



MedDRA Course Descriptions

Advanced Coding: Coding Conventions and the MedDRA “Points to Consider” Document (½ 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)

This one-day course is designed to provide a basic understanding of the "how and why" development history of MedDRA, an introduction to the basic scope, structure, and rules of MedDRA terminology, and reviews the System Organ Classes that are unique to MedDRA. Additionally, it is designed for individuals involved with coding, those affected by coding guidelines and associated standard operating procedures, and those involved with synonym lists.

The course illustrates coding examples as they pertain to the scope of MedDRA, the differences between older coding terminol-

ogies and MedDRA, tools that support coding, and a hands-on approach to coding verbatims and narratives with MedDRA.

MedDRA: Safety Data Analysis and SMOs (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.

Webinar Topics:

Introduction to MedDRA Data Analysis & SMQs for Physicians (1.5 hour webinar session)

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 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 (2 hour webinar session)

The Statisticians 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 (2 hour webinar session)

MedDRA will soon become a regulatory requirement. Most organizations are taking advantage of the time now to de-

velop 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.

What’s New in MedDRA (1.5 hour webinar session)

The What’s New in MedDRA webinar is designed to provide information on changes incorporated into each new version release. Sessions are scheduled to coincide with the corresponding version release.

**All MedDRA courses and Webinars
are available for on-site presentation.**



On-site MedDRA Training: Training Module 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.

MedDRA Training: New Developments

The MSSO is continually interested in providing up-to-date, informative and useful information in our training courses. MedDRA courses are reviewed and revised twice a year to ensure version specific changes are incorporated into the presentation materials and that the general information – such as the regulatory changes involving MedDRA – is kept current.

Along with these periodic revisions to our courses, the MSSO training staff has completely revised the *Coding with MedDRA* course (previously named *Full Scope of MedDRA*), distilling and streamlining the information for efficient and effective delivery. The duration of the course has been reduced from 1.5 days to one day.

In response to subscriber feedback, a new 1.5 hour webinar on MedDRA data analysis and the use of SMQs was developed and will be offered in fall 2007. In comparison with the existing webinar *MedDRA for Statisticians and Programmers*, this course is focused on the medical perspective and intended for clinical research and pharmacovigilance physicians, regulatory affairs professionals, and medical writers.

In an effort to provide reasonably priced and more easily accessible training to all MedDRA users, the MSSO offers various MedDRA topics in a webinar format. Over the past year the MSSO has added several webinar topics to the list. Please access the following link to view the complete MedDRA MSSO course listing: www.meddramsso.com/MSSOWeb/training/courses.htm

Free MedDRA Training for New Subscribers

Since January 2006, the MSSO has been offering free training to new subscribers at the Basic, Core 0, and Core 1 subscription levels. Two slots are available per qualified organization and the training must be accomplished within the first year of the new subscription.

To date, many new subscribers have taken advantage of these specially scheduled classes. If your organization has not taken full advantage of this opportunity, the MSSO encourages your organization's participation.

The New Subscriber sessions cover the same material as is covered in the *Coding with MedDRA* open training course. The New Subscriber training schedule is listed under the Training tab on the MSSO Web site. Please click on the link below to view this schedule: www.meddramsso.com/MSSOWeb/training/newsuscr_trng.htm



Ten Years of MedDRA at FDA– Dr. Lumpkin Shares His Thoughts

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both center’s Information Technology offices, Post-authorization Safety offices, review divisions, offices of training, and many others to implement such a fundamental systematic change in the way we were doing this part of our business – and not just the “entering of reports”, but also developing the algorithms by which research, analyses, and investigations were performed; learning and teaching to others a new, much more granular coding system; and becoming “comfortable” with what it could and could not do. It was a huge amount of work that my CDER and CBER colleagues did with their usual aplomb.

What were some of the challenges and benefits that FDA discovered about MedDRA?

As I remember, the main challenge initially was trying to migrate our legacy database, which was extremely large, from the FDA’s version of COSTART, into MedDRA. There was no “translation” at that time for such, and such a “translation” had to be developed from scratch. My colleagues at CDER and CBER knew it was imperative, though, that they be able to search the entirety of our database to be able to do their jobs properly. And so, we ended up building a new IT system (AERS); transmigrating decades of legacy reports; developing algorithms for common searches; training people on a new system and a new, more granular, coding terminology; developing internal policies and procedures for using this new system; and developing guidances and rules for industry regarding our expectations of this new system – all at the same time. It was rather daunting, but, again, my colleagues at CDER and CBER performed spectacularly.

I think another challenge was being a member of an international maintenance board for an organization that was trying to meet the needs of a very varied international constituency. This was a new process for all of us, and, given that we were all novices, I think it went remarkably well. We had to learn the realities of international tendering, of establishing a legal entity under Swiss law (as the ICH Secre-

tariat was located in Switzerland); of understanding the nuances of and needs for multiple translations of an English-language based terminology; and of developing a pricing-structure that was acceptable to all of those with primary equities in MedDRA’s success (regulators, industry, and the MSSO).

But for all the challenges, the benefits of a recognized, implemented, well-maintained coding terminology were foundational for establishing a more cost- and time-efficient mechanism for processing and analyzing the vast amount of data in our suspected adverse reaction database. Without such, we would not have been able to meet this part of our public health mission.

If there is anything you could change about MedDRA today, what would that be?

Clearly this is a question you’d need to ask those who are involved with MedDRA at US FDA on a daily basis. I am now too far removed from the daily use of MedDRA to answer this from a functional perspective. However, from a broader viewpoint, I think one of MedDRA’s challenges, and thus one of ours, is how we integrate MedDRA into a world where medical records (and all that such a term defines) are clearly becoming more electronic. A decade ago, the idea of national electronic medical records, in the USA and in most countries, was an embryonic idea. With advances in information technology and with the desire to gain efficiencies in health care systems through information technology, this embryo is now much further along in its gestation. When MedDRA was developed, it had a very defined scope of applicability, as it was developed to address specific issues within the world of the regulation of pharmaceuticals. How that now all integrates into larger efforts to develop electronic “norms” for medical records is one of the major challenges. One would hope that those involved in such initiatives around the world would tap into the wealth of knowledge that exists in the MedDRA initiative regarding the “internationalization” and international acceptance of English-language based terminologies and regarding the appropriate maintenance of such.

What is MedDRA’s future at FDA?

US FDA is committed to using MedDRA for the purposes for which it was agreed under ICH – the international exchange and submission of suspected adverse reaction reports. We understand that for all of us in the international community to benefit as much as possible from the information in such reports, we must have a system that facilitates rapid and cost-efficient submission and analysis of these reports. As a member of the international community involved in such analyses, we are committed to MedDRA for this purpose.

We are also part of the US Department of Health and Human Services, and, as our department continues to develop a national electronic medical record for the United States, there are areas outside the scope of the agreements on MedDRA where US FDA must be an active participant to meet our statutory mission. People should not confuse US FDA involvement with the DHHS effort as a lack of support MedDRA and its agreed utilization in the international sphere.

The MSSO is very grateful to Dr. Lumpkin for his time and for his commitment to MedDRA, and we look forward to working with FDA to keep MedDRA up-to-date and user-responsive.