

10th Anniversary of MedDRA 1999 - 2009



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Quick Links...

**What's New for
MedDRA 12.0**

CTCAE Revision Project

All you need is...LLT

More 10th Anniversary...

From Early ICH to Current

Pre-MSSO MedDRA

Batman's Adventure...

MedDRA as ICH Initiative

MedDRA Timeline

**Sixth MedDRA BRP –
Register Today**

Double the MedDRA

MedDRA Training

MedDRA at 10 Years

By Pat Revelle
MSSO Director

As a boy, I remember turning ten years old and being impressed with myself that my age was now in double digits. Upon MedDRA's 10 year anniversary, I have a similar feeling but for very different reasons.

MedDRA in November of 1998 (when the contract was signed) was an exciting new project that needed a lot of work to get off the ground. We did not have a model to follow for an internationally maintained medical dictionary so we were on our own. The first release of MedDRA in March of 1999 was a heroic effort. We did not have much time to congratulate ourselves since the next release was due in just three months (MedDRA was initially released quarterly).

The maintenance process improved over the years to the point that we achieved and currently maintain an ISO 9001:2000 certification that involves regular external audits. A key lesson we learned early on was that the MedDRA user community is not shy in providing feedback on our performance and maintenance decisions. Some of the comments stung a bit but MedDRA and the maintenance process was the better for it.

I think it is also interesting to note the changes in technology during the 10 years of the MSSO. Our initial releases were available in paper, diskette, and CD-ROM (Yes, we had a number of subscribers requesting a hardcopy of MedDRA!). Now, MedDRA is only distributed in electronic format from the MSSO Web site.

MedDRA in 1999 was a hot topic but not always for the right reasons. The implementation of MedDRA in industry and regulatory authorities was not a simple task and, at times, the MSSO felt the heat from the users. This feeling changed over time as the MSSO staff came to know and develop working relationships with the user community. Through User Group meetings, industry meetings, and shared cab rides to the airport, the MSSO learned and applied important lessons from the users.

MedDRA is now a true international standard that is fundamental to the pharmaceutical industry. Our path to the MedDRA's 10 year anniversary has taken many turns. I am proud of what we have achieved with a collaborative spirit with the MedDRA community. ■

Click here to view the [MedDRA Timeline](#).



What's New for MedDRA Version 12.0

By Brian J. O'Hare
Manager, Terminology Maintenance

MedDRA Version 12.0 was made available to subscribers on 1 March 2009 from the MSSO Web site <http://www.meddramsso.com/translations/downloads.htm>. There were a total of 2,624 change requests, including SMQ changes, processed for this version; 1,937 change requests were approved and implemented, and 623 change requests were rejected. There are, in addition, 64 change requests suspended for further consideration and resolution beyond this version.

MedDRA v12.0 is a complex change version which means changes can be made at all levels of the MedDRA hierarchy. Above the PT level, 2 HLGTS were added and 1 HLGTS merged. At the HLT level, 14 HLTs were added, 1 HLT renamed, and 3 HLTs merged. Please see the "What's New MedDRA Version 12.0" document for specific details.

quality terms. A new HLGTS *Product quality issues* was added to SOC *General disorders and administration site conditions* that contains five new product quality HLTs. There were 139 new PT and LLT terms added and 24 existing PT/LLT terms moved under the product quality HLTs, for a total of 163 terms.

SMQs

Seven new level 1 SMQs were released into production in MedDRA v12.0. There are now 74 level 1 SMQs in production as of this version.

Three types of changes were made to SMQs. First, new sub-SMQs were added to group previously ungrouped PTs in a few hierarchical SMQs. Please review the SMQ Introductory Guide and SMQ Spreadsheet for detailed information.

Number of Terms: MedDRA Version 12.0	
System Organ Classes (SOC)	26
High Level Group Terms (HLGT)	333
High Level Terms (HLT)	1,699
Preferred Terms (PT)	18,483
Lowest Level Terms (LLT)	67,159
Standardised MedDRA Queries (SMQ)	74

The second change that occurred to SMQs in v12.0 was to the scope of PTs in the SMQ *Haemorrhages* after a review by the MSSO and the CIOMS SMQ Working Group. Specifically, sub-SMQ *Haemorrhage terms (excl laboratory terms)* – which comprise all clinical terms describing hemorrhages – were changed from broad to narrow scope. Terms in sub-SMQ *Haemorrhage laboratory terms* remain as broad scope with four exceptions: PT *Blood urine*, PT *Blood urine present*, PT *Occult blood positive*, and PT *Gastric occult blood positive*.

The third change to the SMQs was to reduce the number of characters used in the description information field for five SMQs in the SMQ ASCII files. This was done to accommodate space constraints of the description field that were exceeded when translating the descriptions from English into other languages. To correct this problem, the English descriptions were shortened.

The majority of complex changes resulted from two initiatives.

The first initiative came out of recommendations from the fifth Blue Ribbon Panel (BRP), held in November 2006, to divide large HLTs and HLGTS into smaller groupings. These recommendations resulted in the addition of seven new HLTs and the renaming of one HLT.

The second initiative was a proposal by the United States Food and Drug Administration (FDA) to include a set of product quality terms in MedDRA so a single coding system could be used for both adverse events and product quality issues. The MedDRA Management Board approved the proposal to implement the product quality terms in MedDRA v12.0. With input from the MedDRA Expert Panel, the MSSO Medical Team reviewed and processed the change requests of product

Documentation and Version Package Changes

Beginning with MedDRA v12.0, there will no longer be separate downloads for the ASCII, Sequence, and User documentation files. Instead, there will be a single zip file for each language currently available that will contain the ASCII, Sequence, and User documentation files. In addition, the English language download will include three files that were previously available as separate downloads. These files are: the Version Report, the Detail Report, and the SMQ Spreadsheet.

Continued on page 10



The CTCAE Revision Project and MedDRA

By Anna Zhao-Wong, MD, PhD
Deputy Director, MSSO and
Manager, Terminology Development and Services

The Cancer Therapy Evaluation Program (CTEP) of the National Cancer Institute (NCI) has developed the Common Terminology Criteria for Adverse Events (CTCAE) for adverse event reporting in oncology clinical trials. CTCAE is a descriptive terminology of approximately 1,000 adverse event (AE) terms (in v3.0) commonly encountered in oncology, each with an associated severity grading scale.

In order to facilitate data exchange within organizations' own internal databases using MedDRA and for regulatory reporting purposes, a mechanism for "translating" reported CTCAE terms into MedDRA is needed. The MSSO and CTEP therefore jointly developed a mapping of the base AE terms in the current version of CTCAE v3.0, to MedDRA Lowest Level Terms (LLTs). The mapping has been updated annually in March in conjunction with MedDRA complex releases, the most recent being a mapping of CTCAE v3.0 to MedDRA Version 11.0.

The mapping can be a useful starting point for translating CTCAE concepts into MedDRA; however, it is imperfect and has unresolved challenges in its application based on the fundamental differences in scope and structure of the two terminologies. For example, some CTCAE terms combine separate concepts - such as an infection and a specific neutrophil count. In MedDRA, these are represented as two separate medical concepts at the PT/LLT level. In CTCAE's severity grading scale, some base AE terms have critical medical concepts embedded within the grade descriptions. For example, "Anaphylaxis" is embedded as the grade 4 concept (life-threatening severity) for the base term "Allergic reaction/hypersensitivity (including drug fever)."

In April 2006, the MSSO convened a Blue Ribbon Panel of experts to discuss CTCAE to MedDRA mapping issues. One of the key recommendations of the Panel was for stakeholders to address the optimal use of the terminologies and to modify them if needed to achieve harmonization.

In 2008, various NCI groups – including CTEP, the Center for Biomedical Informatics and Information Technology, and the Cancer Biomedical Informatics Grid – jointly initiated the CTCAE v3.0 revision project. The goals of the revision are for CTCAE to be integrated with NCI data systems and to be compliant with MedDRA. This latter goal will be achieved by representing all CTCAE term concepts as MedDRA LLTs and by replacing CTCAE categories with MedDRA System Organ Classes (SOCs). Critical medical concepts that were previously embedded in the grade descriptions will be listed as unique AE terms. The CTCAE grading definitions will also be reviewed for possible modifications. As a result of CTCAE becoming MedDRA-compliant, there will be no need for a mapping between the new CTCAE v4.0 and MedDRA.

Participants in the revision project include NCI, FDA, MSSO, and international representatives from biopharmaceutical companies and cancer centers. Good progress has been made and CTCAE v4.0 is expected to be available for public comment in Spring 2009. Interested subscribers are encouraged to visit the MSSO Web site for further information about the project at http://www.meddramsso.com/MSSOWeb/activities/archive_brp.htm#CTCAE. ■

WE WANT YOUR FEEDBACK!

PLEASE CONTACT US

**TOLL FREE INTERNATIONAL 877-258-8280 (AT&T)
DIRECT: 703 272-5505 (USA) FAX: 703-272-5635 (USA)**

EMAIL: MSSOHELP@NGC.COM

WEB SITE: WWW.MEDDRAMSSO.COM



All you need is...LLT

By Patricia Mozzicato, MD
MSSO Chief Medical Officer
Patrick Revelle, MSSO Director

One of MedDRA's most important and useful features is its hierarchical structure, including its primary and secondary SOC assignments. The PTs, SOCs, and grouping terms (HLTs and HLGTs) allow coded data to be presented in ways that are medically meaningful and yet flexible.

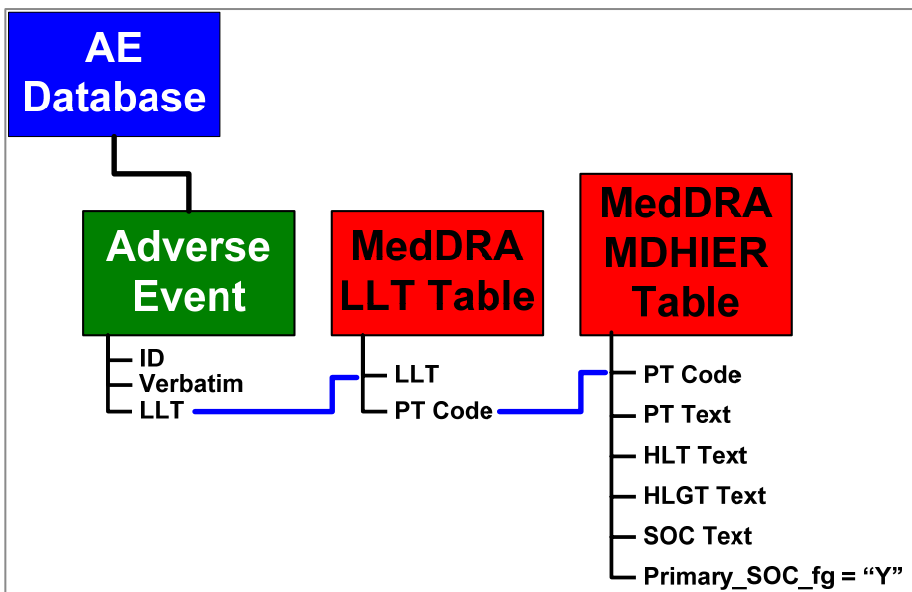
For coding with MedDRA, the user selects the LLT that most closely resembles the reported verbatim information. Through encounters with MedDRA users, the MSSO has learned that some organizations' coding systems require the coder to not only select the LLT, but also to manually select or input the other hierarchy levels (PT, HLT, etc.) to which that LLT is linked. Such users say they need to do this in order for their system to output the coded data (e.g., tables, line listings) with the MedDRA hierarchy represented.

The MSSO thinks such steps are unnecessary to take full advantage of the hierarchy, and there is potential for human error. Also, by storing the full hierarchy, the organization is requiring additional maintenance of the data. From one version to the next, several types of changes could occur for an existing term including changes to the hierarchy. Even though verbatim information may still be appropriately coded to the LLT in question, the hierarchy will need to be reviewed to ensure no changes have been made. *By simply storing the LLT selected*, the organization can later retrieve or present the data and its hierarchy by taking advantage of the MedDRA file structure.

Some simple programming is all that is needed.

All MedDRA LLTs are linked to one and only one PT. By storing the LLT – (the code is all that is absolutely necessary) – and the MedDRA version of the data, a simple query can be developed to provide the full primary hierarchy of any MedDRA term. The diagram below shows a simple relationship (see blue connections) between an adverse event (green table) and the MedDRA LLT and MDHIER tables (red tables, distributed with each release of MedDRA) to produce the full primary SOC hierarchy.

The same approach could be taken to show either all SOC assignments (i.e., remove Primary_SOC_fg from query above) or secondary SOC assignments (i.e., re-



place the "Y" with "N" related to Primary_SOC_fg in the query above).


The MSSO hopes this is useful information to organizations that are coding and outputting their data. If you have any additional questions about the programming steps described, please contact the MSSO Help Desk at mssohelp@ngc.com.





10th Anniversary of MedDRA – from early ICH activities to current situation

By Yasuo Sakurai and
Reiji Tezuka, Japanese Maintenance Organization

 We have a leaflet entitled “MEDDRA NEWS” issued in February 1994 by the MEDDRA Project where Dr. Louise Wood of MCA is noted as the coordinator. With this leaflet, our long time involvement with MedDRA began, first as representatives from users of the industry and later as members of the maintenance organization, JMO.

In 1993, the MEDDRA Working Party started, with representatives from the MCA, other European regulatory authorities and industry and finally involving observers from US, to develop a standard medical terminology within European society. In the fall of 1994, the ICH Steering Committee decided to develop an international medical terminology and to adopt MEDDRA as the basis for its development. MEDDRA version 1.0 was released in November 1994 to relevant and interested organizations around the world to seek their comments. After these preparatory measures, in March 1995, the ICH M1 EWG was held for the first time with Dr. Susan Wood of MCA as the Rapporteur. With her strong leadership, M1 EWG made a tremendous effort to adjust differences in opinions among the three ICH regions, finally reaching consensus in July 1997. This medical dictionary was renamed from MEDDRA (Medical Dictionary for Regulatory Affairs) to MedDRA (Medical Dictionary for Regulatory Activities). At this time, all relevant copyrights were transferred from all ICH sponsors to IFPMA. Without the incredible dedication of the M1 EWG members, particularly Dr. Susan Wood, the completion of

MedDRA would not have been possible.

The ICH agreement on MedDRA included the establishment of an appropriate international maintenance organization.

The Japanese M1 EWG members worked for incorporating the Japanese Adverse Drug Reaction Terminology (JART) into MedDRA because MEDDRA version 1.0 did not include it. They also made a preliminary Japanese translation of MedDRA. Through these activities, we frequently became aware of differences between the United States, European countries, and Japan in their cultures and habits, which affect their languages; the letters they use; and their medical habits and definitions. We strongly felt the necessity of establishing a maintenance organization in Japan in order to make an international terminology as MedDRA accepted widely in Japan. Therefore, the Japanese Maintenance Organization (JMO) was established at the same time as the establishment of the MSSO.

Currently MedDRA is used widely in Japan. One of the reasons is that electronic ICSR reporting is mandatory in Japan. As the Japanese people are known for their characteristically high compliance with regulations, the use rate of E2B/M2 reporting with MedDRA is almost 100%. However, they tend to pay less attention to optional uses of MedDRA features such as SMQs, which are not compulsory, and even those who show some interest may not actually adopt them. Being strict on compliance, they are also strict in demanding a high-level of accuracy in translation. In particular it is much more difficult for us to translate general expressions in English than technical

terms. There are some differences between the English and Japanese versions of MedDRA: The Japanese version is presented along with the English version so that users can always compare the two with each other; the Japanese version has an additional flag for those cases in which multiple English terms are translated into one Japanese term, such as British and American spellings; And there is a sub-file for Japanese synonyms, which supports the cases in which multiple Japanese terms are translated into a single English term.

It is expected that the use of MedDRA will be extended beyond the three ICH regions, increasing its importance as an international medical terminology. JMO is ready to contribute to its development through the maintenance of the Japanese version.

If you are interested in how the Japanese or English version of MedDRA is used in Japan, please contact info.jmo@sjp.or.jp. ■



Personal Perspectives of pre-MSSO MedDRA

By Christina Winter
GlaxoSmithKline

Prior to MedDRA, the existing coding dictionaries were not ideal for drug reactions and had been customised by individual users, thus making them unsuited to electronic data exchange. In 1994, I joined a working party at the MCA (now the MHRA) to review the MCA's ADROIT dictionary. These industry representatives and regulators (UK, Spain and France, with FDA and WHO as observers) had masses of "homework" and very few meetings. One board style meeting room had threadbare carpets as refurbishment was imminent. There was little elbow room, as we were working from giant heaps of paper copies. The print was small and I was seeing spots by lunchtime. The riverside view of central London from one of the upper floors at lunch break restored my visual acuity for the afternoon session. MEDDRA (Medical Dictionary for Drug Regulatory Affairs) resulted from our efforts in 1995.

The terminology was adopted by ICH and in 1997, I was delighted to be invited to represent EFPIA in the ICH M1 Expert Working Group, replacing Elliot Brown who left industry for the MCA. At the Narita ICH M1 EWG meeting, secondary SOC's were assigned by one representative

shouting out the PT and others calling out secondary links; the minute taker was hard pressed to keep up. One of us had a CD Rom version of Stedman's and the rest of us had paper copies of other medical dictionaries. It became a race to see who could find the required definition quickly; the CD Rom won hands down. Secondary links for the Investigations SOC were debated and finally proved impossible to assign. We also struggled with the primary SOC allocation of some neurology/psychiatry terms.

Contrary to popular belief, I found that ICH travel did not allow one to "see the world." The task took all day and there were often pre or post dinner discussions. The hotel was in a wooded location an hour by fast train from Tokyo and I did not fancy seeing Tokyo in the dark. Some desperate colleagues went to Tokyo for dinner one night and reported that they found pizza; not what I'd have expected! When I got home, no one would believe that all I had seen were beautiful Japanese koi carp in the hotel pond and Narita airport. However, this was the beginning of years of working with colleagues from ICH regions and the start of many friendships. ■

Batman's Adventure with MedDRA

By Barry Hammond
GlaxoSmithKline

I joined the pharmaceutical industry in 1990 to fill a newly created role in Glaxo dedicated to coding and terminology management. After initial induction, I clearly recall being taken on a long walk to the far side of the site to meet the Head of Data Management, Mervyn Mitchard, where I was also given a big hug from one of his management colleagues, such was the delight at having this long awaited role in place. Although it made me feel very welcome, I would have been happy with a handshake and I wondered what I had let myself into! Little did I know at the time that Mervyn Mitchard was to become a founder member of the MedDRA Management Board and I would also join the Board later.

In the world I entered I found there were two different medical terminol-

ogies, one based on COSTART and used for pharmacovigilance, and one based on ICD9-CM used for pharmacovigilance and clinical trials. My role was based in a computing department, due to the database management aspects, but all coding was performed manually by the Safety Scientists and Data Managers, and only the 'difficult' terms were supposed to be referred to the new 'Dictionary Administrators.' What was perceived as 'difficult' could range from misspellings (or misreading of what was hand written on the forms) and other minor variants of existing terms in the dictionary to as yet unclassified but valid medical terminology, completely unintelligible ramblings from the site or exact matches of terms already in the dictionary but not noticed.

Having developed coding terminology for entering data into pathology laboratory systems before joining

Glaxo, I was delighted when I was able to join a team developing new in-house coding dictionaries and tools to address perceived deficiencies in the existing in-house and external clinical dictionaries at that time. By 1992, a new multilevel hierarchical medical terminology called MIDAS was born, along with an autoencoder and dictionary management tools. Coding workload rocketed as the granularity of the coding increased significantly, and thousands of synonyms needed to be assigned to the dictionary to enhance autoencoding. It was during this hectic period that I first met Christina Winter, a physician with a keen interest and understanding of terminologies, and soon appreciated her ability to give guidance for the placement of awkward terms.

MIDAS was a revelation and the benefits of increased automation,

Continued on page 7



Batman's Adventure with MedDRA

Continued from page 6

was a revelation and the benefits of increased automation, coding consistency across both pharmacovigilance and clinical trials supported by a central coding team, and detail available in coding reports soon emerged. Although MIDAS continued to grow and survived a merger, it was just populated with the terms encountered within the company and was only seen as a standard within the company. The next revelation was MedDRA.

From 1994 Christina Winter and I developed a complementary partnership in the development of MedDRA. Christina was involved in the clinical development of the terminology from ADROIT to MEDDRA (Medical Dictionary for Drug Regulatory Affairs) and after adoption by ICH as MedDRA (Medical Dictionary for Regulatory Activities). I was involved with the user testing of early versions. As MedDRA would be more dynamic than most existing terminologies, a key role for me, as implementation approached, was advising on what would be needed to maintain and develop MedDRA to ensure that it remained responsive to industry and regulatory needs and developments. Finally, in 1999, MedDRA 2.0 was released along with a new maintenance organisation, the MSSO, with an ICH MedDRA Management Board (MMB), and the challenges of implementation began. For MedDRA to be successful it had to be both widely and consistently implemented and many change projects had to be justified to adapt or create new systems and processes.

To help to address the consistency, I joined the ICH M1 Points to Consider (PTC) Expert Working Group. The first few meetings seemed to focus on agreeing what coding was and what to call our document, but once this hurdle was passed the group soon became a highly cooperative and productive team, and developed the

much needed Term Selection guidelines. Now we not only had a standard medical terminology but also a standard way of using it. The PTC group has gone from strength to strength, with guidelines now covering term selection and retrieval and most company and Regulator working practices are based on the PTC document. I was privileged to be the PTC Rapporteur for a year and Christina is now moving the group forward as Co-Rapporteur.

Communication and collaboration were key aspects in the rollout of MedDRA. In addition to the MMB and PTC activities, Industry and User Group meetings were important vehicles to gather and share MedDRA knowledge and issues. In Europe, Christina and I were founder members of the very active European MedDRA Users Group, which evolved from informal collaboration between three companies, and of the EFPIA MedDRA Topic Group, creating a communication chain to and from the MMB. Other important meetings included those hosted by the DIA, SCDM and ACDM as well as many commercial organisations. Later came the collaboration with CIOMS to develop SMQs. Christina and I continued our complementary partnership, agreeing how to share work and who should attend which meeting, but often both of us would appear at a meeting to address different aspects. We found that this partnership did not go unnoticed, and when we arrived for a European MedDRA Users Group meeting in Copenhagen we found our places at the table labelled as 'Batman' and 'Catwoman.'

Back in the office, the huge task of converting to MedDRA had to be addressed. After two mergers, we now had over 600,000 unique verbatims that could be mapped to MedDRA, systems needed to be changed, new processes needed to be agreed and documented and we needed to con-

vince our users that MedDRA was the future. With tasks prioritised, safety terms were mapped first in time for the first EMEA MedDRA mandate in January 2002, new clinical trials adopted MedDRA from the start and data from older trials was converted later. Over time, tuning of the autoencoder to increase hit rates and centralising failure resolution to the coding group has considerably decreased the effort needed to code data to MedDRA, while also increasing the consistency, and the challenges have now shifted towards analysis of the coded data. MedDRA has been accepted as the standard terminology, and even though not all agree with the placement of terms, there is reassurance that it is the same for everybody.

For Batman, MedDRA has been a hugely worthwhile and successful initiative to work on. The highly collaborative nature of the project has been highly rewarding and I have established many friendships which I hope will long continue as MedDRA continues to evolve. ■

MedDRA MSSO
3975 Virginia Mallory
Drive
Chantilly, VA 20151
USA

Toll Free International
877.258.8280 (AT&T)
Direct
703.272.5505 (USA)
FAX
703.272.5635 (USA)

MSSO-DI-7193-1.0.0



MedDRA as an ICH Initiative Today

By Morell David

UK Medicines and Healthcare
Products Regulatory Agency (MHRA)

The MSSO asked: *As a member of the original M1 EWG, how do you view MedDRA as an ICH initiative today?*

Morell David's response:

Sixteen years ago a fresh-faced young man started work at the UK regulatory agency with the ambition of making a contribution to protecting the public health of UK citizens. At the beginning of his second year in the UK agency he had a discussion with a colleague about some plans that were afoot to develop an international medical terminology (IMT). The colleague had intimated that a small group of key opinion leaders from the Pharma industry and several regulatory agencies had formed a working party with the intention of reviewing the available medical terminologies and make recommendations about which terminology was suitable for further development to create the IMT. He wished the colleague good luck with the project and went away without a second thought. Little did he know that this causal conversation about medical terminology in the corridors of the UK agency would have a major impact on his life and the practice of pharmacovigilance some 16 years later!

In the spring of 1995, about two years after the initial conversation about the IMT, there was great excitement among my colleagues regarding an advertisement that had been placed in one of our internal recruitment magazines for a Deputy Project Coordinator to help with an international project. The project board were looking for someone who had project management experience, was organised, a good communicator and who was not afraid of big challenges and meeting new people. I could not see why people were so excited about this

role, even if the advertisement said that “the successful candidate will get the chance to travel to all ICH regions.” After all, the project was about medical terminology, and what was exciting about that?

Looking back now I am not sure why I said yes when I was asked if I had any interest in taking on this role “which was going to be pivotal to the future development of pharmacovigilance.” It could have been the several attempts of emotional blackmail, flattery, or the offer of more pay! Whatever the reasons were, I said yes and started my apprenticeship under the “two Woods” (Susan and Louise).

The Deputy Coordinator (DC) was a key member of the ICH M1 Working Group (M1), with responsibility for arranging the meeting agenda, transporting all of the key documents for the meetings (which required an additional suitcase) and for looking after the welfare of the M1 members. In addition, the DC was responsible for taking meeting notes, recording action points and for overseeing the agreed changes to the terminology once he was back at base and distributing some of the earlier versions of the terminology.

At the time my colleagues were envious because I was seen to have this glamorous life style of travelling to exotic places and dining in fancy restaurants. They were not aware of the sleepless days and nights that I had to deal with due to severe jetlag and still maintain my composure and stay alert during a 10 hour meeting. I recall vividly one meeting in Japan where we sat for 5 long days reviewing each MedDRA Preferred Term (PT) in detail as part of the Feschareking process (a technique developed by Dr Reinhardt Fescharek) where each term was checked for potential multi-axial linkages. Painful! In those early years I just could not see how we were ever

going to reach agreement on the scope and content of this new terminology. Apart from the enormity of the task there were always the issue of misunderstandings due of cultural, language and political differences which had to be addressed and handled sensitively. But somehow trust and respect won the day and the project progressed and was finally delivered to the Maintenance and Support Services Organisation (MSSO).

Here we are 16 years after the project started and 10 years after establishment of the MSSO, celebrating what has been the most successful ICH project ever. MedDRA has met most of the aims that were envisaged in 1993. It is a global brand which has enabled electronic regulatory communications and removed the need for home grown terminologies. It is used by regulators, the Pharma industry and academic researches and it has overcome the lack of specificity and maintenance issues of other terminologies. But the greatest achievement is that for the first time we have an international recognised terminology which provides users with the ability to classify/code a wider range of information (indications, investigations, etc.) as well as adverse events using a single medical terminology. MedDRA is also pivotal in all of the other key ICH products such as E2B, e-CTD, ESTR1 (M2). Without MedDRA many of these products will not function fully.

I am privileged to have been part of this great success story and to see how this ICH product which was intended for use in the ICH regions has blossomed and grown in 10 years to become the terminology that is used on a global scale for protecting the public health of the world's citizens. ■



Sixth MedDRA Blue Ribbon Panel Scheduled — Register Today!

By Dr. Patricia Mozzicato
Chief Medical Officer, MSSO

The MSSO's sixth Blue Ribbon Panel is scheduled for 13 May 2009 at Schering-Plough in Kenilworth, New Jersey, USA. The topics for the Panel discussion are the extent of versioning and the potential for an annual release of MedDRA.

Blue Ribbon Panels were developed to provide a forum for MedDRA experts from industry and regulatory authorities to discuss and make recommendations on challenging MedDRA issues on behalf of the user

community. Following the meeting, the Panel's recommendations on these issues will be submitted to the MedDRA Management Board for its consideration.

Registration for the meeting is free, but space is limited, so please register today at <http://www.meddramsso.com/MSSOWeb/activities/blueribbonpanels.htm>.

If you have any additional questions about this Blue Ribbon Panel meeting, please contact the MSSO Help Desk at mssohelp@ngc.com. ■

Double the MedDRA

By Scott Vitiello
MSSO Customer Operations

Subscribers will be able to double their MedDRA experience with two meetings held back to back on 26 March 2009 at the Concorde Hotel in Berlin, Germany. The MSSO will conduct its annual MedDRA User Group meeting which will be followed by the MedDRA EU Informal User Group meeting hosted by Bayer Schering Pharma. For MedDRA users this will provide an opportunity to gain additional knowledge and experience from experts in the pharmaceutical industry.

The program for the MedDRA User Group meeting consists of:

- An overview of MedDRA and the MSSO (Pat Revelle)
- Presentation on MedDRA versioning (Jane Knight of Roche)
- New MedDRA desktop browser (Pat Revelle)
- Product Quality Terms in MedDRA (Patty Mozzicato, MSSO)
- Subscriber Forum (Question and Answer session): Nathalie Dubois (The European Organization for Research and Treatment of Cancer) and Dr. Simon Voss (Lilly UK) will discuss the upcoming CTCAE revision.

In addition, the latest Friend of MedDRA award recipient will be announced.

The program for the MedDRA EU Informal User Group meeting consists of:

- Discussion of the upcoming Blue Ribbon Panel on extent of versioning/potential for annual MedDRA release (Pat Revelle)
- Interdisciplinary Coding Approach Both Organizationally and In Process (Martina Viell of Bayer Schering Pharma)
- Company Specific Concepts for Aggregation of MedDRA Coded Data - the GSK and Bayer Schering Pharma Experience (Christina Winter, GlaxoSmithKline and Carol-Ann Wilson, Bayer Schering Pharma)
- Impact of Application of SMQs to Data that were Converted to MedDRA via Mapping Tables (Hilary Vass, AstraZeneca)

Subscribers who would like to attend either meeting should register at the MSSO Web site: <http://www.meddramsso.com/MSSOWeb/activities/usrmtg.htm>. ■

What's New for Version 12.0

Continued from page 2

In previous versions, the Detail Report contained only the approved change requests for a version. Beginning with MedDRA v12.0, the Detail Report will list all requested changes for the version (e.g. add a Preferred Term (PT), move an LLT, etc), the result of the request (e.g. approved, approved not as requested, or rejected), the final placement of the term (if not rejected or suspended), and MSSO comments. As a result of combining both accepted and rejected requests, the Detail Report will replace the following reports: the Change Request Rejection Report, the Approved Terms Report, and the current format of the Supplemental Update Reports, which contain weekly change request activity. Weekly supplemental updates of the Detail Report will be available on the MSSO Web site at <http://www.meddrasso.com/translations/downloads.htm>.

A new ASCII file, meddra_release.asc, has been added to the established set of MedDRA ASCII files. This is an optional file for use with the MedDRA Desktop Browser Release 3.0 Beta (MDB3.0b) that is expected to be available to subscribers in March 2009. The file contains version and language information for the accompanying set of ASCII files that allows MDB3.0b to identify a specific version and language when loading the ASCII files. The new file is included with the ASCII files of previous MedDRA versions found on the MSSO Web site at http://meddrasso.com/Translations/release_archive.htm.



Please visit us at the Drug Information Association Annual Meetings

EuroDIA Annual Meeting

Berlin, Germany
23-25 March 2009

US DIA Annual Meeting

San Diego, California USA
21-25 June 2009

and the MedDRA User Group Meetings

MedDRA User Group Meeting

Berlin, Germany
26 March 2009

San Diego, California USA
26 June 2009

Acknowledgement

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MedDRA Training Schedule **SPRING 2009**

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

Europe:

	CODING WITH MedDRA	ADVANCED CODING	MedDRA: SAFETY DATA ANALYSIS & SMQs
April	Düsseldorf , Germany 23 April 2009		Düsseldorf , Germany 24 April 2009
June	Düsseldorf , Germany 25 June 2009		Düsseldorf , Germany 26 June 2009

North America:

March	Washington Metro Area, USA 17 March 2009	Washington Metro Area, USA 19 March 2009	Washington Metro Area, USA 18 March 2009
April	San Francisco, CA USA 21 April 2009	San Francisco, CA USA 23 April 2009	San Francisco, CA USA 22 April 2009
May	Princeton, NJ, USA 19 May 2009		Princeton, NJ, USA 20 May 2009

Webinars:

MedDRA Coding Basics Please refer to the Free Webinars in the table below.	Introduction to MedDRA Data Analysis and SMQs for Physicians Please refer to the Free Webinars in the table below.
Introduction to MedDRA TBD	
MedDRA Versioning Updates Coming soon	What's New in MedDRA 12.1 Coming in August 2009 (2 sessions)

Free Training Sessions for Subscribers:

	Coding With MedDRA	Introduction to MedDRA Data Analysis and SMQs for Physicians (class)	Free Webinar
March	London, UK 16 March 2009	London, UK 17 March 2009	
	Chicago, IL, USA 24 March 2009	Chicago, IL, USA 25 March 2009	
April	London, UK 20 April 2009	London, UK 21 April 2009	
	Princeton, NJ, USA 21 April	Princeton, NJ, USA 20 April 2009	Introduction to MedDRA Data Analysis and SMQs for Physicians Webinar 29 April 2009
May	Düsseldorf , Germany 19 May 2009	Düsseldorf , Germany 20 May 2009	
June	San Diego, CA, USA 17 June 2009	San Diego, CA, USA 18 June 2009	MedDRA Coding Basics Webinar 4 June 2009
	London, UK 18 June 2009	London, UK 19 June 2009	

Registration for all sessions can be accomplished through the MSSO Web site Training page:
<http://meddramsso.com/MSSOWeb/training/training.htm>. AT&T toll free number: (877) 258-8280