MAY 2002

MESSENGER

Published quarterly by MedDRA® MSSO for our subscribers

Introducing the MedDRA MSSO Medical Team

The MedDRA MSSO has undergone many changes during the past three years, especially in the areas of operations and staffing.

In many cases staffing changes were the result of either natural staff turnover or TRW organizational restructuring.

The most important staffing changes, however, have come from changes in the MSSO operational processes.

Originally, the MedDRA MSSO medical review processes were subcontracted outside of TRW. During the second year of MSSO operations these important processes were brought inside the MSSO and under its direct control.

To support and expand its medical resources, the MSSO has increased in the number of staff members with medical expertise, from three people to ten. The ten members of the MedDRA MSSO Medical Team possess a wide range of background experiences in healthcare.

The team is international, with members educated in France, Germany, Spain, China, India, and the United States. The MSSO also has a partnership in Japan with MedDRA Japanese Maintenance Organization (JMO).

Medical team members participate individually in various MSSO activities such as data conversion, terminology maintenance, training, consulting, and MedDRA needs assessments.

The team also acts as an internal policy review board that meets formally twice a year to discuss issues and questions facing the MSSO, and informally though emails and internal web sites to review documents, term placement questions, and general dialogue. Team members have been very active speaking at various conferences as MSSO representatives.

A collective background in the biopharmaceutical industry and regulatory environments is a team strengh.

MedDRA implementation can be a new experience for some. Many of the Medical Team members have been involved with actual MedDRA implementations, and they are able to provide "real life experience" advice on avoiding implementation pitfalls through consulting services.

The team is also leading the way within the MSSO by working with subscribers to develop search techniques to demonstrate the value of MedDRA as an analysis tool.

The MedDRA MSSO staff

Key members of the MSSO. A brief biography is included for the medical support team.

STAFF

Director MedDRA MSSO
Jim Mundell
Director MedDRA Services
Patrick Revelle
Manager Customer Operations
Elizabeth d'Alelio
Manager Business Operations
Barry Nelen

MEDICAL TEAM

Medical Officer USA
Patricia Mozzicato, M.D.
Medical Officer France
Yanne Douçot-Hermelin, M.D.
Medical Officer Germany
Eva-Beate Rump, M.D.
Medical Officer Spain
Tomás Moraleda Garcia, M.D.
Manager Terminology Maintenance
Marvin Meinders, D.V.M., M.P.V.M.
Term Placement Medical Analyst
Anna Zhao-Wong, M.D., Ph.D.
Medical Analysts
Nandini Mehrotra, M.D.
JoAnn Medbery, R.N., B.S.N.
Carolyn Tanzola, R.N., B.S.N.
Carol McCullough, R.N., M.B.A

The MedDRA Medical Team

YANNE DOUÇOT-HERMELIN (FRANCE)

With more than 20 years experience as a medical doctor and a CRO specialist for pharmaceutical companies, Yanne Douçot-Hermelin, M.D., brings extensive knowledge of clinical research to the team, serving as the MSSO's French International Medical Officer.

Before joining the MSSO in 1999, Douçot-Hermelin served as Quintile's clinical operations director, overseeing a team of 60 scientists. She has written clinical trial protocols and CRFs, moni

Continued inside

MedDRA MSSO Medical Team

Continued from front page

tored trials, managed activities, conducted coding and analyzed results.

In addition, she worked in pharmacovigilance management, regulatory affairs, quality assurance, and project management of worldwide clinical trials in a variety of disciplines.

YANNE DOUÇOT-HERMELIN

Douçot-Hermelin received her medical degree at Paris Medicine University and did a residency in surgery and obstetrics. Her studies include biostatistics, toxicology, marketing, and biomedical ethics.

CAROL MCCULLOUGH (UNITED STATES)

Carol McCullough, R.N., M.B.A., supports legacy data conversion projects and the development of training materials, particularly the AutoCode CS™ 3.0 software program.

CAROL MCCULLOUGH

Before joining the MedDRA team, McCullough served as an advisor to PERI on professional development and continuing education accreditation. She served as the ICH coordinator and as staff liaison to the Pharmaceutical Research and Manufacturers Association from 1988 to 1995, providing professional development support for the clinical data management, project management, information management, and R&D finance groups. In 1992, she earned the PMA President's Exceptional Service Award for her contribution to the ICH project.

McCullough received a diploma in nursing from the Charleston General Hospital School of Nursing in Charleston, WV, and an M.B.A., concentrating in information management, from Marymount University in Arlington, VA. Her nursing career spans management roles in the specialties of eye, ear, nose, and throat; teaching and clinical supervision; orthopedic, cardiovascular, and genitourinary surgery; and administration of ambulatory care services.

JOANN MEDBERY (UNITED STATES)

JoAnn Medbery, R.N., B.S.N., has primary responsibility for MedDRA training at MSSO, and is its representative to the MedDRA Management Board/ICH working group for the MedDRA Points to Consider document. Her responsibilities include AutoCode CS™ training, MedDRA consulting, and assisting companies with MedDRA implementation, project timelines, coding, coding conventions, and IT requirements.

JOANN MEDBERY

Before joining the MSSO, Medbery worked in clinical, industry and IT settings. From a clinical foundation, gained in an acute care setting, she joined the biotechnology and pharmaceutical industry, gaining drug safety knowledge and clinical trials experience. Although mainly responsible for managing adverse event thesauri, drug thesaurus and clinical laboratory data, she has been involved in many IT facets supporting the clinical development process.

NANDINI MEHROTRA (INDIA)

Nandini Mehrotra, M.D., joined the team as a health specialist after spending two years as a coding and quality

User Group Meetings 2002

20 JUNE 2002
1300 -1600
In conjunction with the DIA 38th Annual Meeting
The New Lakeside Center at McCormick Place
Chicago, Illinois, USA

check *www.meddramsso.com*
for information regarding the User Group meetings.

MedDRA® MSSO
c/o TRW, VAR1/8A/MSSO
12011 Sunset Hills Road
Reston, VA 20190-3285
USA

TOLL FREE INTERNATIONAL
877.258.8280 (AT&T)

DIRECT
703.345.7799 (USA)

FAX
703.345.7755 (USA)

SUBSCRIPTION E-MAIL
subscribe@trw.com

MSSO-DI-7110-2.0.0

MedDRA MSSO Medical Team

control specialist supporting regulatory coding of spontaneous reports of adverse events. In that capacity, Mehrotra gained invaluable experience using MedDRA.

NANDINI MEHROTRA

As part of the team, Mehrotra supports legacy data conversion projects, drawing on her experience as a MedDRA quality assurance specialist. She is also involved in terminology maintenance and general medical support within the MSSO.

Mehrotra received her medical degree from Lady Harding Medical College in New Delhi, India, and did postgraduate training in obstetrics, gynecology and psychiatry. She practiced medicine for several years and worked as consultant for the U.S. Air Force. She is certified in adult and pediatric CPR and advanced cardiac life support.

MARVIN D. MEINDERS (UNITED STATES)

As the MSSO's terminology maintenance manager, Marvin D. Meinders, D.V.M., M.P.V.M., leads the team that is responsible for processing changes to MedDRA based on user input and internal reviews.

MARVIN MEINDERS

Meinders started his medical career in a rural veterinary private practice. In 1974, he started a second career as a medical officer in the United States Air Force that lasted 25 years.

Meinders held a series of positions during his military career. Having a solid basis in veterinary medicine, he obtained an additional degree focused on the role of zoonotic diseases in epidemiology and human public health. This helped him transition from veterinary to human health focus.

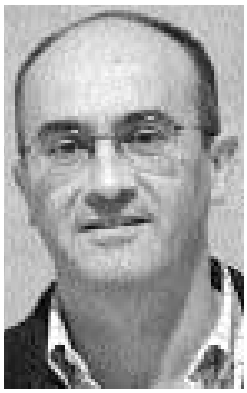
He held several health service positions and was the first Biomedical Sciences Officer selected for a Medical Readiness Internship for the U.S. Air Force Medical Services.

In 1986, he was appointed Chief of Combat Casualty Care, and directed the Wartime Medical (WAR-MED) Program. In 1990, he was appointed Program Director of Medical Readiness for the U.S. Air Force. In 1993 he became the Chairman of the Department of Military Public Health, Wright-Patterson Air Force Base, and finally in 1998 he served as Chief of Medical Readiness for the U.S. Joint Chiefs of Staffs at the Pentagon in Washington, D.C.

Meinders received his D.V.M. from the University of Georgia, and his M.P.V.M. from the University of California, Davis.

TOMÁS MORALEDA GARCÍA (SPAIN)

As the Spanish IMO, Tomás Moraleda García, M.D. processes and reviews terms and translates terms and documents into Spanish.



TOMÁS MORALEDA GARCÍA

Moraleda began his pharmaceutical industry career as a medical adviser at Beecham Laboratories, where he was responsible for anti-allergy products and for developing an antibiotic. Later, at Wellcome Laboratories, he was responsible for pharmacovigilance services, bibliographic issues, and for developing and assessing marketing issues. He was responsible for initiating and managing phases II and IIIA/B trials in therapeutic areas that include cardiology, neurology, intensive care medicine and hematology.

Moraleda served as medical director at two other companies before joining Quintiles, as general manager and head of clinical operations, in Spain. He was responsible for numerous general practice medicine units in Spain's National Health Service, and served as an emergency department physician at a private hospital.

Moraleda graduated from Autonoma University of Madrid with a degree in medicine and surgery.

PATRICIA MOZZICATO (UNITED STATES)

Patricia Mozzicato, M.D., joined the team as a senior manager and medical professional. Her responsibilities include terminology maintenance and medical support for MSSO products and services.

PATRICIA MOZZICATO

Previously, Mozzicato spent five years as a drug safety physician at Bristol-Myers Squibb, where she was deeply involved in implementing, training, and maintaining MedDRA in the drug safety department. She chaired that organization's MedDRA committee.

A graduate of Tufts University School of Medicine, Mozzicato trained in pathology/ neuropathology at the University of Vermont College of Medicine and at Queen's University/Kingston General Hospital in Ontario, Canada. She practiced pathology for several years in Syracuse, NY, and is board-certified in anatomic and clinical pathology with special qualification in neuropathology.

EVA-BEATE RUMP (GERMANY)

Eva-Beate Rump, M.D., began working for the MSSO in 1999. As an IMO, she processes and reviews terms and translates MSSO terms and documents into German.

As an expert in scientific data man-

MedDRA MSSO Medical Team

agement, Rump trains companies in using MedDRA, as well as provides data conversion, and consulting services.

EVA-BEATE RUMP

Rump began her pharmaceutical career as a clinical investigator in a Phase I unit of a German-based CRO. Later, she led a group of up to 25 clinical in-house monitors in a company biometrics department, while working closely with data management and statistics departments. She led a data management group at Quintiles and was a member of its core team for coding and MedDRA implementation. Rump has extensive coding experience, using dictionaries such as WHO-ART, WHO-DRL, COSTART, HARTS and ICD-9/10.

A trained medic with German approbation, Rump studied medicine at the University of Freiburg and earned her doctor's degree for basic research in virology.

CAROLYN TANZOLA (UNITED STATES)

Carolyn Tanzola, R.N., B.S.N., serves as a terminology and implementation specialist on the medical team. She conducts onsite MedDRA needs assessments and develops implementation plans for pharmaceutical, biotechnology, and device companies. In addition, Tanzola supports MedDRA implementation and training, legacy data conversion, term placement, marketing, and proposal development.

CAROLYN TANZOLA

Over her 20-year career, Tanzola has specialized in intensive care and surgical nursing. Before joining TRW, Tanzola served as a contract clinical research associate and as a CRA with pharmaceutical and biopharmaceutical companies. As an independent consultant, Tanzola has managed clinical trials in several therapeutic areas.

Tanzola received her R.N., B.S.N. from Clara Maass Memorial Hospital School of Nursing, Upsala College in Bloomfield, N.J.

ANNA C. ZHAO-WONG (CHINA)

Anna C. Zhao-Wong, M.D., Ph.D., serves as a medical review officer. She began working with MSSO in 1998, and is responsible for term placement, implementing terminology changes, defining issues related to term linkages, and conducting quality assurance activities.

ANNA C. ZHAO-WONG

Zhao-Wong participated in the development of AutoCode CS™, drawing on more than 10 years experience in biomedical research and software development and her experience at the National Cancer Institute. She continues to have a role in testing and maintaining software used by the MSSO to update the MedDRA terminology and to communicate with the user community.

Zhao-Wong earned her M.D. from Beijing Medical University. She received a Ph.D. in biochemistry from the Uniformed Serviced University of the Health Sciences. She has published articles in S&IT Review Journal, Molecular Cell Biology, and the Journal of Biological Chemistry.

ACKNOWLEDGEMENTS

TRW is the name and mark of TRW Inc.

AutoCode CS™ is a trademark of TRW Inc.

MedDRA® is a registered trademark of the International Federation of Pharmaceutical Manufacturers Associations.

Help for customers with communication issues

It has come to our attention that some subscribers are having trouble getting through to the helpdesk or not getting any response.

The MSSO is concerned about the lack of responsiveness comments and wants to resolve any issues.

We request that anyone who has had, or in the future experiences a communication issue with the MSSO, please send an e-mail to Elizabeth d'Alelio, Manager of Customer Operations, at this address: ***Elizabeth.d'Alelio@trw.com.*** Please include the name of the person or area you are trying to reach, along with the e-mail address or phone number being used.

With this information the MSSO can take the needed steps to ensure that this situation is corrected.

MAY-DECEMBER 2002 TRAINING SCHEDULE

The training schedule is periodically updated. Please access www.meddramsso.com for updated information. For your convenience and quick reference, course descriptions are provided.

CLASS	LOCATION	DATES
Full Scope of MedDRA	Reston, VA, USA	14-15 May 2002
Coding with MedDRA	Copenhagen, Denmark	15 May 2002
AutoCode CS™	Reston, VA, USA	16 May 2002
Advanced Training for MedDRA	Reston, VA, USA	16 May 2002
MedDRA Information Technology Training	Reston, VA, USA	17 May 2002
Coding with MedDRA	Frankfurt, Germany	12 June 2002
Full Scope of MedDRA	Culver City, CA USA	16-17 July 2002
Full Scope of MedDRA	Denver, CO USA	13-14 August 2002
Full Scope of MedDRA	New York, NY, USA	17-18 September 2002
Full Scope of MedDRA	Orlando, FL USA	15-16 October 2002
Advanced Training for MedDRA	Orlando, FL USA	17 October 2002
MedDRA Information Technology Training	Orlando, FL USA	18 October 2002
Full Scope of MedDRA	Durham, NC USA	12-13 November 2002
Full Scope of MedDRA	Las Vegas, NV USA	10-11 December 2002
Advanced Training for MedDRA	Las Vegas, NV USA	12 December 2002
MedDRA Information Technology Training	Las Vegas, NV USA	13 December 2002

Registration for all open sessions can be accomplished through the MSSO web site: www.meddramsso.com

MSSO Training Advantages
The MSSO provides expert MedDRA training to members of the pharmaceutical industry. MSSO instructors have an extensive industry and MedDRA background. In addition to this expertise, the MSSO offers continuing education credits to recipients of MedDRA training. Check out the MSSO website for specific information about CEUs for each course: www.meddramsso.com

Up-to-date MedDRA Training
MedDRA training materials are periodically updated to remain current with the latest version of MedDRA. Course materials will reflect MedDRA 5.0 updates starting in late spring 2002.

On-Site Training
In addition to the open enrollment training chart above, the MSSO provides enterprise-wide and individual training courses at your company's location. Percentage discounts apply. Please contact the MSSO for more information.

MedDRA course descriptions

MedDRA Essentials (1 day)
Scope, structure and rules of MedDRA; examination of the idiosyncrasies of each System Organ Class and how it was developed; provides insight into the rules, usage and practices of the medical terminology.

Coding with MedDRA (1 day)
Illustrates coding examples as they pertain to the scope of MedDRA; differences between current terminologies and MedDRA; tools that support coding, and a hands-on approach to coding verbatims and narratives with MedDRA.

The Full Scope of MedDRA (2 days)
MedDRA Essentials and Coding with MedDRA. Offered as a package (more hands on than when offered separately).

Advanced Training for MedDRA (1 day)
Designed for the participant to understand MedDRA's impact on analysis and how to use this impact to their benefit; understand why their data looks different in MedDRA; identify search strategies, and design queries using MedDRA.

MedDRA Information Technology Training (1/2 day)
Covers MedDRA implementation issues from the IT perspective and identifies the key points to consider for existing or new systems data issues, and electronic submissions.

MedDRA for CRAs and Study Coordinators (1/2 day)
Describes how MedDRA is organized and how it is used; impact of MedDRA on adverse event and clinical trial data reporting; how case report form data translates into MedDRA.

AutoCode CS™ (1 day)
Provides an overview of the AutoCode CS™ software program and is intended for users (extractors, classifiers, and reviewers). The course also provides an overall understanding of AutoCode CS™ functionality for those who need this perspective.

REGISTRATION FOR OPEN SESSIONS:
MSSO Web site:
www.meddramsso.com
AT&T toll free number: *(877) 258-8280*

We want your feedback! Please contact us:

E-mail: mssohelp@trw.com Website: www.meddramsso.com
Toll free Int'l: 877-258-8280 (AT&T) Direct: 703-345-7799 Fax: 703-345-7755

MedDRA — Stabilization of the terminology

(Posted April 18, 2002)

The MSSO has requested, and has been given permission from the MedDRA Management Board, to enact measures to stabilize the MedDRA terminology. This action was taken based upon subscriber comments and internal analysis.

Over the past year the MedDRA terminology has been undergoing a great deal of review and analysis, both by the MSSO and the MedDRA subscribers. The MSSO has taken the information generated by these analyses, and has worked to fill holes in the terminology while trying to bring consistency and exactness at the same time.

It is now the concern of the MSSO, and a concern that has been echoed by subscribers, that the MSSO may be at the point of over refinement of MedDRA. The specificity of MedDRA is at a point of becoming academic in nature, and may well hinder MedDRA's effectiveness as a reporting tool.

The MSSO believes that the MedDRA terminology needs to stabilize for a period so that users can have a chance to use it without concern of potentially large number of changes that will impact their coding efforts and data analysis. In proving a period of stabilization, the MSSO will be able to refocus the direction of future MedDRA changes back onto the MedDRA subscribers.

The MSSO has proposed and the MedDRA Management Board has approved the following two steps be taken to stabilize MedDRA:

1. The MSSO will reduce all internal analysis and change requests unless related to a subscriber change request. A large percent of the changes the MSSO has processed are internally generated in an effort to improve MedDRA. This started with MedDRA 4.0 analysis. Most of the identified issues from the MedDRA 4.0 analysis have now been completed.

2. The MSSO will go back to its original change request guideline requirements:

a) All change requests must be justified. In the past the MSSO has processed requests with little or no justification information from the subscriber. Saying that a term is misplaced or simply indicating the desired placement is not enough.

b) A term will only be added to MedDRA if justification is provided that explains why no existing term can be used, and why it is important that the term be added. Many subscribers have complained about the expansion of MedDRA, especially at the PT level, when prior to MedDRA most terminologies had only a fraction of the terms with which to code.

Come see the MSSO at the following events:

RAPS European Conference and Tabletop Exhibition

6-9 May 2002
Hotel Inter-Continental Budapest
Budapest, Hungary

MSSO Speaking 8 May 2002 0900 - 1030
Speaker: Tomas Moraleda Garcia, International Medical Officer, MedDRA MSSO
For more information: www.raps.org

DIA 38th Annual Meeting

June 16-20 Jun, 2002
Stop by our Booth 440-442