



MedDRA MSSO User Group Meeting

Shanghai, China
10 May 2011

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Pharmaceutical Manufacturers and Associations (IFPMA)



Agenda

4:00 – 4:30	Introduction and Update from the MSSO	Anna Zhao-Wong
4:30 – 5:30	MedDRA Coding – Ask the Experts	Coding Expert Panel



Subscription Updates



MedDRA Basic Subscription

- Continued free subscription
- Intended for non-commercial use by:
 - Nonprofit medical libraries
 - Educational institutions
 - Direct patient care providers
- As of 1 January 2011, can submit Change Requests



MedDRA Basic Subscription (cont)


2010 and Prior	2011 and Beyond
English MedDRA	English MedDRA
EU Translations	EU Translations
Help Desk Service	Help Desk Service
User Group Membership	User Group Membership
	100 Change Requests per month

- Propose changes to MedDRA and SMQs
- Search change request history in MSSO database
- Encouraged to join in active maintenance of MedDRA




Chinese Translation Subscription Rate

	Chinese Translation	
	2010 Fee	2011 Fee
Basic	\$100	\$50
Core Services 0	\$100	\$50
Core Services 1	\$100	\$50
Core Services 2	\$500	\$150
Core Services 3	\$1,000	\$300
Core Services 4	\$2,000	\$600
Core Services 5	\$3,000	\$850
Developer	\$1,500	\$450
Regulatory	\$0	\$0



Acronyms / Abbreviations in MedDRA



Acronyms/Abbreviations

- MSSO has published a list of term acronyms and abbreviations
 - Over 200 in initial list
 - Includes term name and meaning

Abbreviation / Acronym	MedDRA LLT (current LLTs only)	Meaning
ABO	ABO isoimmunization	Landsteiner's blood grouping system
ACE	ACE inhibitor foetopathy	Angiotensin-converting enzyme
ACTH	ACTH stimulation test normal	Adrenocorticotrophic hormone
ADA	ADA deficiency	Adenosine deaminase
ADD	ADD	Attention deficit disorder
ADH	ADH normal	Antidiuretic hormone
AFP	AFP result - normal	Alpha-fetoprotein

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Acronyms/Abbreviations (cont)

- Intended to provide clarity and avoid misinterpretation
- Available in a spreadsheet on the MSSO Web site:
http://www.meddramsso.com/subscriber_acronyms_abbreviations.asp
- Updated each MedDRA release
- Users encouraged to submit new entries



MedDRA Training



MSSO Free Training Program

- Formats
 - Face-to-face sessions, webinars, videocasts
- Languages
 - English, French, German, Spanish, Mandarin Chinese
- Locations
 - US, Europe, Asia, and “virtual”



MSSO Free Training Program (cont)

- In 2011, face-to-face sessions hosted by companies
- Larger facilities to accommodate more trainees
- Full-day courses
 - Coding with MedDRA
 - MedDRA: Safety Data Analysis and SMQs
- Benefit to host: more company attendees
- Interested in hosting? Contact msohelp@ngc.com



MSSO Free Training Program (cont)

- Training hosted by regulators
 - EMA (London, UK)
 - Other regulators in EU (watch for dates)
- Sessions open to regulators and industry personnel



Blue Ribbon Panel Meeting



Blue Ribbon Panel

- 12 April 2011
- Hosted by EMA (London)
- Topic: Proposed Revisions to the Neoplasm SOC



Panel Members

Stewart Geary (Eisai)
Jean-Marie Heim (Bristol-Myers Squibb)
Sebastian Monzon (Roche)
Gisele Sarosy (National Cancer Institute, USA
[ret])
Atsuo Takashima (National Cancer Center, Japan)
Kevin Blake (EMA)
Multiple FDA experts (FDA)



Proposal 1

- Remove “Cyst” terms from Neoplasm SOC
 - Rationale: “Cyst” is an anatomic designation which only very rarely confers the quality of “neoplasia” (abnormal growth of cells)
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Proposal 2

- More specific tumor types at PT level
 - Oncologic therapies are being targeted at specific histological types of tumors
 - Often combined with genetics
 - Increased specificity in MedDRA would allow for aggregation and analysis of specific tumor types
 - Some specificity currently at LLT, but in some cases, certain subtypes are missing



Proposal 3

- Update the Neoplasm SOC tumor classifications
 - Many tumor classification systems
 - French-American-British [FAB] classification for acute leukemia
 - World Health Organization (WHO)
 - ICD-O
 - Evolve and change over time
 - Some neoplasms currently in MedDRA are not up-to-date



Summary of Blue Ribbon Panel Recommendations

Proposal 1

- Don't unlink the cysts from the Neoplasms SOC as secondary SOC because there is limited utility to do so for analysis
- Don't create an SMQ for cysts across body systems as there is no identified need
- Keep malignant and pre-malignant cysts linked primarily into Neoplasms SOC



Summary of Blue Ribbon Panel Recommendations

Proposal 2

- There was general support for improvement in specificity at PT by adding histology specific terms
- Process should be driven by real users' needs
- The suggestion was to add terms via change request process or focused proactive additions, rather than widespread review and proactive promotion of LLTs.



Summary of Blue Ribbon Panel Recommendations

Proposal 2, contd.

- There was general support for stage specific terms to be demoted to LLT to avoid dilution of signals
- There was strong support for preservation of non-specific broad terms e.g. breast cancer, at PT level



Summary of Blue Ribbon Panel Recommendations

Proposal 3

- There was support for basing MedDRA on standard classifications e.g. WHO but MedDRA should be stand alone for ease and transparency
- The suggestion was not to add widespread many terms proactively but reference existing standards for individual term additions in response to subscriber request
- International agreement on the system to be used should be sought but could be difficult to achieve across ICH regions



ICH-SFDA MedDRA Workshop



Workshop Program

- Date: 13 – 14 May 2011, Beijing
- Topic: MedDRA's Use in Clinical Trials & Labeling for Drug Registration
 - What is MedDRA and why MedDRA?
 - MedDRA in clinical trial
 - MedDRA in pharmacovigilance
 - MedDRA in drug registration
 - MedDRA in labeling



Workshop Speakers

- **Ms. Heather Sutcliffe**, Director Marketed Health Products Safety & Effectiveness Information Division, Health Canada
- **Dr. Christina Winter**, Medical Director Global Clinical Safety & Pharmacovigilance, GlaxoSmithKline R&D, United Kingdom
- **Dr. Anna Zhao-Wong**, Deputy Director, MedDRA Maintenance & Support Services Organisation



MedDRA Enthusiast Award



MedDRA Enthusiastic Award

- Catherine Xie
- Xiaojun Guo
- Kristin Chen
- Wei Deng
- Yuhong Wang



Thank You!