



# MedDRA MSSO User Group Meeting

Chicago, USA  
23 June 2011

MedDRA® is a registered trademark of the International Federation of  
Pharmaceutical Manufacturers and Associations (IFPMA)



# Agenda

1:15 – 2:00	Introduction and Welcome	Pat Revelle
2:00 – 2:45	Proactive MedDRA Maintenance Model / Blue Ribbon Panel Recommendations on Revisions to the Neoplasm SOC	Brian O'Hare, Patricia Mozzicato
2:45 – 3:15	Friend of MedDRA Award Networking / Coffee Break	
3:15 – 4:15	Signal Detection: MedDRA and other Key Issues	James Buchanan, BioSoteria, Inc.
4:15 – 5:00	Subscriber Forum / Q&A	MSSO Staff



# MedDRA 14.0

- Released 1 March 2011
- Unusual for the number of implemented SMQ changes
  - 4272 implemented changes
    - 3645 SMQ changes (80% of changes)
    - 627 MedDRA term changes



# MedDRA 14.0 SMQ Changes

- One new SMQ
  - *Pregnancy and neonatal topics (SMQ)*
- Total of 85 SMQs in MedDRA 14.0
- SMQs with major modifications
  - *SMQ Adverse pregnancy outcome/reproductive toxicity (incl neonatal disorders)*
  - “Malignant and/or unspecified neoplasms” SMQs (8)
  - *SMQ Premalignant disorders*
  - *SMQ Hypertension*
  - *SMQ Embolic and thrombotic events, vessel type unspecified and mixed arterial and venous*



# Version Report

- All changes are listed in the Version Report

Tab Title	Record Count		
New LLTs Including New PTs	358		
New PTs	189		
Promotions	23		
Demotions	45		
LLT under different PTs	449		
LLT (excl PT) Prim SOC Changes	35		
PT Primary SOC Changes	10		
MedDRA LLT PT Text Changes	6		
Currency Changes	13		
Hierarchy Changes	12		
SMQ Changes	59		
PT Changes in SMQs	6439		
Move cursor over the report title above to view a description of its contents.			



# 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
<b>Basic</b>	\$100	\$50
<b>Core Services 0</b>	\$100	\$50
<b>Core Services 1</b>	\$100	\$50
<b>Core Services 2</b>	\$500	\$150
<b>Core Services 3</b>	\$1,000	\$300
<b>Core Services 4</b>	\$2,000	\$600
<b>Core Services 5</b>	\$3,000	\$850
<b>Developer</b>	\$1,500	\$450
<b>Regulatory</b>	\$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	Adrenocorticotropic hormone
ADA	ADA deficiency	Adenosine deaminase
ADD	ADD	Attention deficit disorder
ADH	ADH normal	Antidiuretic hormone
AFP	AFP result - normal	Alpha-fetoprotein



# 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](http://www.meddramsso.com/subscriber_acronyms_abbreviations.asp)
- Updated each MedDRA release
- Users encouraged to submit new entries



# Hungarian Translation



# Hungarian Translation

- Available 15 March 2011
- Included with MedDRA subscription
- Need MedDRA Desktop Browser version 3.0.2b to view
- Available in the MedDRA Web Based Browser



# WebCR Upgrade




# WebCR Upgrade

- Accepts All Change request categories
  - MedDRA changes
  - SMQ changes
  - Translation corrections
- Addresses issues with current application
  - Could not request changes based on proposed requests
- Improved user interface
  - Intuitive menus
  - Help files for each change request action



# WebCR Login



**WebCR**  
MedDRA User Change Request Application

---

Login to WebCR


Subscriber ID:

Password:

Welcome to the MedDRA User Change Request Data Entry Web site.  
You may submit your MedDRA Change Request to the MSSO here.  
If you have problems logging in, please contact the MSSO Help Desk at [MSSOHelp@ngc.com](mailto:MSSOHelp@ngc.com) or 1-877-258-8280



# Menus



**WebCR**  
MedDRA User Change Request Application

Your Role: CR Submitter  
Subscriber: 19999

**Subscriber CR (Monthly Quota Available: 100)**

Please select from the action items below.

**Add/Change MedDRA Term** ▾

Add MedDRA Term ▾

Move Term/Change Link ▾

Other Actions ▾

Change Status of LLT

**SMQ Changes** ▾

Rename PT/LLT

**Translation Changes** ▶

Rename HLT

**Reconsider** ▶

Rename HLGT

Rename SOC


You have 1 unsubmitted MedDRA term change requests ▾

You have 1 unsubmitted SMQ change requests ▾

- Home
- View Submitted Batches
- Search MedDRA Terms
- Search CR History
- Submitter Profile
- Logout



# Adding a New Term



**WebCR**  
MedDRA User Change Request Application

Your Role: CR Submitter  
Subscriber: 19999

Add a New Term

Proposed Term (Required) ?

Justification statement is required

Justification ?

Attach supporting document (Optional)

Attachment

For multiple attachments, please zip files and submit.

- Home
- View Submitted Batches
- Search MedDRA Terms
- Search CR History
- Submitter Profile
- Logout



# Coming Soon!

- Recently completed testing with a few users
- Expect to put into production by July 2011



# MedDRA Version Analysis Tool (MVAT)



# Background

- User feedback
  - Upversioning is a challenge for small and medium size companies
  - Difficult to track changes of terms cross multiple versions
  - Current Version Report only provides changes between two consecutive releases
- BRP 6 recommendation
  - MSSO to develop tool to assess impact and facilitate upversioning task



# MVAT

- Requirements collected from:
  - MedDRA Users
  - MSSO
  - MedDRA Management Board
- Web-based tool
- Free to subscribers
- Anticipated release date
  - Late 2011



# MVAT (cont)

- Features
  - Reports can compare any two MedDRA versions
    - Term changes and path changes
    - Includes translation changes
  - Spreadsheet or delimited ASCII output
  - Static reports
  - Interactive reports (optional)
- Reports are informational only
  - Will not perform coding tasks



# Static Report Menu

**MedDRA Version Analysis Tool (MVAT)**

Select Different Versions to Compare

Language:  
English

Starting Version:  
MedDRA 6.1 English

Ending Version:  
MedDRA 14.0 English

Run Report



# Static Report Results

## MedDRA Version Report

### Selected MedDRA

Starting Version: **MedDRA 6.0 English**

Ending Version: **MedDRA 14.0 English**

MedDRA Term Version Report Summary

Report Title	Total Changes
<a href="#">New LLTs Including New PTs</a>	10459
<a href="#">New PTs</a>	5189
<a href="#">Promotions</a>	1317
<a href="#">Demotions</a>	3761
<a href="#">LLT under different PTs</a>	16726
<a href="#">LLT (excl PT) Primary SOC Changes</a>	1397
<a href="#">PT Primary SOC Changes</a>	245
<a href="#">MedDRA LLT PT Text Changes</a>	130
<a href="#">Currency Changes</a>	355
<a href="#">Hierarchy Changes</a>	124

SMQ Version Report Summary

Report Title	Total Changes
<a href="#">SMQ Changes</a>	205
<a href="#">PT Changes in SMQ</a>	12036



# Static Report Details

## MedDRA Version Report Detail: New PTs

### Selected MedDRA Data

Starting Version: **MedDRA 6.0 English**

Ending Version: **MedDRA 14.0 English**

MVAT Home

Spreadsheet Analysis

Ad Hoc Query

Logout

(Total: 5189)

[Back](#)

<a href="#">MedDRA Code</a>	<a href="#">PT</a>	<a href="#">HLT</a>	<a href="#">HLGT</a>	<a href="#">Primary SOC</a>
10068581	Acquired haemoglobinopathy	Haemoglobinopathies NEC	Haemoglobinopathies	Blood and lymphatic system disorders
10068370	Acquired protein S deficiency	Coagulation factor deficiencies	Coagulopathies and bleeding diatheses (excl thrombocytopenic)	Blood and lymphatic system disorders
10069495	Acquired Von Willebrand's disease	Coagulation factor deficiencies	Coagulopathies and bleeding diatheses (excl thrombocytopenic)	Blood and lymphatic system disorders
10066468	Anaemia of pregnancy	Anaemia deficiencies	Anaemias nonhaemolytic and marrow depression	Blood and lymphatic system disorders
10069509	Autoimmune pancytopenia	Marrow depression and hypoplastic anaemias	Anaemias nonhaemolytic and marrow depression	Blood and lymphatic system disorders
10061590	Blood disorder	Haematological disorders	Haematological disorders NEC	Blood and lymphatic system disorders



# Interactive Reports

- Require input from the user
  - Verbatim (optional)
  - LLT/PT code (required)
  - Company database identifier (i.e., record number - optional)
- Provide more of a “tuned” list of changes
  - New MedDRA LLTs directly matching verbatims
  - Currently used LLTs with a currency change
  - Changes in hierarchy for currently used terms



# Sample Interactive Report Output

User Data				MVAT Findings		
ID Num	Verbatim	LLT Code	LLT Text	Category of Finding	MedDRA 12.0 Term	Additional Information
1	Intramedullary rod insertion	10051079	Orthopedic procedure	New direct match	Intramedullary rod insertion	
2	Brachialgia	10033421	Pain in arm	New direct match	Brachialgia	
3	Bariatric surgery	10059610	Obesity surgery	New direct match	Bariatric surgery	
4	Pharmacist noted that patient misused the product	10068467	Drug misuse	Term non-current	Intentional drug misuse	
5	Extremity was noted to be extensively swollen	10067316	Extensive limb swelling	Term non-current	Extensive swelling of vaccinated limb	
6	Gash on foot became infected	10031644	Other and unspecified superficial injury to foot and toes, infected	Term non-current	Localised infection	
7	Abdominal wall strained	10000106	Abdominal wall strained	Primary SOC Change	Injury, poisoning and procedural complications	Gastrointestinal disorders
8	Hands cold	10009860	Cold hands	Primary SOC Change	Vascular disorders	General disorders and administration site conditions



# 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 [mssohelp@ngc.com](mailto:mssohelp@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



# MedDRA Browsers



# MedDRA Browsers

- MedDRA Desktop Browser
- MedDRA Web-Based Browser
  - Requires username and password (from the MSSO)



# MedDRA Browser Videos

- MedDRA Desktop Browser videocast
  - MDB Research Bin and Export Functions
- Web-based Browser tutorial video
  - Recorded Webinar: Overview of the Functions of the MedDRA Web-Based Browser



# MedDRA Web-Based Browser

- WBB available for over 1 year
- MedDRA Management Board and MSSO collected feedback in a survey
  - Feedback response was strong (over 300 survey responders)
  - All types of users represented
  - Over 80% were satisfied or very satisfied
  - Several users identified ideas for improvement or development
  - Presenting findings to MedDRA Management Board
  - Summary results will be made available



# MedDRA Desktop Browser

- Minor update (3.0.2b) to accommodate Hungarian translation
- MSSO considering other changes to Desktop Browser
  - Additional search options
  - Better support for networked installations (easier installations, version updates)
  - View MedDRA hierarchy side by side with SMQs
- Do you have suggestions?



# Thank You



# Friend of MedDRA

