



MedDRA MSSO User Group Meeting

Boston, USA

26 June 2008

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Pharmaceutical Manufacturers and Associations (IFPMA)

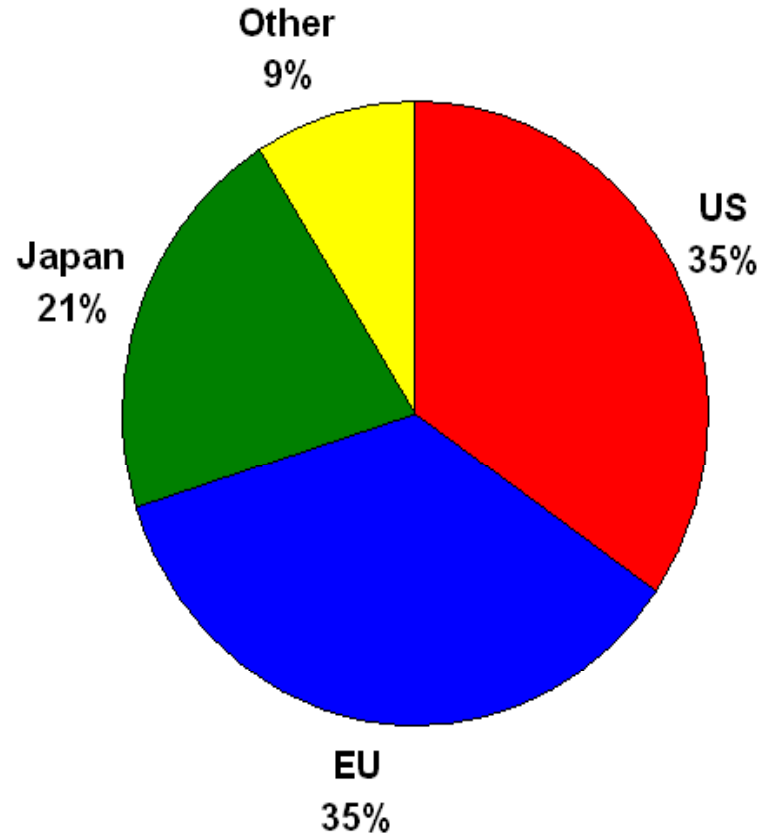


Agenda

12:30 – 1:15	Networking Lunch	
1:15 – 2:00	Introduction and Welcome	Pat Revelle
2:00 – 3:00	Practical Applications of SMQs in an Industry Pharmacovigilance Group	Roberta Michaelis
3:00 – 3:30	Friend of MedDRA Award Networking / Coffee Break	Pat Revelle
3:30 – 4:00	Update on Device Terms	Judy Harrison
4:00 – 4:45	Subscriber Forum / Q&A	Patty Mozzicato



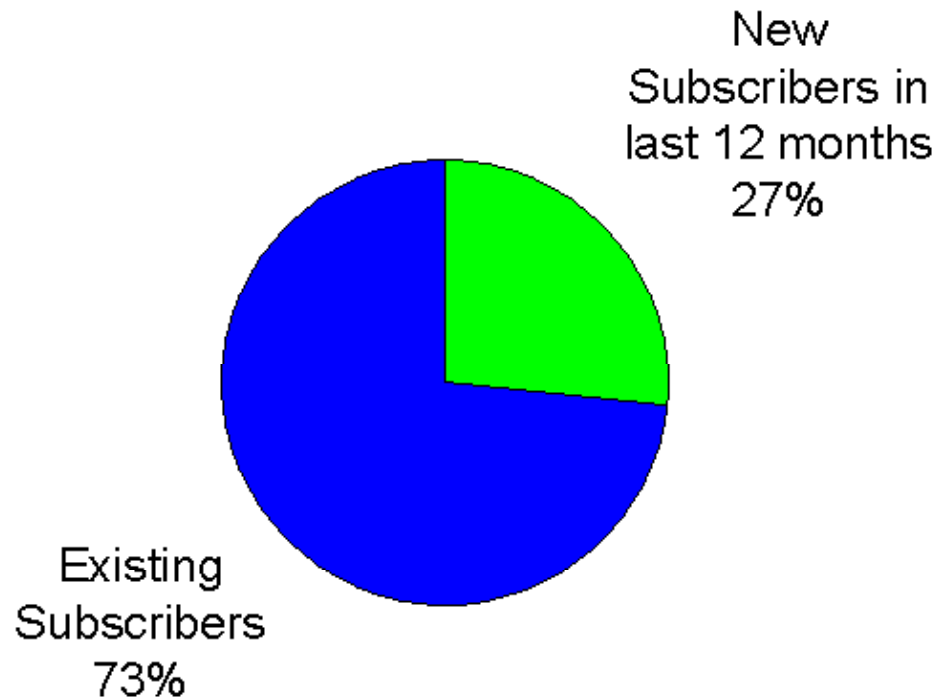
MedDRA Subscriber Update



2255 Subscribers
Worldwide (as of 31 May)



Subscriber Growth





MedDRA Version 11.0

- Change request summary:
 - A complex release
 - Released on 1 March 2008
 - MSSO considered 1770 change requests (incl SMQ change requests)
 - Approved: 1145 (SMQ: 127)
 - Rejected: 590 (SMQ: 105)
 - Suspended: 35 (SMQ: 15)



SMQ Status

- With the release of MedDRA 11.0, we have 58 SMQs in production
- Newly released SMQs
 - Glaucoma
 - Haemodynamic oedema, effusions and fluid overload
 - Ischaemic colitis

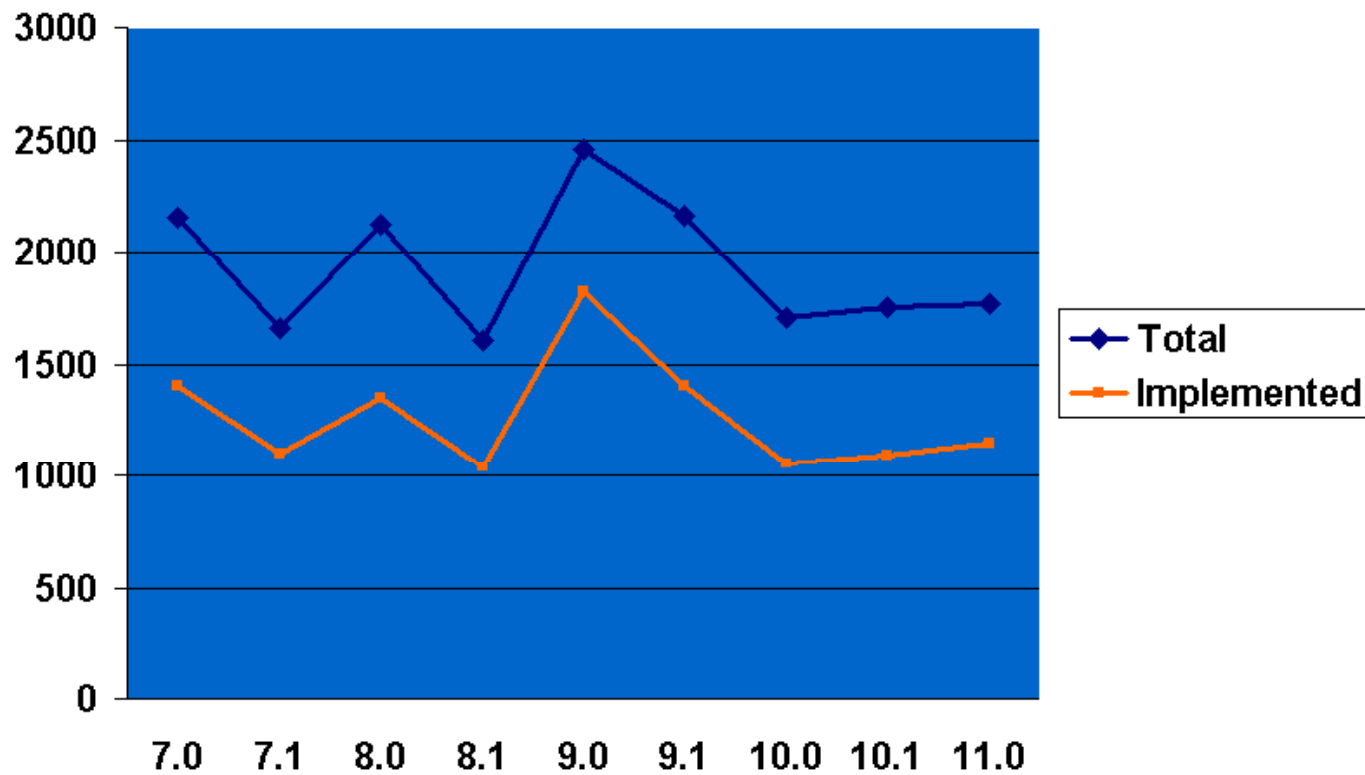


SMQ Status (cont)

New 11.1 SMQs (1 September 2008)
Breast neoplasms, malignant and unspecified
Cardiomyopathy
Corneal disorders
Demyelination
Hypertension
Lens disorders
Optic nerve disorders
Ovarian neoplasms, malignant and unspecified
Prostate neoplasms, malignant and unspecified
Uterine and fallopian tube neoplasms, malignant and unspecified



Total and Implemented Change Requests MedDRA Versions 7.0 - 11.0





WebCR

- Currently, a spreadsheet is used to submit change requests

Subscriber Change Request Form (Updated 01/05/07)				
****Note: Please do not submit this form with terms in all capital letters ****				
Submitter Organization / User ID		Requester Phone		
Change Request ID		Fax		
Password		Email Address		
Requester Name		Date of Request		
#	Action	Proposed Term	Proposed Placement (Optional)	Justification/Reason for the Request
1				
2				
3				




WebCR (cont)

- Starting 16 June, subscribers can submit change requests online
 - Immediate confirmation on submission
 - Multiple logins from a organization
 - Facilitate the information sharing within a organization with different geographic sites
 - Access to the MSSO's change request database (since V5.1)
 - Error checking (e.g., the proposed term already exists in MedDRA)



WebCR (cont)

**MSSO Subscriber Change Request Data Entry (WebCR)**

Action ▶ Batch ▶ Retrieve ▶ Preference ▶ Logout

Add a New PT/LLT Monthly Change Request Quota Available: 69

Proposed Term (Required)

PT LLT Either

Placement Consideration

Justification (Required)

Attachment



WebCR (cont)

- Search change request history

MSSO Subscriber Change Request Data Entry (WebCR)

Action ▸ Batch ▸ Retrieve ▸ Preference ▸ Logout

Search Change Request History

Description (Allow wild char %)

Term Change Request Number Batch Number

(Total: 87) [Search by Date](#)

Action	Term	Received Date	Status	Batch Number	Change Request Number	MSSO Final Comment
Demote a PT	Painful red eyes	02 Feb 2002	Approved as Requested	10000015	2002027037	View
Change Status of LLT	Painful red eyes	02 Feb 2002	Rejected	10000015	2002027094	View
Link (move) an LLT to another PT	Pain peptic ulcer	09 Apr 2002	Approved as Requested	10000088	2002100003	View
Change Status of LLT	Pain hips, knees & shoulders	11 Apr 2002	Approved as Requested	10000090	2002101029	View
Add a New Term	Painful redness of finger	18 Apr 2002	Rejected	10000098	2002108001	View
Add a New LLT	Pain cervix uteri	16 May 2002	Approved as Requested	10000111	2002135052	View
Link (move) an LLT to another PT	Painful joints	28 Jun 2002	Rejected	10000160	2002181059	View



WebCR (cont)

- Initial prototype tested by volunteer subscribers
- Released for subscriber use on 16 June 2008
 - MSSO offering free webinars for WebCR orientation
- The MSSO will accept both email and WebCR submissions for a period of time



MedDRA in Vigibase

- MSSO worked with WHO at the Uppsala Monitoring Center to include MedDRA in Vigibase
- Vigibase includes several million AE cases collected around the world
- All Vigibase events now have a MedDRA term assigned
- Vigibase provides searches and reports that support MedDRA
- Currently available



Free Access to EU Translations

- All EU translations of MedDRA are available to all MedDRA subscribers as of 1 January 2008
 - Czech, Dutch, French, German, Italian, Portuguese, and Spanish
- Intended to promote the use of translations by subscribers
- Japanese translation remains at \$850 for an annual subscription



Chinese Translation

- MSSO received a Mandarin Chinese translation of MedDRA from IFPMA
 - Update from MedDRA 7.1
 - Develop user documentation
 - Looking for volunteers to review prior to release
- MSSO will maintain translation with other languages
- Goal is to make translation available to subscribers in late 2008
 - Additional fee for this translation



Gender/Pediatric Adverse Event Lists

- MSSO posted on the MSSO Web site a set of PT adverse event term lists
 - Gender list (Over 800 female terms, over 400 male terms)
 - Pediatric list (Over 400 terms)
- Intended to improve data quality
- Not a regulatory requirement
- Available now for download from the MSSO Web site
 - Maintained with each version of MedDRA



Pediatric Term Adverse Event List Sample

PT	PT Code
Abnormal labour affecting foetus	10000154
ABO haemolytic disease of newborn	10000205
Accidental drug intake by child	10064368
Acne infantile	10000507
Adolescence	10001318
Adoption	10001322
Adrenal insufficiency neonatal	10001368
Adrenocortical insufficiency neonatal	10001391
Agitation neonatal	10001500
Alloimmunisation	10060935
Amblyopia	10001906
Anaemia neonatal	10002068
Anaesthetic complication foetal	10052850
Anaesthetic complication neonatal	10052851
Anencephaly	10002320
Aorticopulmonary window repair	10066834
Apgar score	10062552



Gender Adverse Event Term List Samples

Female	
PT	PT Code
Abnormal labour	10000153
Abnormal labour affecting foetus	10000154
Abnormal product of conception	10060927
Aborted pregnancy	10000209
Abortion	10000210
Abortion complete	10061614
Abortion complete complicated	10000212
Abortion complicated	10061615
Abortion early	10052846
Abortion incomplete	10000217
Abortion incomplete complicated	10000218
Abortion induced	10000220

Male	
PT	PT Code
Acquired hydrocele	10000555
Amputation of penis	10002011
Androgen insensitivity syndrome	10056292
Andropause	10062756
Anorchism	10002641
Aspermia	10003495
Aspiration epididymal cyst	10003514
Aspiration epididymal cyst abnormal	10003515
Aspiration epididymal cyst normal	10003516
Aspiration spermatocele	10003527
Aspiration spermatocele abnormal	10003528
Aspiration spermatocele normal	10003529



MSSO Training

- In 2007 the MSSO conducted free training for new subscribers and regulatory authorities
- In coordination with the MedDRA Board, the MSSO extended this free training program in 2008



MSSO Training (cont)

- 2008 Training
 - More locations in Europe and US
 - Basic and Advanced classes
 - Available free to all subscribers
 - Done in conjunction with regulatory agencies (when possible)
- Check MSSO Web site for scheduled classes



MSSO Office Move

- The MSSO office has moved
New street address:
3975 Virginia Mallory Drive
Chantilly, Virginia 20151, USA
Fax: +1.703.272.5635
- Help Desk toll free number unchanged
– 877.258.8280
- MSSO staff phone numbers have changed as well



Discussion