



MedDRA MSSO User Group Meeting

Berlin, Germany
26 March 2009

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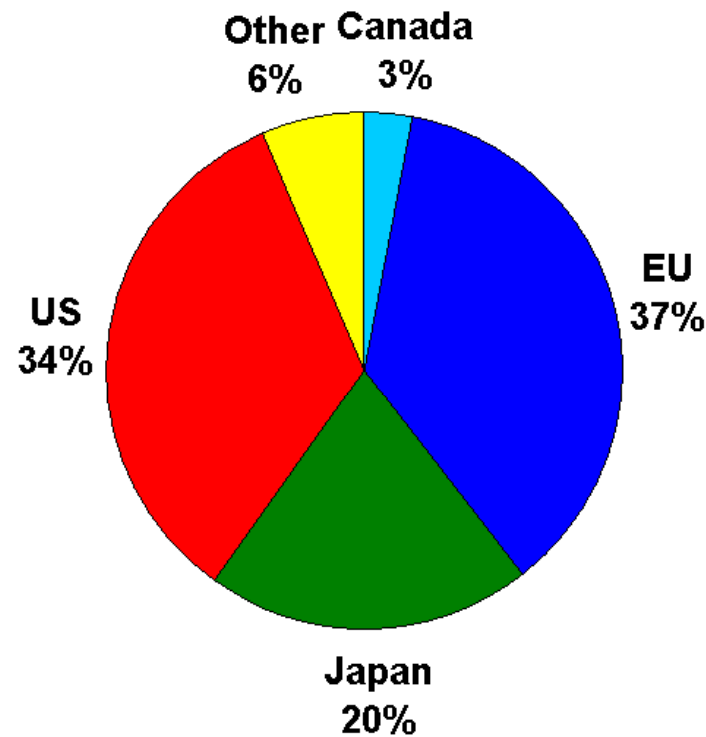


10 Year Anniversary

- This month, the MSSO is celebrating 10 years of MedDRA
 - MedDRA v2.1 released 1 March 1999
- MedDRA has developed into a real standard
- Check our “Web site” for monthly anniversary activities



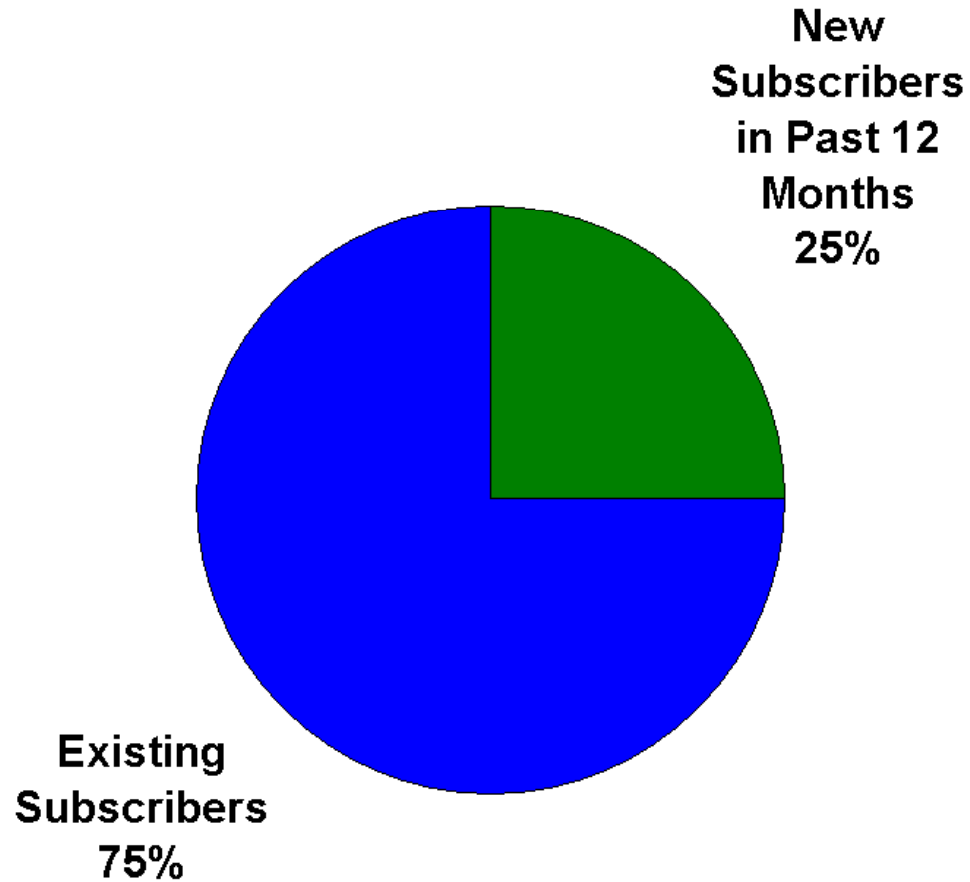
MedDRA Subscriber Update



2430 Subscribers
Worldwide



Subscription Growth





Summary of MedDRA v12.0

- Change request summary:
 - A complex release
 - Released on 1 March 2009
 - MSSO considered 2624 change requests
 - Approved: 1937
 - Rejected: 623
 - Suspended: 64



Version Report

- All changes are listed in the Version Report

	A	B	C	D
1	Tab Title	Record Count		
2	New LLTs Including New PTs	572		
3	New PTs	285		
4	Promotions	38		
5	Demotions	49		
6	LLT under different PTs	243		
7	LLT (excl PT) Prim SOC Changes	77		
8	PT Primary SOC Changes	20		
9	MedDRA LLT PT Text Changes	2		
10	Currency Changes	10		
11	Hierarchy Changes	24		
12	SMQ Changes	21		
13	PT Changes in SMQs	1189		
14				
15	Move cursor over the report title above to view a description of its contents.			



Report Sample – New PTs

	A	B	C	D	E	F
1	MedDRA Code	PT	HLT	HLGT	SOC	Primary SOC Flag
2	10068851	Splenic peliosis	Spleen disorders	Spleen, lymphatic and reticuloendothelial system disorders	Blood and lymphatic system disorders	Y
3	10069167	Kounis syndrome	Ischaemic coronary artery disorders	Coronary artery disorders	Cardiac disorders	Y
4	10069140	Myocardial depression	Myocardial disorders NEC	Myocardial disorders	Cardiac disorders	Y
5	10068793	Aldroem syndrome	Retinal disorders congenital	Eye disorders congenital	Congenital, familial and genetic disorders	Y
6	10068841	Cobb syndrome	Vascular anomalies congenital NEC	Cardiac and vascular disorders congenital	Congenital, familial and genetic disorders	Y
7	10069153	Congenital myopia	Ocular disorders congenital NEC	Eye disorders congenital	Congenital, familial and genetic disorders	Y
8	10068850	Cryopyrin associated periodic syndrome	Musculoskeletal and connective tissue disorders of limbs congenital	Musculoskeletal and connective tissue disorders congenital	Congenital, familial and genetic disorders	Y
9	10069098	Cutaneovisceral angiomatosis with thrombocytopenia	Vascular anomalies congenital NEC	Cardiac and vascular disorders congenital	Congenital, familial and genetic disorders	Y
10						



Distribution Changes

- Single release zip file includes:
 - ASCII files
 - Release documents
 - Version report spreadsheet
 - SMQ spreadsheet
 - Sequential ASCII files



Distribution Changes (cont)

- New Release File
 - Meddra_release.asc
 - Contents of the file describe the language and version of the release
 - Used by updated Desktop Browser
 - Can also be used by subscribers to identify versions
 - No impact to load routines



WebCR Tool



MSSO Subscriber Change Request Data Entry (WebCR)

Welcome to the MSSO Subscriber Change Request Data Entry web site. You may submit your MedDRA Change Request to the MSSO here.

Verify Subscriber

Subscriber ID

Password

Login

Cancel

If you have problems logging in, please contact the MSSO Help Desk at MSSOHelp@ngc.com OR [1-877-258-8280](tel:1-877-258-8280)



Change Request Justification

MedDRA
10th Anniversary
MSSO

MSSO Subscriber Change Request Data Entry (WebCR)

Action ▶ Batch ▶ Retrieve ▶ Preference ▶ Logout

Add a New PT/LLT

Proposed Term (Required)

PT LLT Either

Placement Consideration

Justification (Required)

Attachment

- Required to submit a change request
- Needed by MSSO to understand the context of request



Change Request Justification (cont)

- MSSO will come back to subscribers if the justification provided is not sufficient
- Help the MSSO make the best decision based on the right information



Change Requests

- Some subscribers seem reluctant to submit changes
 - “Not enough time”
 - “I’m too new”
- How many subscribers have submitted changes ever?
 - How many in the past year?
- MSSO encourages you to make your voice heard



Expansion of Medical Device Terms

- In response to users' requests, MSSO is expanding device terms in MedDRA
- External sources of device terms
 - FDA Center for Devices and Radiological Health (CDRH)
 - Patient problem codes (events/procedure in patient)
 - Device problem codes (refer to device itself)
 - International Organization for Standardization/ Technical Committee 210 (ISO/TC 210)



Expansion of Medical Device Terms (cont)

- MSSO reviewed Patient Problem Codes with CDRH experts
- Implemented those that fit MedDRA rules and conventions
- Created self-explanatory device terms to avoid confusion with patient terms
- 60 terms added to MedDRA in versions 11.0 and 11.1



Expansion of Medical Device Terms (cont)

- MSSO formed a MedDRA Device Working Group
 - Industry, FDA, JMO, and MSSO
- Goals
 - Identify terms appropriate for MedDRA
 - Develop device specific acceptance criteria
 - Develop possible MedDRA hierarchy modifications
 - Develop draft coding guidance for device terms for inclusion in Term Selection: PTC document



Expansion of Medical Device Terms (cont)

- Started in October 2008
- Plan to complete by mid 2009
- MSSO to implement approved proposals in MedDRA v12.0



SMQ Update

- Seven new SMQs added
 - Corneal disorders
 - Eosinophilic pneumonia
 - Hearing and vestibular disorders
 - Retinal disorders
 - Skin neoplasms, malignant and unspecified
 - Thyroid dysfunction
 - Vasculitis
- As of MedDRA v12.0 there are 74 SMQ topics



Chinese Translation

- Will be released on 15 September 2009
- Requires fee for Chinese translation subscription
- Will be validated by subscriber volunteers and the MSSO
 - Participating companies will get the Chinese translation free for the first two years



Chinese Translation (cont)

- Receive 50% discount on subscription if you subscriber before 15 September

Subscription Levels	2009
Basic	\$100
Core 0 (Annual Revenue/Turnover \$0M - < \$1 Million)	\$100
Core 1 (Annual Revenue/Turnover \$1M - < \$10 Million)	\$200
Core 2 (Annual Revenue/Turnover \$10M - < \$500 Million)	\$500
Core 3 (Annual Revenue/Turnover \$500M - < \$1 Billion)	\$1,000
Core 4 (Annual Revenue/Turnover \$1 Billion - < \$5 Billion)	\$2,000
Core 5 (Annual Revenue/Turnover greater than \$5 Billion)	\$3,000
Developer	\$1,500



MedDRA Certification

- MSSO plans to provide a new service in mid-2009
- MedDRA Coding Certification
 - Fee required to take a web-based test
 - Upon successfully passing test, MSSO will issue a certificate
 - Valid for 2 years
- Other related services may be added over time



Thank You