



MedDRA Update

Presented by
Brian O'Hare,
MedDRA Terminology Maintenance Manger

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Topics

- Summary of MedDRA v14.1 changes
- Update on Proactivity Initiatives
- Software Tool Updates
- Other Developments
- ICD-10 to MedDRA Mapping?



Summary of v14.1 Changes

- Change request summary:
 - A simple release
 - Released on 1 September 2011
 - MSSO considered 1337 change requests, including 248 SMQ requests
 - Approved: 1041
 - Rejected: 233
 - Suspended: 63



Version Report

- All changes are listed in the Version Report

Tab Title	Record Count		
New LLTs Including New PTs	505		
New PTs	253		
Promotions	25		
Demotions	70		
LLT under different PTs	335		
LLT (excl PT) Prim SOC Changes	54		
PT Primary SOC Changes	8		
MedDRA LLT PT Text Changes	1		
Currency Changes	4		
Hierarchy Changes	0		
SMQ Changes	38		
PT Changes in SMQs	332		
Move cursor over the report title above to view a description of its contents.			



Summary of SMQ Changes

- Two new SMQs added: total is 86
 - *Fertility disorders (SMQ)*
 - *Hypotonic-hyporesponsive episode (SMQ)*
- One sub-search SMQ renamed
 - *SMQ Events specifically reported as alcohol-related*
 - *Renamed to SMQ Hepatic disorders specifically reported as alcohol-related.*

“Pregnancy” SMQ Changes

- *SMQ Pregnancy and neonatal topics*

- SMQ Pregnancy and neonatal topics (SMQ)
- +SMQ Congenital, familial and genetic disorders (SMQ)
- +SMQ Foetal disorders (SMQ)
- SMQ Lactation related topics (incl neonatal exposure through breast milk) (SMQ)
 - +SMQ Functional lactation disorders (SMQ)
 - +SMQ Neonatal exposures via breast milk (SMQ)
- +SMQ Neonatal disorders (SMQ)
- +SMQ Normal pregnancy conditions and outcomes (SMQ)
- +SMQ Pregnancy, labour and delivery complications and risk factors (excl abortions and stillbirth) (SMQ)
- +SMQ Termination of pregnancy and risk of abortion (SMQ)

New v14.0

- Existing *SMQ Adverse pregnancy outcome/reproductive toxicity (incl neonatal disorders)* **inactive**

- SMQ Adverse pregnancy outcome/reproductive toxicity (incl neonatal disorders) (SMQ) [20000074]
 - +SMQ Disorders of the offspring (SMQ) [20000078]
 - +SMQ Pregnancy complications (SMQ) [20000076]
 - +SMQ Reproductive toxicity (SMQ) [20000075]

Inactive v14.0

- SMQ Adverse pregnancy outcome/reproductive toxicity (incl neonatal disorders) (SMQ) [20000074]
 - +SMQ Congenital, familial and genetic disorders (SMQ) [20000077]
 - +SMQ Disorders of the offspring (SMQ) [20000078]
 - +SMQ Pregnancy complications (SMQ) [20000076]
 - +SMQ Reproductive toxicity (SMQ) [20000075]

Active v13.1



Fate of the Inactive SMQ

- In v14.0
 - Inactive - SMQ *Adverse pregnancy outcome/reproductive toxicity (incl neonatal disorders)*
 - Updated and included in ASCII files
 - Warning: the Congenital sub-SMQ is no longer under this SMQ
- In v14.1
 - Inactive SMQ is no longer maintained or included in ASCII files
 - Inactive SMQ (v13.1) archived on the MSSO Web site



Translation Corrections

- Changes to replace misspelled or mistranslated terms in non-English versions of MedDRA
 - In v14.1
 - 7 Chinese
 - 90 French
 - 4 German
 - 2 Spanish
- Users welcome to submit changes



Update on Proactivity Initiatives



Update on Proactivity Initiatives

- To date, **9** proposals have been received
 - 4 reviewed by MSSO Medical Team
 - One is implemented
 - Add “bleeding” LLTs to “Haemorrhage” PTs (e.g., add LLT *Muscle bleeding* to PT *Muscle haemorrhage*)
- Remaining 5 pending review



Submission of Proactivity Ideas

- Submit your ideas to the MSSO Help Desk:
msohelp@ngc.com
- Justification for submitted ideas is appreciated
- Example:
 - “Please identify all HLTs with only one PT and determine if the PT can be consolidated into other existing HLTs. Consolidating these ‘single’ PTs into existing HLTs could work to improve safety signal strength.”



Software Updates



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 (e.g., add new LLT to *proposed* new PT)
- Improved user interface
 - Intuitive menus
 - Help files for each Change Request action



Menus

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

Rename PT/LLT

Rename HLT

Rename HLGT

Rename SOC

SMQ Changes ▾

Translation Changes ▶

Reconsider ▶

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



Requesting a New LLT




Freeze Date for MedDRA 15.0
1 December 2011

Your Role: CR Submitter
Subscriber: 1997


[WebCR Quick Start Guide](#)

Add a New LLT

Proposed LLT (Required) 

PT to Link to (Optional)

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](#)

Requesting a New SMQ

Add a new SMQ

Proposed SMQ (Required) 

Hypoglycaemia related events

To SMQ (Optional)

Justification statement is required

Justification 

For each request for a new SMQ, please answer the following questions in your justification field:


1. What is the scientific/pharmacovigilance question that led to the request for this SMQ?
2. Is the current MedDRA hierarchy (e.g., HLTs, PTs) or any existing SMQ suitable to address the question? If not, what are the deficiencies in the hierarchy or existing SMQs that should be addressed?
3. Would your organization be able to address this question without this new SMQ, and if so, how? (That is, what would be the strategy and terms used?)
4. Which SMQ structure (i.e., broad/narrow, hierarchical, algorithm) do you think would best address the question?
5. How often would your organization need this SMQ (e.g., only once to address a very specific emerging issue or regularly/routinely)?

Please attach a list of PTs for the SMQ.



Requesting a Translation Correction

Rename Translated Term (all fields are required)

English Term Name 


MedDRA Code

Language

Current Translated Term Name

Replacement Translated Term Name

Justification statement is required

Justification 



MedDRA Desktop Browser Enhancements

- Next MDB release
 - Network-based installation option
 - Synonym pair for hemorrhage and bleeding
 - Optional dual panel display as a default
 - Synonym lists for each supported language
 - History file for each language
 - Several bug fixes
- Due first half of 2012



Other Developments



Other Developments

- Company-hosted free training
 - Initial one in July 2011 was very successful
 - Please contact us (mssohelp@ngc.com) if your company is interested in hosting training



Other Developments (cont)

- Proposal to remove legacy **codes**

PT - Preferred Term : 14.0 - English

PT - Preferred Term

MedDRA Code	<input type="text" value="10028813"/>
MedDRA Term	<input type="text" value="Nausea"/>
COSTART Sym	<input type="text" value="NAUSEA"/>
WHO-ART Code	<input type="text" value="0308001"/>
ICD9 Code	<input type="text"/>
HARTS Code	<input type="text" value="3535"/>
ICD10 Code	<input type="text"/>
ICD9-CM Code	<input type="text"/>
JART Code	<input type="text" value="0061"/>



Other Developments (cont)

- Proposal to remove legacy **codes** (cont)
 - Codes intended for early days of MedDRA to facilitate data conversion
 - No longer as relevant for that purpose
 - Not maintained
 - Other mappings are available (e.g., WHO-ART-to-MedDRA bridge) or could become available
 - **Please send us feedback by 1 November (mssohelp@ngc.com)**



Other Developments (cont)

- BRP7 recommendations
 - Proposal 1 was to “delink” cyst terms from Neoplasm SOC
 - BRP did not agree to proposal
 - MedDRA Management Board (MB) endorsed Panel’s recommendation
 - Therefore, no change to “cyst” terms



Other Developments (cont)

- BRP7 recommendations (cont)
 - Proposal 2: BRP recommended to demote “stage” terms to LLT; add more histologic sub-types at PT level on as-needed basis
 - Proposal 3: BRP recommended to reference standard tumor classifications when adding new terms
 - MB has requested more data on impact of proposed changes; has deferred endorsement for now



ICD-10 to MedDRA Mapping?



ICD10 to MedDRA Mapping?

- Are you interested in using ICD-10 coded data in pharmacovigilance?
 - mining reimbursement data to proactively perform pharmacovigilance
- If so, do you see a need for a mapping from ICD-10 to MedDRA?
 - Using electronic health records for pharmacovigilance purposes



ICD10 to MedDRA Mapping?

- If a mapping were pursued would you be interested participating in:
 - Mapping scope investigation
 - Mapping methodology investigation
 - Mapping acceptance criteria investigation
 - Validation of the mapping



Questions?