



Extending SMQ Hierarchies in TMS

Defining Filter Dictionary Structures to Allow Maximum, Flexible Design for Customized SMQs

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TMS Focus Group

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- Many thanks to everyone who participated in the development of presentation.



Agenda

- What is a SMQ?
- TMS Support for SMQs
- Beyond MSSO – Custom SMQs
- Custom SMQs in TMS
- Additional Considerations



What is a SMQ?

- SMQ – Standardized MedDRA Query
 - Group of Preferred Terms (PTs) and Lower Level Terms (LLTs) relating to a medical condition
- MedDRA MSSO
 - Medical Dictionary for Regulatory Activities Maintenance and Support Services Organization
- First introduced with MedDRA Version 8.0
 - Incremental releases timed with MedDRA Dictionary Updates
 - Special Search Categories (SSCs) fully converted and obsolete by MedDRA Version 10.0



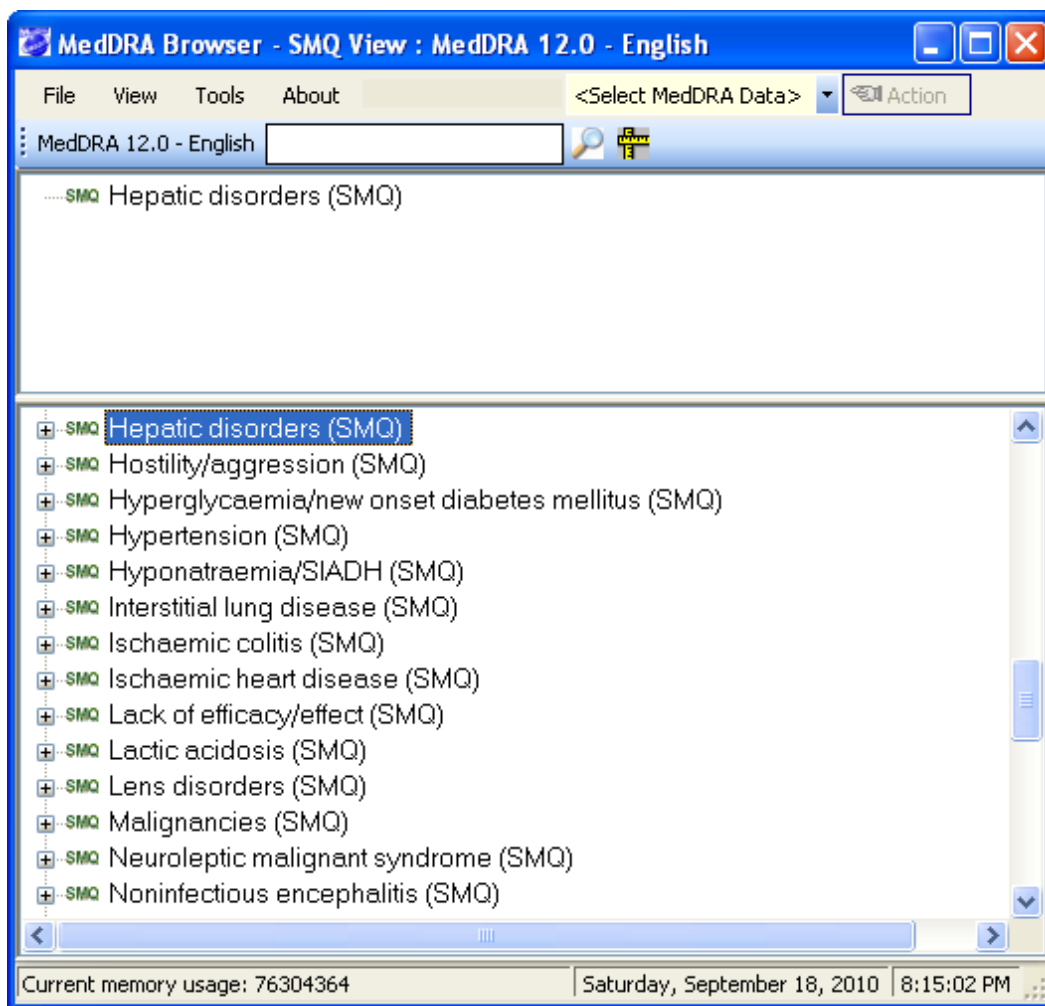
What is a SMQ?

- Group of Terms
 - Could include ANY term: HLT, HLGT
 - In practice, just PTs and LLTs
- Query can include Hierarchies
 - Hepatic Disorder (SMQ 1)
 - Drug Related... (SMQ 2)
 - Severe Events (SMQ 3)
 - Coagulation and Bleeding (SMQ 3)
 - Etc.
 - Pregnancy Related... (SMQ 2)
 - Liver Infections (SMQ 2)
 - Alcohol Related (SMQ 2)
 - Etc.



What is a SMQ?

MSSO Browser





What is a SMQ?

MSSO Browser

MedDRA Browser - SMQ View : MedDRA 12.0 - English

File View Tools About <Select MedDRA Data> Action

MedDRA 12.0 - English

- SMQ Hepatic disorders (SMQ)
- SMQ Haematopoietic cytopenias (SMQ)
- SMQ Haemodynamic oedema, effusions and fluid overload (SMQ)
- SMQ Haemolytic disorders (SMQ)
- SMQ Haemorrhages (SMQ)
- SMQ Hearing and vestibular disorders (SMQ)
- SMQ Hepatic disorders (SMQ)
 - SMQ Congenital, familial, neonatal and genetic disorders of the liver (SMQ)
 - SMQ Events specifically reported as alcohol-related (SMQ)
 - SMQ Liver infections (SMQ)
 - SMQ Possible drug related hepatic disorders - comprehensive search (SMQ)
 - SMQ Pregnancy-related hepatic disorders (SMQ)
- SMQ Hostility/aggression (SMQ)
- SMQ Hyperglycaemia/new onset diabetes mellitus (SMQ)
- SMQ Hypertension (SMQ)
- SMQ Hyponatraemia/SIADH (SMQ)
- SMQ Interstitial lung disease (SMQ)

Right click on a term to see more options Saturday, September 18, 2010 8:04:08 PM



What is a SMQ?

MSSO Browser

MedDRA Browser - SMQ View : MedDRA 12.0 - English

File View Tools About <Select MedDRA Data> Action

MedDRA 12.0 - English

- [-] SMQ Hepatic disorders (SMQ)
 - [-] SMQ Possible drug related hepatic disorders - comprehensive search (SMQ)
- [+] SMQ Haematopoietic cytopenias (SMQ)
- [+] SMQ Haemodynamic oedema, effusions and fluid overload (SMQ)
- [+] SMQ Haemolytic disorders (SMQ)
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- [+] SMQ Hearing and vestibular disorders (SMQ)
- [-] SMQ Hepatic disorders (SMQ)
 - [+] SMQ Congenital, familial, neonatal and genetic disorders of the liver (SMQ)
 - [+] SMQ Events specifically reported as alcohol-related (SMQ)
 - [+] SMQ Liver infections (SMQ)
 - [-] SMQ Possible drug related hepatic disorders - comprehensive search (SMQ)
 - [+] SMQ Cholestasis and jaundice of hepatic origin (SMQ)
 - [+] SMQ Liver related investigations, signs and symptoms (SMQ)
 - [+] SMQ Possible drug related hepatic disorders - severe events only (SMQ)
 - [+] SMQ Possible liver-related coagulation and bleeding disturbances (SMQ)
 - [+] SMQ Pregnancy-related hepatic disorders (SMQ)
- [+] SMQ Hostility/aggression (SMQ)

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What is a SMQ?

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MedDRA Browser - SMQ View : MedDRA 12.0 - English

File View Tools About <Select MedDRA Data> Action

MedDRA 12.0 - English

- SMQ Hepatic disorders (SMQ)
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 - SMQ Cholestasis and jaundice of hepatic origin (SMQ)
 - SMQ Liver related investigations, signs and symptoms (SMQ)
 - SMQ Possible drug related hepatic disorders - severe events only (SMQ)
 - SMQ Hepatic failure, fibrosis and cirrhosis and other liver damage-related
 - SMQ Hepatitis, non-infectious (SMQ)
 - SMQ Liver neoplasms, benign (SMQ)
 - SMQ Liver neoplasms, malignant and unspecified (SMQ)
 - SMQ Possible liver-related coagulation and bleeding disturbances (SMQ)

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What is a SMQ?

MSSO Browser

MedDRA Browser - SMQ View : MedDRA 12.0 - English

File View Tools About <Select MedDRA Data> Action

MedDRA 12.0 - English

- SMQ Hepatic disorders (SMQ)
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 - SMQ Hepatic failure, fibrosis and cirrhosis and other liver damage-related c

SMQ Possible drug related hepatic disorders - severe events only (SMQ)

- SMQ Hepatic failure, fibrosis and cirrhosis and other liver damage-related c
 - PT Acute hepatic failure
 - PT Anorectal varices
 - PT Anorectal varices haemorrhage
 - PT Ascites
 - PT Asterixis
 - PT Bacterascites
 - PT Biliary cirrhosis
 - PT Biliary cirrhosis primary
 - PT Biliary fibrosis
 - PT Cholestatic liver injury
 - PT Chronic hepatic failure
 - PT Coma hepatic

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What is a SMQ?

MSSO Browser

MedDRA Browser - SMQ View : MedDRA 12.0 - English

File View Tools About <Select MedDRA Data> Action

MedDRA 12.0 - English

- [-] SMQ Hepatic disorders (SMQ)
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 - [-] SMQ Possible drug related hepatic disorders - severe events only (SMQ)
 - [-] SMQ Hepatic failure, fibrosis and cirrhosis and other liver damage-related c
 - [-] PT Acute hepatic failure
 - [-] SMQ Possible drug related hepatic disorders - severe events only (SMQ)
 - [-] SMQ Hepatic failure, fibrosis and cirrhosis and other liver damage-related c
 - [-] PT Acute hepatic failure
 - LT Acute hepatic failure
 - LT Acute liver failure
 - LT Acute on chronic hepatic failure
 - LT Fulminant hepatic failure
 - [-] PT Anorectal varices
 - [-] PT Anorectal varices haemorrhage
 - [-] PT Ascites
 - [-] PT Asterixis
 - [-] PT Bacterascites
 - [-] PT Biliary cirrhosis
 - [-] PT Biliary cirrhosis primary

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TMS Support for SMQs

- TMS Version 4.6 added
 - Filter Dictionary type to support MedDRA SMQs
 - TMS 4.6.1 User Guide -- Chapter 6
 - MedDRA SMQ is the filter dictionary of MedDRA (base dictionary)
 - Algorithm Informative Note
 - Supports algorithms used by some SMQs to return search results
- TMS Lite Browser can view SMQs



TMS Support for SMQs

ORACLE Terminology Management System **TMS Lite Browser** Logout Help

Exploration Reports

Terminologies Verbatim Term Assignment Verbatim Term Status Hierarchies

Logged in as/Database OPAPPS DBMS /OPA46
Last Updated 31-Jul-2010 00:19:40

Terminologies

Simple search

Enter search criteria or click Advanced Search for additional options. Advanced search

Terminology: SMQ
Domain: All domains
Term:

Terms Viewed

- No terms viewed.

Results

Term	Approved	Level	Code	Domain	Alt.code	Id
Rhabdomyolysis/myopathy (SMQ)	Yes	SMQ1	20000002	GLOBAL	11.1	868561
Acute renal failure (SMQ)	Yes	SMQ1	20000003	GLOBAL	11.1	868571
Torsade de pointes/QT prolongation (SMQ)	Yes	SMQ1	20000001	GLOBAL	11.1	868551
Cardiac failure (SMQ)	Yes	SMQ1	20000004	GLOBAL	11.1	868581
Hepatic disorders (SMQ)	Yes	SMQ1	20000005	GLOBAL	11.1	868591
Liver related investigations, signs and symptoms (SMQ)	Yes	SMQ3	20000008	GLOBAL	11.1	868621
Cholestasis and jaundice of hepatic origin (SMQ)	Yes	SMQ3	20000009	GLOBAL	11.1	868631
Hepatitis, non-infectious (SMQ)	Yes	SMQ4	20000010	GLOBAL	11.1	868641
Liver neoplasms, malignant and unspecified (SMQ)	Yes	SMQ4	20000011	GLOBAL	11.1	868651
Hepatic failure, fibrosis and cirrhosis and other liver damage-related conditions (SMQ)	Yes	SMQ4	20000013	GLOBAL	11.1	868671
Congenital, familial, neonatal and genetic disorders of the liver (SMQ)	Yes	SMQ2	20000014	GLOBAL	11.1	868681
Liver infections (SMQ)	Yes	SMQ2	20000016	GLOBAL	11.1	868701
Events specifically reported as alcohol-related (SMQ)	Yes	SMQ2	20000017	GLOBAL	11.1	868711
Pregnancy-related hepatic disorders (SMQ)	Yes	SMQ2	20000018	GLOBAL	11.1	868721
Haemolytic disorders (SMQ)	Yes	SMQ1	20000019	GLOBAL	11.1	868731
Severe cutaneous adverse reactions (SMQ)	Yes	SMQ1	20000020	GLOBAL	11.1	868741
Anaphylactic reaction (SMQ)	Yes	SMQ1	20000021	GLOBAL	11.1	868751
Acute pancreatitis (SMQ)	Yes	SMQ1	20000022	GLOBAL	11.1	868761
Agranulocytosis (SMQ)	Yes	SMQ1	20000023	GLOBAL	11.1	868771
Anoedema (SMQ)	Yes	SMQ1	20000024	GLOBAL	11.1	868781

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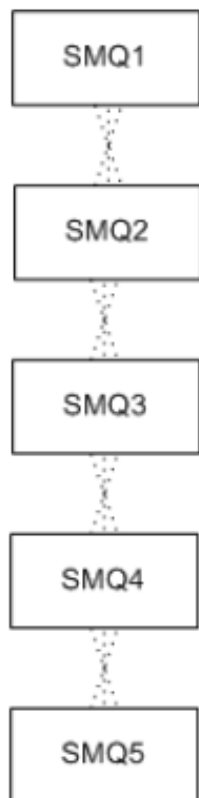
Exploration Reports Logout Help

About TMS Version 4.6 Copyright 2003,2006 Oracle Corporation. All rights reserved.

TMS Support for SMQs

Typical SMQ Structure

TMS 4.6.1 -> Definition -> Define Dictionaries



Oracle TMS Define Dictionaries window configuration for SMQ:

- Short Name: SMQ
- Name: SMQ
- Description: MedDRA SMQ Dictionary
- Language: English
- Dict. Type: Filter
- Folder Type: Strong
- Status: Active
- Label Prefix: 12.1
- VT Level Required?:
- Web Search Accessible?:
- Accessible to Light Browser?:
- Term Uniqueness enforced?:
- Autoqueried in Light Browser?:
- Dictionary Term Display Procedure: [Empty]
- Audit Information:
 - Created By: TMS_LOAD
 - Modified By: TMS_LOAD
 - Creation Time: 13-JAN-2010 02:35:57
 - Modification Time: 14-JAN-2010 09:49:12



Beyond MSSO – Custom SMQs

- TMS is well-suited to maintain SMQs and integrates well with MedDRA
- If you have a need to update attributes of a specific SMQ:
 - Add or remove a PT or LLT
 - Add or update an attribute of a SMQ
 - Or, Create a new SMQ

**TMS can help Create and Maintain
Custom SMQs (CSMQs)**



Custom SMQs in TMS

- Maintain new data within a SMQ
 - Custom Fields (tms_dict_contents' value_1, value_2, etc. columns) can be defined to store variables
 - Possible, also, to create multiple fields within any one of these fields
 - Informative Notes can also be added
- Add or Remove PTs and LLTs from a SMQ
- Create New (or Custom) SMQs (CSMQs)



Custom SMQs in TMS

- TMS offers rich APIs to enable maintenance of CSMQs
- Changes to CSMQs are maintained in audit trail
- CSMQs can be integrated with SMQs
- TMS can allow processes/users to update SMQs
 - Leverage `tms_dict_contents.term_subtype` to differentiate between "C" (Company) and "E" (External) terms
 - Enable update of external terms
 - Reference Codelist MAINTAINEXT can be set to "Y"
 - Or, programmatically set to "Y" then return to "N" for more controlled updates
- TMS Lite Browser can view CSMQs
 - But, export to another format, or development of a "CSMQ-aware" browser might be essential (depending on your customizations).



Custom SMQs in TMS

- Altering MSSO SMQs can be “Risky Business”
 - Change to some non-key values can be Supported
 - Requires modification to SMQ Load program to ignore MSSO’s values of these non-key values
 - Technically may not be difficult; but modification of internal processes and procedures may not be as easy...



Custom SMQs in TMS

- Consider “Clone” of SMQs and new hierarchy levels and relationships
 - Existing SMQ hierarchy:
 - SMQ1 -> SMQ2 -> SMQ3 -> SMQ4
 - New CSMQ Hierarchy
 - SMQ1 -> SMQ2 -> SMQ3 -> SMQ4
 - CSMQ1 -> CSMQ2 -> CSMQ3 -> CSMQ4
 - CSMQ1 -> SMQ1; CSMQ1 -> SMQ2; through CSMQ1 -> SMQ4
 - CSMQ2 -> SMQ1; CSMQ2 -> SMQ2; through CSMQ2 -> SMQ4
 - Etc.
 - Create in TMS using two data changes and multiple calls to an Oracle API.
 - Unapprove Dictionary
 - Add new records to hierarchy using TMS API
 - Approve Dictionary
 - Unnecessary to unload/reload existing SMQ dictionary
 - The use of Groups within Dictionary hierarchy impacts operation of the TMS Lite Browser



Additional Considerations

- Impact Assessment
 - When MSSO releases a new version you have to consider impact on your CSMQs
 - Progress CSMQs along with MSSO SMQs?
 - Impact assessment process will need to consider Dictionary after activation of MSSO SMQs
 - Wait for activation; or develop software to perform activation “off-to-the-side” (either physically or logically)
- Approval Process
 - Changes to CSMQs require approval
 - Activation Groups (AGs) can manage workflow
 - Designate AGs as specific workflow levels
 - PL/SQL procedures can move terms from one AG to another
 - Only activate from the "Approved" AG



Additional Considerations

- Load Scripts
 - Already have CSMQs?
 - Model script after SMQ Load Script
 - Maintain CSMQs external to TMS?
 - Consider Validation Risk
- Custom Browser (to maintain CSMQs (and SMQs))
 - Leverage TMS APIs!
 - Utilize `tms_dict_contents.sub_type` flag (E/C values)
 - Don't inappropriately update MSSO SMQs
- MSSO SMQs ONLY refer to other SMQs and PTs/LLTs
 - Consider allowing CSMQs to also refer to HLTs and HLGTS
 - Could assist with Impact Assessment following new MSSO release



Additional Considerations

- Do nothing (or very little) to impact upgrading SMQs with MSSO's next release
 - The fewer changes to SMQs the better
 - Consider a "clone" operation to copy a SMQ to a CSMQ and then update the CSMQ.



Conclusions

- SMQs can be useful data analysis tools offering efficiencies and consistency across your organization
- SMQs can be customized to better reflect your data
 - Additional fields can be added
 - Additional queries can be added
 - All while maintaining the integrity of MSSO SMQs
- SMQs can be tailored to your own needs
 - Requires processes and procedures to manage change
- Modifications to TMS can support Custom SMQs
 - Meta data changes to dictionary structure
 - Little or no impact to MSSO SMQs
 - Internal Processes may be Impacted



Questions and Answers

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- Sunil is a Global Oracle Health Sciences deployment expert for DBMS Consulting. He has been an active member of the OCUG community since 1996 and is extremely grateful for this opportunity to make these presentations at OCUG 2010.

Denise Clark, TMS Specialist, DBMS Consulting, Inc.

- Denise has over 20 years of experience working as an analyst and database developer using Oracle's RDBMS. She has 12 years of pharmaceutical industry related experience and specializes in Oracle's *Thesaurus Management System* (TMS). Denise designs automated custom client applications used for defining, loading, upgrading and validating dictionaries in TMS as well as other dictionary related custom applications.

Bill Caulkins, Director, DBMS Consulting, Inc.

- Bill has over 20 years experience working with the Oracle RDBMS and has worked in the pharmaceutical industry since the early 1990s as an Oracle developer, technical team leader, and project manager.