



REMATH - Repeated Maintenance of Thesauri

Problem

Thesaurus Management System (TMS) from Oracle® serves to maintain thesauri of any kind. Examples for thesauri are MedDRA, WHO-DRL B2 format, WHO-DRL C format, WHO-ART, COSTART, ICD9, ICD9CM, ICD10, and MESH. A dictionary specific load script to transfer each dictionary into TMS needs to be written and validated. Oracle® provides sample scripts to load WHO-DRL B2 format and MedDRA.

The thesauri are maintained by the issuers in regular intervals. The WHO centre in Uppsala delivers an updated version of WHO-DRL every quarter, MSSOC delivers an updated version of MedDRA every half year. The TMS application programming interface (API) possesses procedures that allow to update an old dictionary version to a new dictionary version. Oracle® provides a dictionary specific sample script for MedDRA, only.

Solution

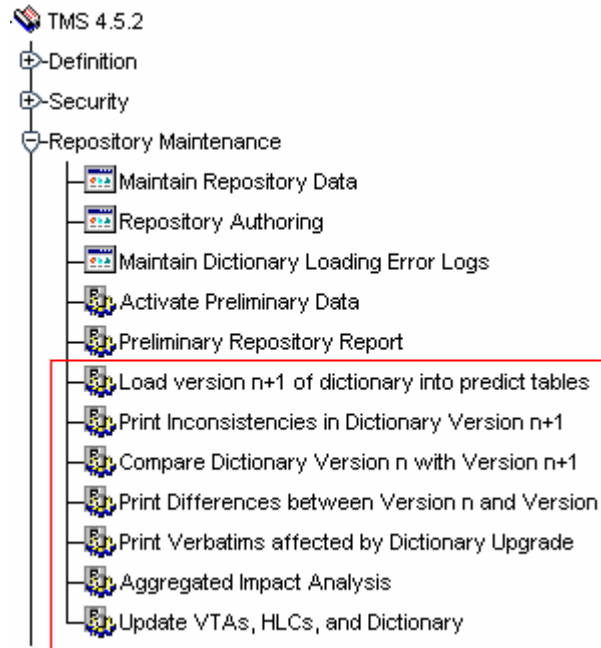
REMATH is a software package to be added to TMS to aid with the maintenance of thesauri. REMATH has the following features:

- Graphical user interface
- REMATH forms and reports are seamlessly integrated with TMS
- REMATH maintains any dictionary that can be loaded into TMS, no dictionary specific maintenance scripts are needed
- REMATH takes care of coding already performed according to the following business rules:
 - Verbatims for which the derivation path changes are automatically re-derived
 - Verbatims that were coded on terms to be deleted will be released
 - Verbatims for which new direct matches are found are recoded on full matches
 - High-level classification, e. g., selection of preferred ATC in WHO-DRL or preferred body system in WHO-ART is handled accordingly
- Workflow support of REMATH:
 - Load of new version of thesaurus using initial load script
 - Report about health check of dictionary, especially WHO-DRL is known for unique and foreign key problems
 - Determination of thesaurus version differences
 - Report to document differences between thesaurus versions
 - Report to document impact on already coded verbatim terms concerning classification and high-level re-classification



- Update of thesaurus to new version including handling of already coded verbatim terms (including high-level re-classification)
- Manual re-coding of released verbatim terms and high-level re-classifications
- Freeze of old thesaurus version as virtual dictionary in TMS
- REMATH works in replicated environments
- REMATH has been validated for TMS 4.0, TMS 4.5.0, and TMS 4.5.2.

Integration in TMS GUI



Reported Inconsistencies in system test

Below dictionary levels for which unique key constraint violations for terms exist:

Dictionary level with duplicate terms: PTS

Term Duplicates: VOMITING

Codes of Duplicates:

000000

100020

Below lower level terms have no corresponding upper level term despite of foreign key constraints:

The following terms for lower level PTS have no term in upper level PT:

VOMITING - 000000

Below upper level terms have no corresponding lower level term despite of foreign key constraints:

The following terms for upper level PT have no term in lower level PTS:

BIG PAINHEAD - 10007



Reported differences between MedDRA 5.1 and MedDRA 6.1

Update report for MEDDRA levels

High Level Group Term

Deletes

Drug effects (excl toxicity) - 10013686
High Level Term: Interactions - 10022528 - E
High Level Term: Therapeutic and nontherapeutic responses - 10043409 - E
System Organ Class: General disorders and administration site conditions - 10018065 - E
Lymphatic noninfective disorders - 10025231
High Level Term: Lymphangiopathies - 10025221 - E
High Level Term: Lymphoedemas - 10052790 - E
System Organ Class: Vascular disorders - 10047065 - E

Inserts

Lymphatic vessel disorders - 10025231
High Level Term: Lymphangiopathies - 10025221 - E
High Level Term: Lymphoedemas - 10052790 - E
System Organ Class: Vascular disorders - 10047065 - E
Therapeutic and nontherapeutic effects (excl toxicity) - 10062915
High Level Term: Interactions - 10022528 - E
High Level Term: Therapeutic and nontherapeutic responses - 10043409 - E
System Organ Class: General disorders and administration site conditions - 10018065 - E

Business Rule 1 for MedDRA 5.1 and 6.1

BR1: VTAs with changed derivation path

VTA: OTITIS MEDIA

- LLT -
PT_CODE Old: 10033084 --- New: 10033078
- PT -
TERM Old: Otitis media NOS --- New: Otitis media
CATEGORY Old: UNDEFINED --- New: ADVERSE EVENT
DICT_CONTENT_CODE Old: 10033084 --- New: 10033078
- HLT -
TERM Old: Ear infections --- New: Middle ear infections and inflammations
DICT_CONTENT_CODE Old: 10014013 --- New: 10027586
- HLGT -
TERM Old: Infections - pathogen class unspecified --- New: Middle ear disorders (excl congenital)
DICT_CONTENT_CODE Old: 10021879 --- New: 10027584
- SOC -
TERM Old: Infections and infestations --- New: Ear and labyrinth disorders
DICT_CONTENT_CODE Old: 10021881 --- New: 10013993
SOC_ABBREV Old: Infec --- New: Ear
Study REMATHM2 unfrozen: 1 times

Business Rule 3 for MedDRA 5.1 and 6.1

BR3: VTAs that will be mapped to anew direct match in the classification level

VTA: DYSSOMNIA

- LLT -
TERM Old: Sleep disorder --- New: Dyssonmia
CATEGORY Old: ADVERSE EVENT --- New: UNDEFINED
DICT_CONTENT_CODE Old: 10040984 --- New: 10061827
PT_CODE Old: 10040989 --- New: 10061827
- PT -
TERM Old: Sleep disorder NOS --- New: Dyssonmia
DICT_CONTENT_CODE Old: 10040989 --- New: 10061827
- HLT -
TERM Old: Sleep disorders NEC --- New: Dyssonmias
DICT_CONTENT_CODE Old: 10040993 --- New: 10013980
Study REMATHM1 unfrozen: 1 times



Business Rule 4 for WHODRL 2Q2002 and 2Q2003

BR4: Source terms for which the high-level classified relation was deleted

Study: REMATHW1 unfrozen, Pat: M1001, Ev: ANNEX, DCM: CONMEDS, Doc: D11892001, Verb: ASKORBINSYRE

Old ATC code: A11GA -- New ATC code : 0

ATC code A11GA deleted for PT ASCORBIC ACID

Business Rule 5 for WHODRL 2Q2002 and 2Q2003

BR5: Source terms for which at least one additional high-level relation was inserted

Study: REMATHW1 unfrozen, Pat: M1001, Ev: ANNEX, DCM: CONMEDS, Doc: D11892101, Verb: HEPARIN

Old ATC code: B01AB -- New ATC code : 0

NEW ATC code C05BA added for PT HEPARIN

Cumulative Report for Validation Dictionary REMATH

See last page as attachment.

Offer

REMATH is crafted in a modular way, thus each of the above workflow steps can be replaced by modules with similar functionality from other vendors or Oracle®. REMATH comes as software package with full software development life cycle documentation:

- User requirements
- Design specification
- Module build and test
- System Test
- User Acceptance Test
- User Manual
- System Manual

The user acceptance test can be customised to address specific customer settings and to include an adequate performance test.

Current Customer Basis

- 1 large French pharmaceutical company
- 5 mid size French, German, and Israeli pharmaceutical companies
- 3 CROs

Availability for Thesaurus Management System Versions

- TMS 4.6.1
- TMS 4.6
- TMS 4.5.2



Pricing

- €500 per TMS user (Coding or read-only)
- €100 per TMS user annual maintenance and support fee
- customisation and implementation on a time and material basis

For more information please contact:

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Attachment – Aggregated Impact Analysis Report

Report for an artificial dictionary (REMATH) used for validation. REMATH is an adverse event dictionary with a structure that resembles WHODRL. The report shows the impact analysis for Oracle Clinical (OCL) and the client's drug safety system (REMATH). See next page.



Aggregated Impact Analysis Report

System/Instance: OCL/RELICO02

Dictionary: AEDICT

Project: REMATH1P

Not Frozen Studies

	BR1		BR2		BR3		BR4		BR5	
	VTs	VTAs	VTs	VTAs	VTs	VTAs	VTs	VTAs	VTs	VTAs
REMATH1	9	6	2	2	2	2	2	2	2	2

Project: REMATH2P

Not Frozen Studies

	BR1		BR2		BR3		BR4		BR5	
	VTs	VTAs	VTs	VTAs	VTs	VTAs	VTs	VTAs	VTs	VTAs
REMATH2	9	6	2	2	2	2	2	2	2	2

System/Instance: REMATH/RELICO02

Dictionary: AEDICT

Most Suspect Drug: DRUG 1

	BR1		BR2		BR3		BR4		BR5	
	VTs	VTAs	VTs	VTAs	VTs	VTAs	VTs	VTAs	VTs	VTAs
	9	6	2	2	2	2	2	2	2	2

Most Suspect Drug: DRUG 2

	BR1		BR2		BR3		BR4		BR5	
	VTs	VTAs	VTs	VTAs	VTs	VTAs	VTs	VTAs	VTs	VTAs
	9	6	2	2	2	2	2	2	2	2

VTs: number of verbatim terms affected
VTAs: number of verbatim term assignments

BR1: VTAs with changed derivation path
BR2: VTAs for which the classification level term will be deleted
BR3: VTAs that will be mapped to a new direct match in the classification level
BR4: Source terms for which the high-level classified relation was deleted
BR5: Source terms for which at least one additional high-level relation was inserted