

DBMS Consulting Overview, OPA
Support Outsourcing Solutions,
Generic TMS Dictionary Updater
Demo, and TMS Update Scripts
for WHODrug



Introduction

- Sunil G. Singh of DBMS Consulting, Inc.
- Specialize in Oracle Pharmaceutical and E-Business implementations and long-term support.
- Thanks to the OCUG for this demo/discussion opportunity.



Agenda

- Present an overview of DBMS Consulting
- Present an overview of DBMS Consulting's OPA Support Outsourcing solutions
- Present an overview of TMS Dictionary Updating issues.
- Present an overview of new functionality for Generic TMS Dictionary Updater Tool.
- Discuss Certified TMS WHODrug loading and updating scripts and conversion scripts from WHODrug Legacy Type B (INTDIS) format to WHODrug Type C (Vigibase) format.



Overview of DBMS Consulting

- Consulting organization specializing in OPA and Oracle E-Business Suite Apps 11i implementations.
- Specialize in migrations, installation and configuration, technical and functional support and customized training.
- Support can be either long-term on-site support or remote support on an as needed basis.



OCUG Prague 2004: DBMS Consulting Demo OPA Outsourcing/Generic TMS Dictionary Updater



Overview DBMS Consulting (3)

- All full-time staff travel extensively to client sites and are usually on-call 24-hours.
- DBMS Consulting currently maintains a long-term presence in several companies.
- Additionally, 24 x 7 remote support and OPA Application Support Outsourcing is provided to several organizations.
- Total number of companies that have employed the services of DBMS Consulting for OPA related work is over 30, including CROs, Biotechs, Pharmaceuticals, Medical Device Companies and Academic Institutions



Overview DBMS Consulting (4)

- Alliance Member Partner of Oracle Corporation
- Channel Alliance Partner with Mercury Interactive
- DBMS is very price competitive and cost-conscious
- Tremendous effort to reduce expenses to customers.
- Guarantee customer satisfaction on all work or no billing for that work.

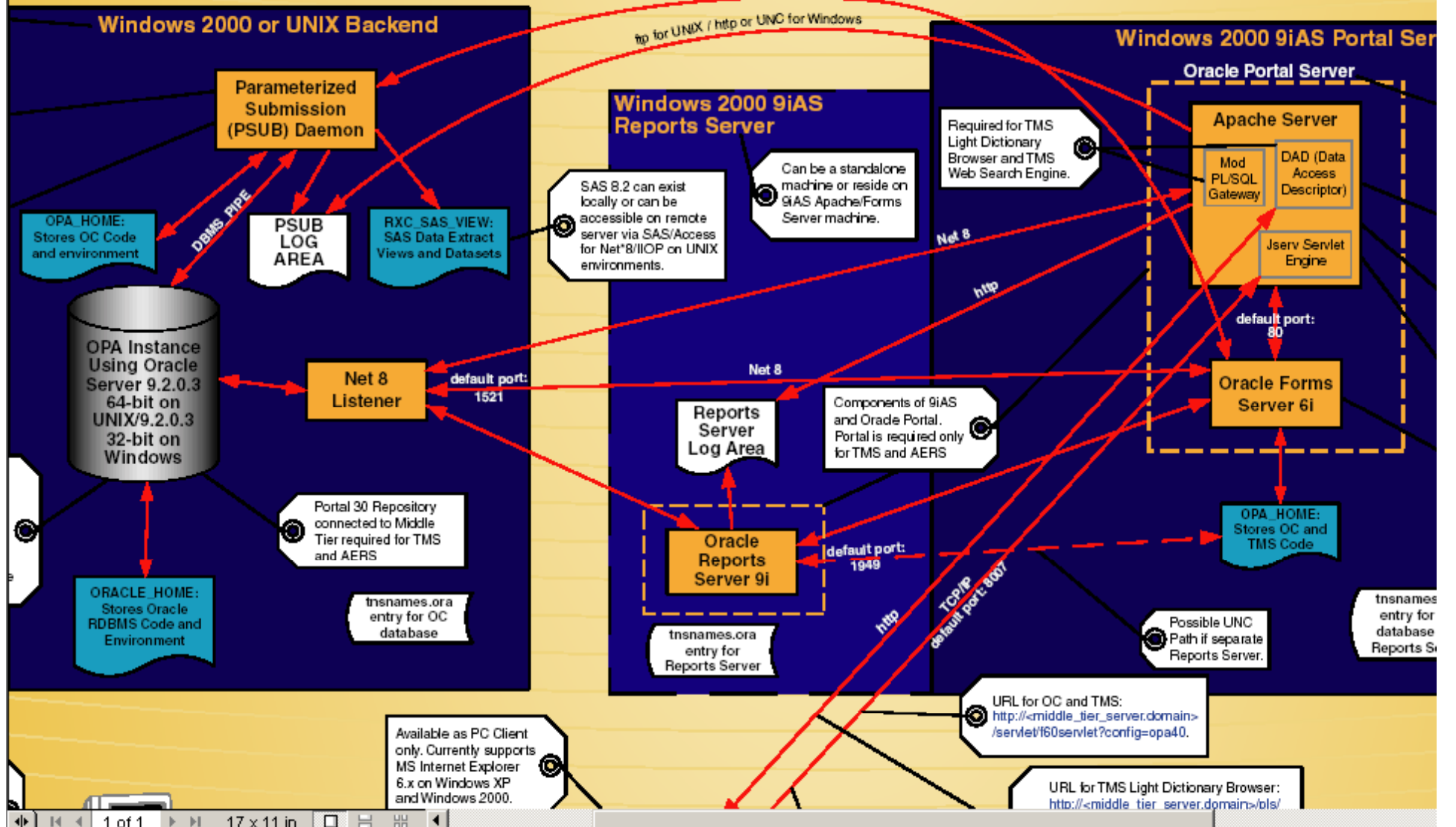


Overview DBMS Consulting (5)

- Tremendous technical expertise in Oracle, with most members of DBMS having an Oracle DBA or Development background in either the Pharmaceutical or Financial sector.
- Typically, we are called to solve the most difficult technical issues or to offer strategic implementation advise.
- Created a series of architecture diagrams for the OPA to assist customers with the true understanding of OPA and the myriad configuration options available.



Oracle Pharmaceutical Applications 4.5 3-Tier Co



Available as PC Client only. Currently supports MS Internet Explorer 6.x on Windows XP and Windows 2000.

URL for OC and TMS:
http://<middle_tier_server.domain>/servlet/160servlet?config=opa40

URL for TMS Light Dictionary Browser:
http://<middle_tier_server.domain>/ols/

Other OPA-Related Products and Services

- OPA Support Outsourcing and India-based OPA Support Centers
- Partnership with the WHO-UMC to develop certified loading and update scripts for all WHO dictionaries for TMS, including updating WHODrug Type B to WHODrug Type C Dictionaries already loaded in TMS.
- Custom development and integration with other 3rd party tools.
- Flat-rate customized functional and technical OPA training.
- Technical recruiting for Oracle-related requirements
- Full set of Validation test cases for Oracle AERS and Oracle OPA
- Developing an automated testing tool for the OPA, called OPA-Tester.
- Working with PharmaSOL to develop and market the Generic TMS Dictionary Updater in US and Asia markets.



DBMS Consulting's India-based Activities

- Started DBMS Consulting India, Private Limited based in New Delhi supporting India and Asia-based OPA customers, in a reverse outsourcing/reverse off-shore model
- Provides all aspects of implementation expertise and long term support for several Oracle Pharmaceutical Applications customers
- DBMS Consulting recently set up the first OC and RDC 4.5 pilot study in PDF Data Entry mode in India for an India-based Pharmaceutical company
- Working with partners with large Application Support Infrastructures in India to develop OPA Application Support Outsourcing Centers



Landscape of OPA in India

- India-based Generic Pharmaceutical Manufacturers will become global players in discovery-based medicines
 - Upon changes to the laws governing generic drug patents and the admittance of India into the WTO/MFN, there will be more pressure on the generic manufacturers within India to shift to discovery based medicines
- Global CROs have already seen the potential to outsource clinical trials and conduct studies within India, especially given
 - Abundance of available patients at relatively little costs
 - Existence of Clinical Data Management skills and Pharmaceutical experience throughout India
 - Existence of technology infrastructure to allow secure patient data transfer to and from remote sites in India
 - Abundance of English-speaking resources and relatively reduced costs to performs all clinical trial related tasks



Landscape of OPA in India

- It is only a question of which local India-based CROs can also capitalize on this same trend, and the utilization of OPA is a key advantage in attracting MNC Pharmaceutical, Biotech, and Medical Device Sponsors
- The international regulatory approval and marketing of new discovery-based medicines rests in large part on an enterprise-standard clinical trial system, and this is major consideration for OPA for India-based pharmaceuticals and India-based CROs in the immediate future.



DBMS Consulting's Experience in OPA Support

- DBMS Consulting already provides OPA Support on an on-call 24 x 7 basis to several companies.
 - CROs which demand real-time support but can not afford on-site consulting resources
 - Medical Device companies where assistance for on-line OPA support and ad-hoc SQL reporting
 - Large Pharmaceuticals with broadband VPN access that provide laptops for connectivity into their environments where on-site support staff may not be available
 - Large Biotech companies which need both Oracle DBA and Oracle OPA support
 - Asian based Pharmaceuticals which have no OPA support in their time zones.



Why Outsource OPA Support?

- There are gaps in the level of support currently provided by OPA
 - APAC users do not have access to real-time OPA Support “6-hour APAC Gap”
 - Global users do not have support from OPA for customizations “OPA Customization Gap”
 - There is no direct access to OPA development through OPA Support “Developer access Gap”
- OPA is constantly in a development and deployment mode. Unlike other applications which reach a “plateau of stability”, the nature of OPA requires that there is an ongoing cycle of
 - Request for changes, enhancements, bug fixes, or maintenance upgrades/patches
 - Validation
 - Deployment
 - Training



Why Outsource OPA Support? (2)

- OPA Customers are examining methods to **reduce the support and maintenance costs of all of its large applications**, which includes OPA, as well as operational costs overall. This is an industry trend for all global companies across all sectors, not restricted to only Pharmaceutical companies
- Many OPA customers have already developed a huge internal support infrastructure with so many parts and pieces. Running this internal support organization, coordinating and routing issues, and sharing the knowledge and expertise across all parts of the organization is a difficult task, which itself has management and overhead costs associated with it.
- Some OPA customers have a huge internal support infrastructure, which may be performing redundant tasks globally



Why Outsource OPA Support? (3)

- OPA Customers are Pharmaceutical/Medical Device/CROs, not IT Service Providers and not Application Support Providers
 - OPA Customers have strategically aligned themselves with Oracle in the concept of OPA as a Commercial Off-the-Shelf (COTS) system.
 - However, many OPA Customers find themselves in an ever increasing role to support and maintain all various aspects of OPA, from routine maintenance of user accounts and security, to testing new enhancements and functionality on behalf of Oracle.



OPA is big but not as big as Oracle Apps 11i

- While OPA is a big application to the OPA customer, it is small to Oracle Corporation as whole. This explains why OPA took so long to be considered a “Tier-1” application from Oracle, and why only this year (2004), OPA was moved from part of the “Oracle Tools” group to part of the “Oracle Applications” Group, reporting to Ron Wahl.
- Oracle E-Business Suite Applications 11i has an installed base of over 10,000 customers and represents Oracle’s strategic growth engine for the next few years. This is also the reason that Oracle has gone through great legal trouble to forcibly acquire PeopleSoft through an out-of-style late 80’s hostile takeover process.
- Oracle Apps 11i has over 200+ modules compared to OPA’s 7.



OPA is big but not as big as Oracle Apps 11i (2)

- Oracle Apps 11i has had 10 major releases since the introduction of Oracle Apps 11i in late 2000 (11.5.1, 11.5.2 ... 11.5.10). There are approximately 50 patches per module per release on average, making the number of patches approximately 10,000 per major release! This means that the total number of patches for 11i is over 100,000+! This is so many that Oracle Apps has:
 - A special toolset, adpatch, which only installs and verifies applied patches
 - A special bundling of patches, called Family Packs, which collectively organizes these individual patches into groups
 - A concept of concurrent worker queues to simultaneously apply patches during the installation of a Family Pack set



DBMS Consulting's OPA Support Outsourcing Solution

- Partner with an Industry Leader in Applications Support and Outsourcing
- Leverage existing enterprise Oracle Apps 11i Support and Application Outsourcing centers located in India
- Combine DBMS Consulting's overwhelming expertise in OPA with global Call Centers, Development Centers and Support Centers already handling much larger Oracle Applications
- Develop long-term OPA support resources which will first service India and APAC based OPA customers, as well as global OPA customers
- Offer a Unique OPA-Specific Application Support Model



The Need for an OPA-specific Application Support Model

- Unlike the “Big” Oracle Apps, there is not an equivalent **large body of technical or functional experience** in the OPA user-base
- **No OPA Outsourcing Support Model exists from Oracle**
- OPA has **specific validation and change-management requirements** which do not apply to many larger commercial applications
- **OPA support can be limited to OPA alone.** The large number of customizations required in an enterprise OPA environment, especially where integration to legacy systems exists, requires a specific knowledge of each customer’s OPA environment. This, in turn, requires at least a conceptual understanding of the legacy applications or other common applications integrated with OPA, such as Documentum.



Why Is Our Model Unique?

- DBMS Consulting is providing two of its own OPA experienced resources into an existing application support outsourcing infrastructure
- DBMS Consulting is training resources skilled in Oracle Applications to become OPA support specialists, reducing learning curves and also provided large application experienced resources.
- DBMS Consulting is training resources with Pharmaceutical Industry experience with 21-CFR Part 11 experience
- Access to development groups
- Multi-lingual support



An Example OPA Support Outsourcing Model

- DBMS Consulting have developed specific call routing sequences depending on the OPA customers' individual needs. As an example, one OPA customer has the following types of requests routed to the DBMS Partner OPA Call Center:
 - New OPA Account creation
 - Change in existing Study Access for a user
 - Change in GLIB Domain access for a user
 - Request for enhancement in base OC product
 - Request for enhancement in OC customization (integration with Lab system, integration with SAS, etc...)
 - Request for change in Data Entry Form for RDC 4.5 (PDF)
 - Report of RDC 4.5 bugs (disconnects)
 - Request for performance enhancements in OPA 4.5



Background of the TMS Dictionary Updating Issues

- The current process to update a vendor dictionary in TMS, such as WHODrug or MedDRA, requires the creation of an additional update script. The initial loading script for these dictionaries can only be used once, for the initial load.
- The creation or development of this update script is not a straightforward process. It requires either
 - calling `tms_load_dictionary.migrateterms` which depends on `DICT_CONTENT_CODE` mappings
 - calling `tms_user_mt_dictionary.updateterms` which depends on `DICT_CONTENT_ID` mappings



Background of the TMS Dictionary Updating Issues (2)

- Generally, the effort and resource costs to create these update scripts is much more than effort to create the initial loading scripts.
- Additionally, several other problems exist in the current TMS Dictionary updating process.
 - Existing VTAs need to be manually remapped to new matches, if new autoencoding matches are available
 - Global VTAs need to be manually copied to a Virtual TMS Dictionary domains, since currently Global VTAs are not propagated to the Virtual Dictionary Domain.
 - Impact Reports need to be developed to show potential changes to coded terms and VTs before an actual update is performed in a production environment
 - The update to the base dictionary needs to occur within the same calendar day, otherwise VTA changes may not be visible in the same Virtual Dictionary



Overview of Generic TMS Dictionary Updater Tool

- As a solution to all of these problems, DBMS Consulting and PharmaSOL have developed a tool to perform updates based upon the initial TMS loading script.
- The idea behind this tool is to leverage an organization's existing investment in their initial loading scripts without having to re-invent and develop specialized updating scripts
- The Generic TMS Dictionary Updater also provides powerful impact reports which will predict the effect of an update on a given TMS environment without actually performing this update



Specific Advantages of the TMS Dictionary Updater Tool

- The Generic TMS Dictionary Updater Tool works independently of the TMS Dictionary structure, i.e., it works for updating any valid TMS Dictionary structure regardless of external Vendor dictionaries, such as WHODrug and MedDRA, or internal custom dictionaries.
 - Group Level Classifications
 - Updates to non-derivable levels
 - Primary Path and Primary Link Dictionary Structures
- Tremendous cost savings to existing TMS customers since update scripts need not be developed, tested, and validated for each dictionary



Specific Advantages of the TMS Dictionary Updater Tool (2)

- Predictive update impact reports can be generated as soon as the TMS_PREDICT_CONTENTS and TMS_PREDICT_RELATIONS are loaded with the initial loading script
- Automatic reclassification of VTAs when an exact autoencoding match exists
- Very simple interface to use and operate
- Very simple installation procedure



New Features of the TMS Dictionary Updater Tool (3)

- Creation of Virtual Dictionaries
 - Virtual Dictionary Domain Creation
 - Assignment of Virtual Dictionary to Domain
 - Copying of VTAs to a Virtual Dictionary Domain
- Upload of external VTAs from simple database table
 - Verbatim Term
 - Term
 - Code



New Features of the TMS Dictionary Updater Tool (3)

- Declassification or deletion of terms if a Company is a replaced by a dictionary or vendor Term
 - Declassification of existing VTAs
 - Deletion of Company Terms
- Reports
 - Listing all used Updated coding level terms (currently used by VTAs)
 - Improved Patient Information on all reports
- Reduced Pricing



Updating a TMS dictionary using the TMS Dictionary Updater

- Identify the new source data for an update (such as MedDRA 7.1 distribution)
- Load the Data into TMS predict tables as if it was an initial TMS Dictionary Load, using the existing procedures and code.
- Before Activation, launch the Generic TMS Dictionary Updater
- Run the impact Reports to see the potential inserts to Dictionary Levels and Reclassified VTAs



Updating a TMS dictionary using the TMS Dictionary Updater (2)

- Launch the Prepare PREDICT step, spawning Batch jobs in the database
- Examine the Declassification Report, which shows all Declassified VTAs
- Optionally run Activation in Check Mode or Transfer Mode



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Examples – New Automatch

pharmasol.de - [Applications & Consulting]

File Options Special Custom Reports Help Window

Generic TMS Dictionary Updater v0.94

Page 1: Prepare PREDICT tables

Predict Group MEDDRAV1 Dictionary MEDDRA1

Choose Options...

Update version information of old terms

New version information 7.1

Declassify New Automatches

Create Virtual Dictionary MEDDRA60V

New Virtual Dict. Domain MEDDRA60

Display optional Report...

List ALL new Dict. terms

List new Automatches for VTAs

Display Unapproved Terms

Exit 1/2 Prepare PREDICT

Log

Log file: G:\development\TMS\Dictionaryes\upgrades Change Dir

This computer program is protected by copyright law and international treaties.
Unauthorized use of this program, or any portion of it, is strictly forbidden.
However, you may copy, use and distribute this program for evaluation purposes.

Record: 1/1 <OSC> <DBG>



Examples – New Automatch (2)

Coding before the dictionary update

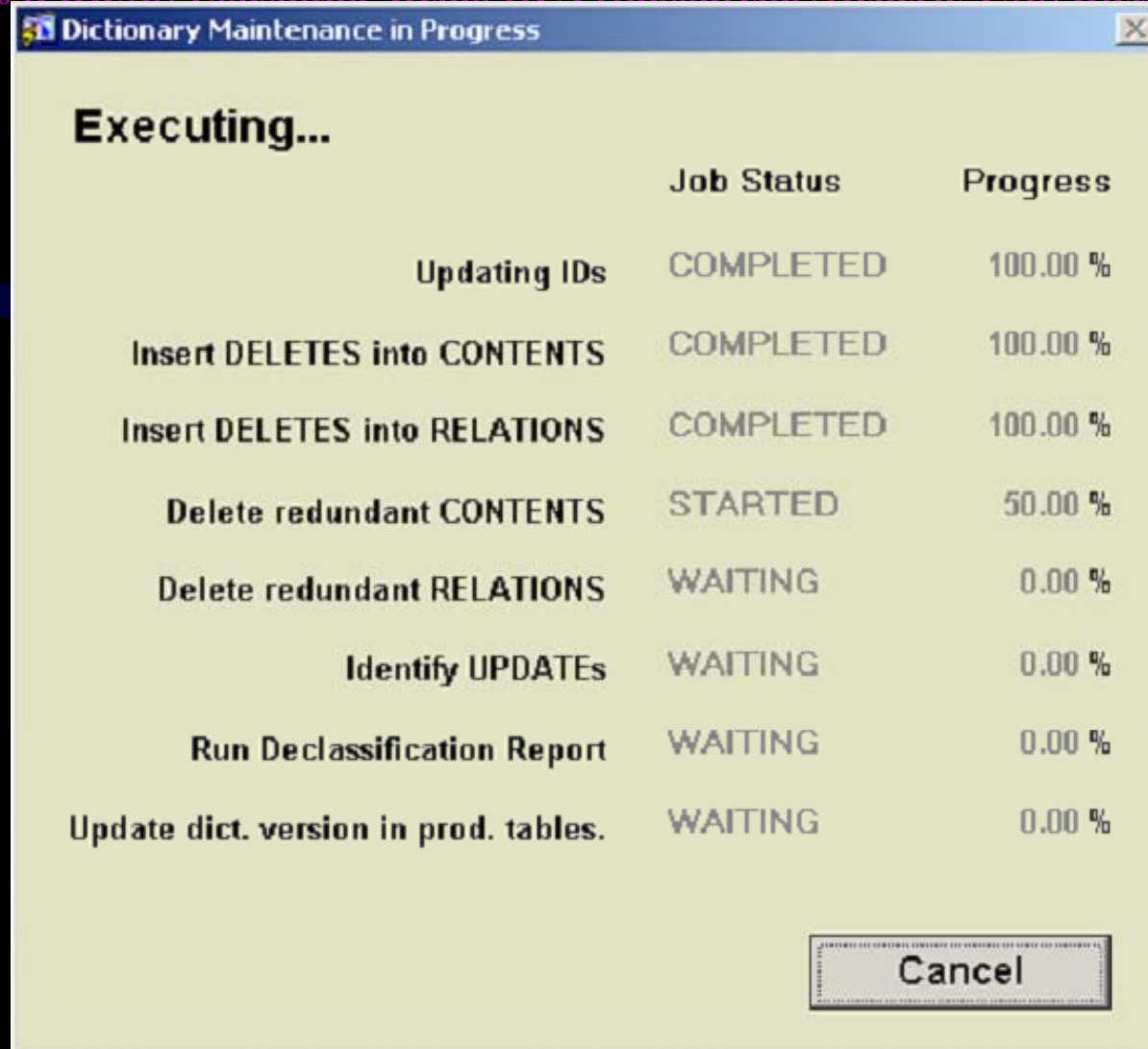
Verbatim	OLD Coding	NEW Coding	Expected Outcome
Hematuria Traumatic	<i>manual coding to resolve Omission</i>	Hematuria traumatic	Manual match will be declassified and new automatch will be coded
Hemophilia A		Hemophilia A	

Test Data for "GENERIC TMS DICTIONARY UPDATER" -TESTING- purposes

Verbatim Term	LLT	PT	SOC
ERYTHROBLASTS	ERYTHROBLASTS	ERYTHROBLASTS	INVESTIGATIONS
UPDATEDCLASS	NONTRAUMATIC FRACTURE	NONTRAUMATIC FRACTURE	MUSCULOSKELETAL AND CONNECTIVE TIS
GLARE	GLARE	GLARE	INJURY, POISONING AND PROCEDURAL CO
MANUAL PLAGUE	BLACK PLAGUE	BLACK PLAGUE	INFECTIONS AND INFESTINATIONS
HEMATURIA, TRAUMATIC	PAIN	PAIN NOS	GENERAL DISORDERS AND ADMINISTRATIC
HEMOPHILIA A	NEOPLASM THYROID	THYROID NEOPLASM NOS	NEOPLASMS BENIGN, MALIGNANT AND UN:
COXIELLA BURNETI INFECTION	COXIELLA BURNETI INFECTION	Q FEVER	INFECTIONS AND INFESTINATIONS
VARICOSE ULCERATION	VARICOSE ULCERATION	VARICOSE ULCERATION	VASCULAR DISORDERS
PARACETAMOL	PARACETAMOL	PARACETAMOL	INVESTIGATIONS
POST-ICTAL STATE	POST-ICTAL STATE	POST-ICTAL STATE	NERVOUS SYSTEM DISORDERS

Manual Coding
which should be
Replaced with
better direct
match
After Dictionary
Update





	Job Status	Progress
Updating IDs	COMPLETED	100.00 %
Insert DELETES into CONTENTS	COMPLETED	100.00 %
Insert DELETES into RELATIONS	COMPLETED	100.00 %
Delete redundant CONTENTS	STARTED	50.00 %
Delete redundant RELATIONS	WAITING	0.00 %
Identify UPDATES	WAITING	0.00 %
Run Declassification Report	WAITING	0.00 %
Update dict. version in prod. tables.	WAITING	0.00 %

&
Activation
&

Batch Validation Session ...



Examples – New Automatch (3)

Coding after the Dictionary Update

Test Data for "GENERIC TMS DICTIONARY UPDATER" -TESTING- purposes

Verbatim Term	LLT	PT	SOC
ERYTHROBLASTS	ERYTHROBLASTS	ERYTHROBASTS	INVESTIGATIONS
UPDATEDCLASS	NON-TRAUMATIC FRACTURE	NONTRAUMATIC FRACTURE	MUSCULOSKELETAL AND CONNECTIVE TIS
GLARE			
MANUAL PLAGUE			
HEMATURIA TRAUMATIC	HEMATURIA TRAUMATIC	HAEMATURIA TRAUMATIC	INJURY, POISONING AND PROCEDURAL CO
HEMOPHILIA A	HEMOPHILIA A	FACTOR VIII DEFICIENCY	FACTOR VIII DEFICIENCY
COXIELLA BURNETI INFECTION	COXIELLA BURNETI INFECTION	Q FEVER	INFECTIONS AND INFESTINATIONS
VARICOSE ULCERATION	VARICOSE ULCERATION	VARICOSE ULCERATION	VASCULAR DISORDERS
PARACETAMOL	PARACETAMOL	PARACETAMOL	INVESTIGATIONS
POST-ICTAL STATE	POST-ICTAL STATE	POST-ICTAL STATE	NERVOUS SYSTEM DISORDERS

Existing Coding
was declassified
And new
Automatch was
coded



Examples – New Automatch (4)

Predictive Impact Report identifies manual codings which will be obsoleted **before** the update is carried out.

Manual Matches



pharma)SOL solutions for the pharmaceutical industry		Dict. Upgrade VTA Declassifications								
		Dictionary: MEDDRAPL Migrating from version 40 to 60								
Declassified Verbatim Terms	Domain	Declass. Reason	Project	Study	Patient	Event	DCI	Doc. No.		
GLARE	MEDDRAPL	TERM DELETED	MYPROJECT	MYTEST01	9	VISIT1	MEDPL	DEMO		
HEMATURIA TRAUMATIC	MEDDRAPL	NEW AUTOMATCH	MYPROJECT	MYTEST01	9	VISIT1	MEDPL	DEMO		
HEMOPHILIA A	MEDDRAPL	NEW AUTOMATCH	MYPROJECT	MYTEST01	9	VISIT1	MEDPL	DEMO		
MANUAL.PLAGUE	MEDDRAPL	TERM DELETED	MYPROJECT	MYTEST01	9	VISIT1	MEDPL	DEMO		



Examples – New Automatch (5)

An additional report is available to provide a quick overview of all potential new automatches before the update is carried out.

pharma SOL		Dictionary Upgrade Added Terms			
solutions for the pharmaceutical industry		Listed Dictionary: MEDDRAPL (Migrating from version 40 to 60)			
		List Unapproved Terms: No			
Verbatim Term coded to New Term	Domain	New term	New code	Old Term used for coding	Old Code used for coding
HEMATURIA TRAUMATIC	MEDDRAPL	Hematuria traumatic	10060606	Pain	10033371
HEMOPHILIA A	MEDDRAPL	Hemophilia A	10060612	Neoplasm thyroid	10029099



Examples – Updates

Coding before the dictionary update

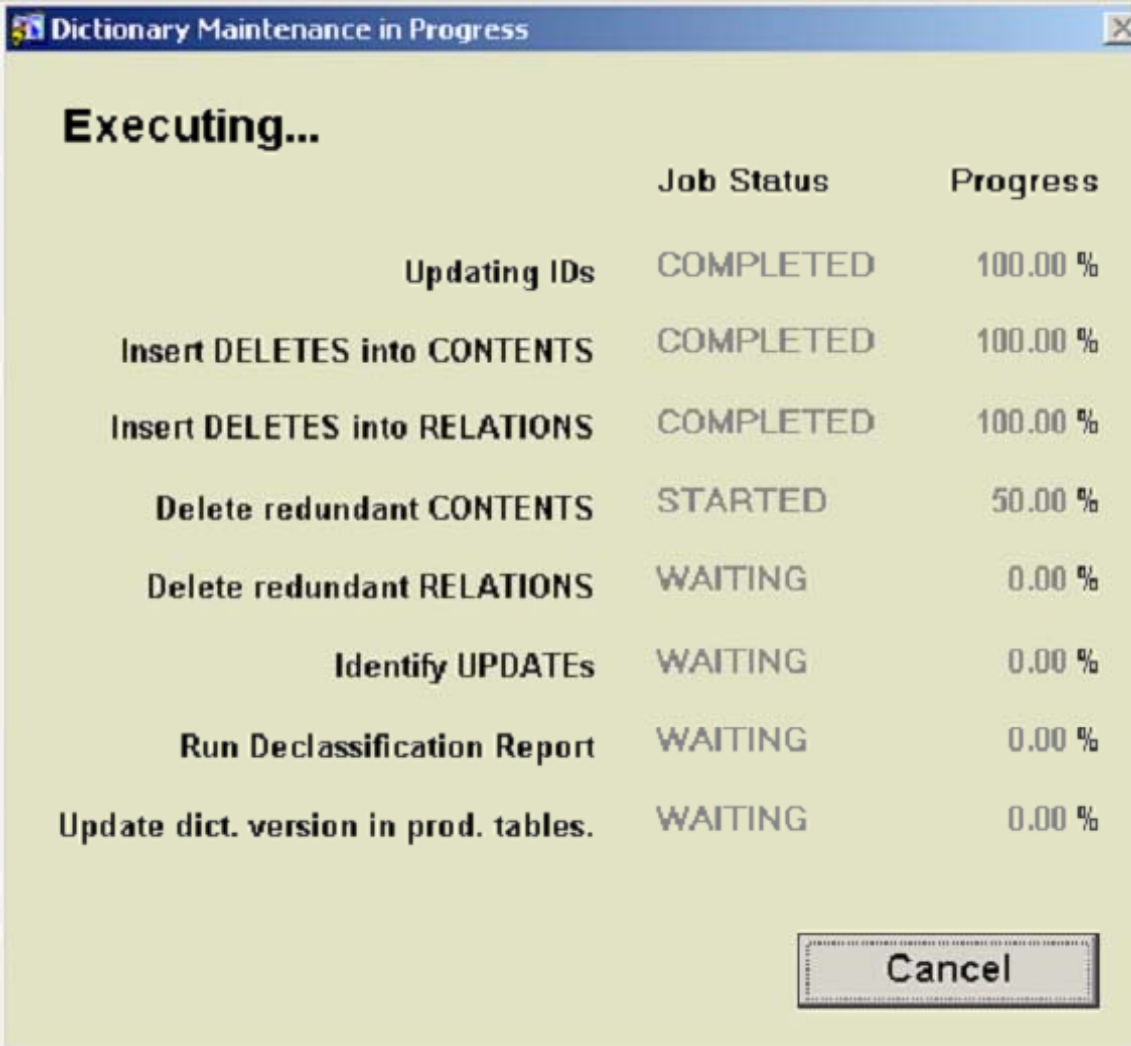
Verbatim Term	OLD Coding	NEW Coding	Expected Outcome
Erythroblasts	Erythrocasts	Erythroblasts	Term Updated
UpdateDeclass	Nontraumatic fracture	Non-traumatic fracture	Term Updated

Test Data for "GENERIC TMS DICTIONARY UPDATER" -TESTING- purposes

Verbatim Term	LLT	PT	SOC
ERYTHROBLASTS	ERYTHROCASTS	ERYTHROBLASTS	INVESTIGATIONS
UPDATEDCLASS	NONTRAUMATIC FRACTURE	NONTRAUMATIC FRACTURE	MUSCULOSKELETAL AND CONNECTIVE TIS
GLARE	GLARE	GLARE	INJURY, POISONING AND PROCEDURAL CO
MANUAL PLAGUE	BLACK PLAGUE	BLACK PLAGUE	INFECTIONS AND INFESTINATIONS
HEMATURIA TRAUMATIC	PAIN	PAIN NOS	GENERAL DISORDERS AND ADMINISTRATIC
HEMOPHILIA A	NEOPLASM THYROID	THYROID NEOPLASM NOS	NEOPLASMS BENIGN, MALIGNANT AND UN
COXIELLA BURNETI INFECTION	COXIELLA BURNETI INFECTION	Q FEVER	INFECTIONS AND INFESTINATIONS
VARICOSE ULCERATION	VARICOSE ULCERATION	VARICOSE ULCERATION	VASCULAR DISORDERS
PARACETAMOL	PARACETAMOL	PARACETAMOL	INVESTIGATIONS
POST-ICTAL STATE	POST-ICTAL STATE	POST-ICTAL STATE	NERVOUS SYSTEM DISORDERS



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	Job Status	Progress
Updating IDs	COMPLETED	100.00 %
Insert DELETES into CONTENTS	COMPLETED	100.00 %
Insert DELETES into RELATIONS	COMPLETED	100.00 %
Delete redundant CONTENTS	STARTED	50.00 %
Delete redundant RELATIONS	WAITING	0.00 %
Identify UPDATES	WAITING	0.00 %
Run Declassification Report	WAITING	0.00 %
Update dict. version in prod. tables.	WAITING	0.00 %

Cancel

&
Activation
&
Batch Validation Session ...



Examples – Updates (2)

Coding after the dictionary update

Updates were
successfully
Applied to
Dictionary Terms

Test Data for "GENERIC TMS DICTIONARY UPDATER" -TESTING- purposes

Verbatim Term	LLT	PT	SOC
ERYTHROBLASTS	ERYTHROBLASTS	ERYTHROBLASTS	INVESTIGATIONS
UPDATEDCLASS	NON-TRAUMATIC FRACTURE	NONTRAUMATIC FRACTURE	MUSCULOSKELETAL AND CONNECTIVE TIS
GLARE			
MANUAL PLAGUE			
HEMATURIA TRAUMATIC	HEMATURIA TRAUMATIC	HAEMATURIA TRAUMATIC	INJURY, POISONING AND PROCEDURAL CO
HEMOPHILIA A	HEMOPHILIA A	FACTOR VIII DEFICIENCY	FACTOR VIII DEFICIENCY
COXIELLA BURNETI INFECTION	COXIELLA BURNETI INFECTION	Q FEVER	INFECTIONS AND INFESTINATIONS
VARICOSE ULCERATION	VARICOSE ULCERATION	VARICOSE ULCERATION	VASCULAR DISORDERS
PARACETAMOL	PARACETAMOL	PARACETAMOL	INVESTIGATIONS
POST-ICTAL STATE	POST-ICTAL STATE	POST-ICTAL STATE	NERVOUS SYSTEM DISORDERS



Examples – Updates (3)

- This Report lists all **Updated** Coding Level Terms to provide a quick overview whether existing codings are still valid after the Dictionary Update



Updated Coding Level Term	New Term	Coded Verbatim Term	Study	Patient	Event	DCI	Doc. No.
Erythroblasts	Erythroblasts	ERYTHROBLASTS	MYTEST01	9	VISIT1	MEDDRAPL	DEMO
Nontraumatic fracture	Non-traumatic fracture	UPDATEDECLASS	MYTEST01	9	VISIT1	MEDDRAPL	DEMO



Validation

- Available Validation Document Set
 - Installation Qualification
 - Requirements Specification
 - Functional Test Protocol
 - Traceability Matrix
 - SDLC Development and Configuration Management Protocol
 - User and Installation Guide
- Validation process is the comparison of updated dictionaries using the Generic TMS Dictionary Updater of standard MedDRA and WHODrug dictionary to initial loads of the more current version (e.g. compare update of MedDRA 5.1 to 6.0 against the data for an initial MedDRA 6.0 load)
- Additional comprehensive test cases for VTA declassification and reclassification and report accuracy.



Overview TMS Loading/Update Scripts for WHO Dictionaries

- DBMS Consulting has a partnership with the WHO-UMC to produce the certified TMS Loading scripts for the new Type C (Vigibase) and existing WHODrug (Type B) format
- Certified update scripts for existing TMS Customers with legacy WHODrug format who wish to use new WHODrug Type C (Vigibase) format
- This update retains the previous TMS structure used by customers based on the WHODrug structure previously defined in the TMS documentation.



Overview TMS Loading/Update Scripts for WHO Dictionaries (2)

- Since Type C is now based on a new key of Medicinalprod_id, this Medicinalprod_id must be mapped to the previous key, which is the concatenation of Drug Record Number with Sequence1 with Sequence2
- DBMS Consulting and WHO-UMC have worked on a mapping algorithm to join these two sets of keys.
- Additionally, some specific techniques must be employed to overcome the classification level uniqueness requirement in TMS, since the Drug Name itself is no longer unique, but was previously unique
- See more in the DBMS Consulting, WHO-UMC presentation on implementing the Type C structure in the TMS Focus Group



Development and Testing process for WHODrug Updates

- Dictionary update files and cumulative dictionary files are released to DBMS on a quarterly basis.
- WHO-UMC provides specific data on number of expected records, checksums and specific pieces of data and their expected derivations.
- DBMS loads a new dictionary and updates the previous quarter's dictionary.
- DBMS and WHO-UMC verify the expected records, checksums and the specific test cases/expected derivations in a test protocol document.
- WHO-UMC certifies that specific quarter's initial load and update into TMS.



Current Products

- Initial Certified TMS Loading scripts for Vigibase WHODrug format into a new TMS format.
- Certified Update TMS Loading scripts for Vigibase WHODrug format into existing (Type B) TMS structures.



Additional WHO-related products

- Special WHODrug autoencoder for TMS.
- Concatenated ATC -> Level Detail certified WHODrug structure.
- Certified WHOArt and ICD TMS Dictionary Loading/Update Scripts.



Q&A.

- Please come to Vendor booth with any additional questions and more detailed demos
- Single-page hand-out describing OPA Support Outsourcing model in detail
- Also for more Brochures, posters and business cards

